

FEDERAL REGISTER

Vol. 86 Wednesday

No. 85 May 5, 2021

Pages 23843-24296

OFFICE OF THE FEDERAL REGISTER



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

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How To Cite This Publication: Use the volume number and the page number. Example: 86 FR 12345.

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Contents

Federal Register

Vol. 86, No. 85

Wednesday, May 5, 2021

Agriculture Department

See Food and Nutrition Service See Forest Service

Antitrust Division

NOTICES

Proposed Final Judgment and Competitive Impact Statement:

United States v. Stone Canyon Industries Holdings, LLC, et al., 23982–23998

Children and Families Administration

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals: Grants to States for Access and Visitation, 23973–23974

Civil Rights Commission

NOTICES

Meetings:

California Advisory Committee, 23920

Coast Guard

RULES

Safety Zone:

Commencement Bay, Tacoma, WA, 23865–23866 Special Local Regulation:

Miami Beach Air and Sea Show, Atlantic Ocean, Miami Beach, FL, 23865

PROPOSED RULES

Drawbridge Operations:

Rainy River, Rainy Lake and their tributaries, Rainier, MN, 23880–23882

Commerce Department

See Economic Analysis Bureau

See International Trade Administration

See National Institute of Standards and Technology See National Oceanic and Atmospheric Administration

Order Denying Export Privileges:

Abel Hernandez, Jr., 23920–23921 Mehmet Hakan Atilla, 23922–23923

Sergio Daniel Serrano-Lopez, 23921-23922

Drug Enforcement Administration

NOTICES

NOTICES

Decision and Order:

Emmanuel A. Ayodele, M.D., 24020–24022 Melanie Baker, N.P., 23998–24012 Michele L. Martinho, M.D., 24012–24020

Economic Analysis Bureau

NOTICES

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

Quarterly Survey of Transactions in Selected Services and Intellectual Property with Foreign Persons, 23923–23925

Education Department

NOTICES

Request for Nominations:

National Advisory Committee on Institutional Quality and Integrity; Students, 23949–23950

Employment and Training Administration NOTICES

Change in Status of the Extended Benefit Program: Virgin Islands, 24025–24026

Trade Adjustment Assistance; Determinations, 24022–24025, 24027–24028

Worker Adjustment Assistance; Investigations, 24026–24027

Energy Department

See Federal Energy Regulatory Commission PROPOSED RULES

Energy Conservation Program:

Test Procedure for Commercial and Industrial Pumps, 23875–23876

Environmental Protection Agency NOTICES

Disclosure of Information Claimed as, or Determined by EPA to be, Confidential Business Information in Renewable Fuel Standard Small Refinery Exemption Petitions and All RFS Related Information in EPA's Moderated Transaction System, 23963–23964

Privacy Act; Systems of Records, 23958–23962

Requests to Voluntarily Cancel Uses for Dicloran, 23962–23963

Export-Import Bank

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 23964–23965

Federal Communications Commission RULES

10-Application Limit for NCE FM New Station Applications in Upcoming 2021 Filing Window, 23866–23868Radio Broadcasting Services:

Various Locations, 23868-23869

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 23965–23966

Federal Energy Regulatory Commission

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 23953–23957 Application:

Allete, Inc., 23951–23952

Eugene Water and Electric Board, 23957–23958 Jordan Hydroelectric Limited Partnership, Virginia, 23950–23951

Combined Filings, 23952, 23954

Initial Market-Based Rate Filings Including Requests for Blanket Section 204 Authorizations: Light Power and Gas LLC, 23958

Federal Reserve System

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 23966–23973

Change in Bank Control:

Acquisitions of Shares of a Bank or Bank Holding Company, 23966

Formations of, Acquisitions by, and Mergers of Bank Holding Companies, 23966

Fish and Wildlife Service

RULES

Endangered and Threatened Wildlife and Plants: Three Salamander Species Not Warranted for Listing as Endangered or Threatened Species, 23869–23872

PROPOSED RULES

Endangered and Threatened Species:

Removing Five Species from San Clemente Island from the Federal Lists of Endangered and Threatened Wildlife and Plants, 23882–23913

NOTICES

Endangered and Threatened Species:

Initiation of 5-Year Status Reviews of 23 Species in the Southwest, 23976–23978

Updated Collision Risk Model Priors for Estimating Eagle Fatalities at Wind Energy Facilities, 23978–23979

Food and Nutrition Service NOTICES

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

Special Supplemental Nutrition Program for Women, Infants, and Children Infant and Toddler Feeding Practices Study–2 Year 9 Extension, 23914–23916

Forest Service

NOTICES

Meetings:

Daniel Boone Resource Advisory Committee, 23917–23918

Lynn Canal Icy-Strait Resource Advisory Committee, 23917

Wenatchee-Okanogan Resource Advisory Committee, 23916–23917

Newspapers Used for Publication of Legal Notices by the Intermountain Region:

Utah, Idaho, Nevada, and Wyoming, 23919–23920 Newspapers Used for Publication of Legal Notices by the Rocky Mountain Region:

Colorado, Kansas, Nebraska, and parts of South Dakota and Wyoming, 23918–23919

Health and Human Services Department

See Children and Families Administration See National Institutes of Health RULES

Patient Protection and Affordable Care Act:

Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards, 24140–24295

Homeland Security Department

See Coast Guard

Interior Department

See Fish and Wildlife Service

Agency Information Collection Activities; Proposals, Submissions, and Approvals: Helium Contracts, 23979–23980 Oil and Gas, or Geothermal Resources: Transfers and Assignments, 23980–23981

Internal Revenue Service

RULES

Tax on Excess Tax-Exempt Organization Executive Compensation; Correction, 23865

International Trade Administration

NOTICES

Antidumping or Countervailing Duty Investigations, Orders, or Reviews:

Certain Steel Nails from the People's Republic of China, 23932–23933

Finished Carbon Steel Flanges from Spain, 23931–23932 Initiation of Administrative Reviews, 23925–23931

International Trade Commission

NOTICES

Investigations; Determinations, Modifications, and Rulings, etc.:

Boltless Steel Shelving Units Prepackaged for Sale from China, 23981–23982

Justice Department

See Antitrust Division

See Drug Enforcement Administration

Labor Department

See Employment and Training Administration ${\bf NOTICES}$

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

DOL-Only Performance Accountability, Information, and Reporting System, 24028–24029

Management and Budget Office

NOTICES

Methods and Leading Practices for Advancing Equity and Support for Underserved Communities through Government, 24029–24032

National Endowment for the Arts

Agency Information Collection Activities; Proposals, Submissions, and Approvals: NEA Panelist Profile Data, 24032–24033

National Foundation on the Arts and the Humanities

See National Endowment for the Arts

National Institute of Standards and Technology NOTICES

Meetings:

Information Security and Privacy Advisory Board, 23936–23937

Manufacturing Extension Partnership Advisory Board, 23934

National Advanced Spectrum and Communications Test Network: LTE Impacts to Aeronautical Mobile Telemetry and LTE Waveform Measuremen, 23934— 23935

National Advanced Spectrum and Communications Test Network: Characterizing User Equipment Emissions, 23933–23934

National Construction Safety Team Advisory Committee, 23935–23936

Visiting Committee on Advanced Technology, 23935

National Institutes of Health

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

Generic Clearance to Collect Stakeholder Feedback on the Research Domain Criteria Initiative, National Institute of Mental Health, 23974-23975

Meetings:

National Institute of Biomedical Imaging and Bioengineering, 23974-23975

National Institute of Diabetes and Digestive and Kidney Diseases, 23975-23976

National Oceanic and Atmospheric Administration RULES

Fisheries Off West Coast States:

Modifications of the West Coast Commercial and Recreational Salmon Fisheries; Inseason Actions Nos. 10 through 16, 23872-23874

NOTICES

Meetings:

Council Coordination Committee, 23937

Fisheries of the Gulf of Mexico and Atlantic; Southeast Data, Assessment, and Review, 23937–23938

Fisheries of the South Atlantic; Southeast Data, Assessment, and Review, 23949

Mid-Atlantic Fishery Management Council, 23938 Pacific Fishery Management Council, 23948-23949

South Atlantic Fishery Management Council, 23947-23948

Takes of Marine Mammals Incidental to Specified Activities:

Ferry Berth Improvements in Tongass Narrows, AK, 23938-23947

Nuclear Regulatory Commission

NOTICES

Meetings; Sunshine Act, 24033

Postal Regulatory Commission

NOTICES

Transfer of Bound Print Matter Parcels, 24033-24034

Postal Service

NOTICES

Product Change:

Priority Mail Negotiated Service Agreement, 24034

Presidential Documents

PROCLAMATIONS

Special Observances:

Asian American and Native Hawaiian/Pacific Islander Heritage Month (Proc. 10189), 23843-23844

Jewish American Heritage Month (Proc. 10190), 23845-

Law Day, U.S.A. (Proc. 10197), 23859-23860 Lovalty Day (Proc. 10198), 23861-23862

National Building Safety Month (Proc. 10191), 23847-

National Foster Care Month (Proc. 10192), 23849-23850 National Mental Health Awareness Month (Proc. 10193), 23851-23852

National Physical Fitness and Sports Month (Proc. 10194), 23853-23854

National Teacher Appreciation Day and National Teacher Appreciation Week (Proc. 10195), 23855-23856

Public Service Recognition Week (Proc. 10196), 23857-23858

Securities and Exchange Commission NOTICES

Meetings; Sunshine Act, 24059

Self-Regulatory Organizations; Proposed Rule Changes:

BOX Exchange, LLC, 24119-24124

Cboe BYX Exchange, Inc., 24059–24066

Cboe BZX Exchange, Inc., 24066, 24083-24090

Cboe C2 Exchange, Inc., 24125-24132

Cboe EDGA Exchange, Inc., 24076-24083

Choe EDGX Exchange, Inc., 24044-24052

Cboe Exchange, Inc., 24052-24059

Miami International Securities Exchange, LLC, 24106-24109

MIAX Emerald, LLC, 24072-24076, 24117-24119

MIAX PEARL, LLC, 24114–24117 Nasdaq PHLX, LLC, 24109–24114

National Securities Clearing Corp., 24067–24072

New York Stock Exchange, LLC, 24038-24041, 24101-24103

NYSE American, LLC, 24036-24038, 24041-24044

NYSE Arca, Inc., 24093–24096, 24098–24100

NYSE Chicago, Inc., 24096-24098, 24103-24106

NYSE National, Inc., 24034-24036, 24090-24093

Small Business Administration

RULES

HUBZone Program:

Extending Map Freeze, 23863-23865

NOTICES

Disaster Declaration:

Hawai'i, 24132

Major Disaster Declaration:

New Jersey, 24132

State Department

NOTICES

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

Law Enforcement Officers Safety Act Photographic Identification Card Application, 24133

Surface Transportation Board NOTICES

Acquisition and Operation Exemption:

Bogalusa Bayou Railroad, LLC d/b/a Geaux Geaux Railroad; Geaux Geaux Railroad, LLC, 24133-24134

Lease Exemption with Interchange Commitment:

Stillwater Central Railroad, LLC; BNSF Railway Co., 24134

Transportation Department

PROPOSED RULES

Regulatory Review, 23876-23877

Treasury Department

See Internal Revenue Service

See United States Mint

NOTICES

Reporting Requirements:

Mandatory Survey of Foreign Ownership of U.S. Securities, 24134-24135

U.S.-China Economic and Security Review Commission NOTICES

Hearing, 24135

United States Mint

PROPOSED RULES

Exchange of Coin, 23877-23880

Veterans Affairs Department

Agency Information Collection Activities; Proposals, Submissions, and Approvals: Fiduciary Agreement, 24135–24136 Requests for Nominations: Advisory Committee on Tribal and Indian Affairs, 24136–24137

Separate Parts In This Issue

Part II

Health and Human Services Department, 24140-24295

Reader Aids

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

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

CFR PARTS AFFECTED IN THIS ISSUE

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

Reader Aids section at the	ne end o
3 CFR	
Proclamations:	
10189	.23843
10190	
10191	.23847
10192	.23849
10193	.23851
10194	.23853
10195	
10196	
10197	
10198	.23861
10 CFR	
Proposed Rules:	
431	23875
13 CFR	0070
126	00060
	23003
14 CFR	
Proposed Rules:	
Ch. I	.23876
Ch. II	
Ch. III	.23876
23 CFR	
Proposed Rules:	00070
Ch. I	.23876
Ch. II	
Ch. III	.23876
26 CFR	
53	.23865
31 CFR	
Proposed Rules:	
100	23877
	20077
33 CFR	00005
100	.23865
165	23603
Proposed Rules:	
117	.23880
45 CFR	
147	.24140
150	
153	
155	.24140
156	
158	
184	.24140
46 CFR	
Proposed Rules:	
Ch. II	23876
	.20070
47 CFR	00000
73 (2 documents)	
	23868
48 CFR	
Proposed Rules:	
Ch. 12	.23876
49 CFR	0070
Proposed Rules:	
Ch. I	
Ch. II	
Ch. III	.23876
Ch. V	.23876
Ch. VI	
Ch. VII	
Ch. VIII	
Ch. X	
Ch. XI	.23876
50 CFR	
17	
660	.23872
Proposed Rules:	

Proposed Rules:

17.....23882

Federal Register

Vol. 86, No. 85

Wednesday, May 5, 2021

Presidential Documents

Title 3—

Proclamation 10189 of April 30, 2021

The President

Asian American and Native Hawaiian/Pacific Islander Heritage Month, 2021

By the President of the United States of America

A Proclamation

This May, during Asian American and Native Hawaiian/Pacific Islander Heritage Month, we recognize the history and achievements of Asian Americans, Native Hawaiians, and Pacific Islanders (AANHPIs) across our Nation. In the midst of a difficult year of pain and fear, we reflect on the tradition of leadership, resilience, and courage shown by AANHPI communities, and recommit to the struggle for AANHPI equity.

Asian Americans, and Native Hawaiians, and Pacific Islanders make our Nation more vibrant through diversity of cultures, languages, and religions. There is no single story of the AANHPI experience, but rather a diversity of contributions that enrich America's culture and society and strengthen the United States' role as a global leader. The American story as we know it would be impossible without the strength, contributions, and legacies of AANHPIs who have helped build and unite this country in each successive generation. From laying railroad tracks, tilling fields, and starting businesses, to caring for our loved ones and honorably serving our Nation in uniform, AANHPI communities are deeply rooted in the history of the United States.

We also celebrate and honor the invaluable contributions the AANHPI communities have made to our Nation's culture and the arts, law, science and technology, sports and public service—including the courageous AANHPIs who have served on the front lines of the COVID–19 pandemic as health care providers, first responders, teachers, and other essential workers.

During this year's Asian American and Native Hawaiian/Pacific Islander Heritage Month, our Nation celebrates the achievements of Vice President Harris, the first person of South Asian descent to hold the Office of the Vice President. Vice President Harris has blazed a trail and set an example for young people across the country to aspire to follow, including members of AANHPI communities and AANHPI women in particular.

In spite of the strength shown and successes achieved, the American dream remains out of reach for far too many AANHPI families. AANHPI communities face systemic barriers to economic justice, health equity, educational attainment, and personal safety. These challenges are compounded by stark gaps in Federal data, which too often fails to reflect the diversity of AANHPI communities and the particular barriers that Native Hawaiian, Pacific Islander, Southeast Asian, and South Asian communities in the United States continue to face.

My Administration also recognizes the heightened fear felt by many Asian American communities in the wake of increasing rates of anti-Asian harassment and violence during the COVID–19 pandemic, and the increasingly observable layers of hate now directed toward women and elders of Asian descent in particular. Our Nation continues to grieve the senseless killings of six women of Asian descent in Atlanta, and the unconscionable acts of violence victimizing our beloved Asian American seniors in cities across the country.

Acts of anti-Asian bias are wrong, they are un-American, and they must stop. My Administration will continue to stand shoulder to shoulder with AANHPI communities in condemning, denouncing, and preventing these acts of violence. We will continue to look for opportunities to heal together and fight against the racism and xenophobia that still exists in this country.

Present-day inequities faced by AANHPI communities are rooted in our Nation's history of exclusion, discrimination, racism, and xenophobia against Asian Americans. Asian Americans, Native Hawaiians, and Pacific Islanders have endured a long history of injustice—including the Page Act of 1875, the Chinese Exclusion Act of 1882, the incarceration of Japanese American citizens during World War II, the murder of Vincent Chin, the mass shooting of Southeast Asian refugee children in 1989, and the targeting of South Asian Americans, especially those who are Muslim, Hindu, or Sikh, after the national tragedy of 9/11. It is long past time for Federal leadership to advance inclusion, belonging, and acceptance for all AANHPI communities. My Administration is committed to a whole-of-government effort to advance equity, root out racial injustices in our Federal institutions, and finally deliver the promise of America for all Americans.

Vice President Harris and I affirm that Asian Americans, Native Hawaiians, and Pacific Islanders make our Nation stronger. I urge my fellow Americans to join us this month in celebrating AANHPI history, people, and cultures.

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 May 2021 as Asian American and Native Hawaiian/Pacific Islander Heritage Month. I call upon the people of the United States to learn more about the history of Asian Americans, Native Hawaiians, and Pacific Islanders, and to observe this month with appropriate programs and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of April, in the year of our Lord two thousand twenty-one, and of the Independence of the United States of America the two hundred and forty-fifth.

R. Beder. J.

Proclamation 10190 of April 30, 2021

Jewish American Heritage Month, 2021

By the President of the United States of America

A Proclamation

The Jewish American experience is a story of faith, fortitude, and progress. It is a quintessential American experience—one that is connected to key tenets of American identity, including our Nation's commitment to freedom of religion and conscience. This month, we honor Jewish Americans—past and present—who have inextricably woven their experience and their accomplishments into the fabric of our national identity.

Generations of Jewish people have come to this Nation fleeing oppression, discrimination, and persecution in search of a better life for themselves and their children. These Jewish Americans have created lives for themselves and their families and played indispensable roles in our Nation's civic and community life, making invaluable contributions to our Nation through their leadership and achievements.

And this year, we also recognize two historic firsts, as America saw the Vice President take the oath of office alongside her Jewish spouse, and a Jewish American became the first Majority Leader of the United States Senate and the highest-ranking Jewish American elected official in our Nation's history.

Alongside this narrative of achievement and opportunity, there is also a history—far older than the Nation itself—of racism, bigotry, and other forms of injustice. This includes the scourge of anti-Semitism. In recent years, Jewish Americans have increasingly been the target of white nationalism and the antisemitic violence it fuels.

As our Nation strives to heal these wounds and overcome these challenges, let us acknowledge and celebrate the crucial contributions that Jewish Americans have made to our collective struggle for a more just and fair society; leading movements for social justice, working to ensure that the opportunities they have secured are extended to others, and heeding the words of the Torah, "Justice, justice shall you pursue."

A central concept in Judaism, "l'dor v'dor", or "from generation to generation," recognizes both the continuity of the Jewish people and the intergenerational responsibility we have to heal the world for our children. During Jewish American Heritage Month, we honor Jewish Americans, who, inspired by Jewish values and American ideals, have engaged in the ongoing work of forming a more perfect union.

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 May 2021 as Jewish American Heritage Month. I call upon all Americans to visit www.JewishHeritageMonth.gov to learn more about the heritage and contributions of Jewish Americans and to observe this month with appropriate programs, activities, and ceremonies.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of April, in the year two thousand twenty-one, and of the Independence of the United States of America the two hundred and forty-fifth.

L. Beder. fr

[FR Doc. 2021–09571 Filed 5–4–21; 8:45 am] Billing code 3295–F1–P

Proclamation 10191 of April 30, 2021

National Building Safety Month, 2021

By the President of the United States of America

A Proclamation

Throughout this past year, we have come to appreciate the contributions and complexity of our building and built environment. During the COVID—19 pandemic, many people saw their homes become more than a place of dwelling, evolving into a comprehensive space for education, work, childcare, and entertainment. During National Building Safety Month, we recognize the importance of strengthening our buildings and infrastructure to serve the needs and ensure the safety of every American. We also honor the building safety professionals dedicated to creating safe, sustainable, and resilient communities.

We also recognize that now is the time to repair and modernize our buildings and infrastructure, not only to meet the needs of today, but to address the challenges of tomorrow, especially the existential threat of climate change. The unrelenting impact of climate change affects every one of us, but too often the brunt falls disproportionately on vulnerable communities—especially low-income communities and people of color—who are facing new and worsening natural hazards like hurricanes, floods, extreme heat, and wildfires due to climate change. These communities are less likely to have the means to prepare for and recover from these hazards, which have increased in frequency, duration, and intensity. The buildings where we live and work provide an important line of defense against these growing hazards. Investing in our infrastructure and adopting and implementing modern building codes are the most effective mitigation measures communities can undertake.

This is why I have issued several Executive Orders related to buildings and resiliency as part of a Government-wide approach to the climate emergency. My Administration has also put the climate crisis at the center of U.S. foreign and national security policy, and established the White House Office of Domestic Climate Policy and the National Climate Task Force. We are committed to creating climate-friendly and environmentally conscious communities that not only protect the people who live and work in them, but also will boost our economy in the long-term.

In order for us to safeguard the health, safety, and economic future of our Nation's people, we must also invest in our infrastructure more broadly. From upgrading homes in disadvantaged communities, to modernizing our Nation's schools, to replacing lead water pipes, to securing affordable, high-speed broadband, the American Jobs Plan is an investment for all Americans. It will create millions of good jobs, rebuild our crumbling infrastructure, and promote access to opportunity for all.

To support these efforts, my Administration is also calling for broad input and collaboration from all levels of government and our partners in the non-profit and private sectors. We must all share the responsibility for ensuring that our communities are safe and resilient against the growing threat of climate change. In America and around the globe, initiatives such as the Global Resiliency Dialogue aim to increase building and climate-based science into the solution. This important work is underway, but we recognize that there is much more to do.

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 May 2021 as National Building Safety Month. I encourage citizens, government agencies, businesses, nonprofits, and other interested groups to join in activities that raise awareness about building safety. I also call on all Americans to learn more about how they can contribute to building safety at home and in their communities.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of April, in the year of our Lord two thousand twenty-one, and of the Independence of the United States of America the two hundred and forty-fifth.

R. Beder. fr

[FR Doc. 2021–09572 Filed 5–4–21; 8:45 am] Billing code 3295–F1–P

Proclamation 10192 of April 30, 2021

National Foster Care Month, 2021

By the President of the United States of America

A Proclamation

Every child deserves to grow up in a supportive, loving home where they can thrive and prosper. During those unfortunate times when children cannot remain safely in their own homes, the individuals and families who open their hearts and homes to foster children provide a vital service to their communities. During this National Foster Care Month, we share our gratitude for those who support youth and families by being a resource to children in need and supporting birth parents so that they may safely reunite with their families whenever possible. We also recognize that it takes collaboration and community effort—from local organizations to Federal agencies—to support children, birth parents, and resource and kin families during challenging times.

Young people in foster care have been particularly impacted by the COVID-19 pandemic. They are navigating circumstances that are already tough, and those challenges are compounded by a public health crisis that made housing, employment and educational opportunities even harder to access.

To support the immediate needs of youth in foster care, my Administration is implementing Federal programs authorized by the Supporting Foster Youth and Families through the Pandemic Act. This law provides additional flexibility and support for youth aging out of foster care, and allows them to access critical services to help them stay in school or participate in a job training program, pay the bills, and better make the difficult transition to adulthood. We have an expression in the Biden family, "If you have to ask for help, it's too late." As a Nation, we can proactively help children by advancing a holistic approach to child and family well-being across the country—before it's too late.

As we work to address immediate needs, we must be clear about longstanding challenges in child welfare and commit to advancing child and family well-being in every way we can. Our children, birth parents, and resource and kin families deserve nothing less. So this National Foster Care Month, we also recognize the histories of injustice in our Nation's foster care system. Throughout our history and persisting today, too many communities of color, especially Black and Native American communities, have been treated unequally and often unfairly by the child welfare system. Black and Native American children are far more likely than white children to be removed from their homes, even when the circumstances surrounding the removal are similar. Once removed, Black and Native American children stay in care longer and are less likely to either reunite with their birth parents or be adopted. Too many children are removed from loving homes because poverty is often conflated with neglect, and the enduring effects of systemic racism and economic barriers mean that families of color are disproportionately affected by this as well. Children with disabilities are over-represented among youth in care and may be inappropriately placed in group settings instead of provided the individualized support they need. Children in foster care—particularly youth of color and LGBTQ+ children who are already subject to disproportionate rates of school discipline and criminalization—are also at an increased risk of becoming involved in the

juvenile justice system. And for LGBTQ+ foster youth, foster care systems are not always equipped to safely meet their needs.

My Administration is committed to addressing these entrenched problems in our Nation's child welfare system, advancing equity and racial justice for every child and family who is touched by the foster care and child welfare system, and focusing on policies that improve child and family well-being. This is why my Administration's discretionary funding request for 2022 includes \$100 million in competitive grants for State and local child welfare systems to advance racial equity and prevent unnecessary child removals.

National Foster Care Month is an opportunity for us to celebrate the resource and kin families who are supporting children by opening their homes and sharing their love. Crucially, it is also an opportunity to celebrate foster youth and all of their accomplishments, and to celebrate and encourage the many biological parents who are working hard to safely reunite with their children. And it provides an opportunity for us to fulfill our responsibility as a Nation to take care of each other and provide our vulnerable youth and families with the support they need.

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 May 2021 as National Foster Care Month. I call upon all Americans to observe this month by reaching out in their neighborhoods and communities to the children and youth in foster care and their families, those at risk of entering foster care, and resource and kin families and other caregivers.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of April, in the year of our Lord two thousand twenty-one, and of the Independence of the United States of America the two hundred and forty-fifth.

L. Beder. J.

[FR Doc. 2021–09573 Filed 5–4–21; 8:45 am] Billing code 3295–F1–P

Proclamation 10193 of April 30, 2021

National Mental Health Awareness Month, 2021

By the President of the United States of America

A Proclamation

Mental health is essential to our overall health, and the importance of attending to mental health has become even more pronounced during the COVID–19 pandemic, which has not only negatively impacted many people's mental health but has also created barriers to treatment.

Millions of adults and children across America experience mental health conditions, including anxiety, depression, schizophrenia, bipolar disorder, and post-traumatic stress disorder. Nearly one in five Americans lives with a mental health condition. Those living with mental health conditions are our family, friends, classmates, neighbors, and coworkers. Before the Affordable Care Act, insurance companies could discriminate against people based on pre-existing conditions, including mental health conditions, and mental health and substance use services were not covered by insurance. Still discrimination against those with mental health conditions in our society remains, and can make it difficult to find and reach out for help. While our Nation has made progress in promoting mental health services, many communities face pervasive barriers in accessing mental health care.

The COVID–19 pandemic and the resulting economic crisis has impacted the mental health of millions of Americans. Isolation, sickness, grief, job loss, food instability, and loss of routines has increased the need for mental health services. At the same time, the need to protect people from COVID–19 has made it more challenging for people to access mental health services, and harder for providers to deliver this care.

Even before COVID-19, the prevalence of mental health conditions in our Nation was on the rise. In 2019, nearly 52 million adults experienced some form of mental illness. Recent data from the Centers for Disease Control and Prevention indicates that one in four adults reported experiencing symptoms of an anxiety or depressive disorder in February 2021—a significant increase from the prior year. Youth mental health is also worsening, with nearly 10 percent of America's youth reporting severe depression. We must treat this as the public health crisis that it is and reverse this trend.

Too many people with mental health needs feel they have nowhere to turn. Suicide is the tenth leading cause of death in the United States and the second leading cause of death for our Nation's youth today. Suicide rates are disproportionately high among Black youth, and LGBTQI+ persons are at disproportionate risk of death by suicide as well as suicidal ideation, planning, and attempts. My Administration is committed to advancing suicide prevention best practices and improving non-punitive crisis response. Even as we build and enhance existing systems for prevention and response within communities, immediate assistance is available for those in need of help by calling the National Suicide Prevention Lifeline at 1–800–273–TALK or by calling 1–800–662–HELP.

My Administration is committed to ensuring that people living with mental health conditions are treated with compassion, respect, and understanding. We must also address the disparities that underserved communities, especially communities of color, face and work to ensure that everyone has access to affordable, quality, and evidence-based mental health care.

As President, I know that we can and must address these critical issues, especially for those who have shouldered the burden of standing on the front lines in responding to the pandemic. That is why the American Rescue Plan includes substantial investments to promote mental health among the health care workforce. We are also building on the progress made through the 21st Century Cures Act by integrating mental health and addiction treatment into primary care settings, schools, and homes.

My Administration is focused on building an improved, expanded system of care for the mental health needs of adults and children. This will require an increase in the number of mental health professionals. Building on a program in the American Rescue Plan, I have requested \$1 billion in funding to expand the number of school-based mental health professionals, including school psychologists and counselors to address the mental health needs of students. The American Rescue Plan also delivered \$3 billion for substance use and mental health care block grants. These funds also ensure that States provide pathways to prevention, intervention, treatment, and recovery services—especially for underserved communities. The American Rescue Plan also included \$420 million in funding to support Certified Community Behavioral Health Clinics to expand access to high-quality, evidence-based behavioral health services. Certified Community Behavioral Health Clinics are also committed to involving peers and families, who are essential to mental health recovery.

My Administration is committed to ensuring that everyone knows that they are not alone, that help exists, and that we will provide the mental health support needed to heal, recover, and 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 May 2021 as National Mental Health Awareness Month. I call upon citizens, government agencies, organizations, healthcare providers, and research institutions to raise mental health awareness and continue helping Americans live longer, healthier lives.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of April, in the year of our Lord two thousand twenty-one, and of the Independence of the United States of America the two hundred and forty-fifth.

R. Beden. Ja

Proclamation 10194 of April 30, 2021

National Physical Fitness and Sports Month, 2021

By the President of the United States of America

A Proclamation

Despite the unprecedented challenges and disruptions of the past year, we continue to see examples of Americans finding innovative ways to stay active and healthy. Some have moved their workouts into their living rooms or garages. Others have taken up new sports. Many have simply rediscovered the satisfaction of a walk through their neighborhood. Despite this creativity, far too many people struggle to incorporate regular physical activity into their daily lives. Socioeconomic disparities, lack of opportunities for safe play, and limited access to programs for increased activity are just a few of the inequities that many Americans face—inequities that have been further exacerbated by the pandemic. During this National Physical Fitness and Sports Month, we encourage all Americans to stay active for their health and wellbeing. Whether by pursuing a more active lifestyle, making physical activity a priority and an essential part of everyday living, or supporting efforts in local communities that increase access to sports and physical fitness opportunities for all, participating in physical activities leads to a healthier lifestyle.

Physical activity is one of the best tools we have to help combat chronic diseases experienced by over half of all Americans. Even a single session of moderate-to-vigorous physical activity can boost your mood, sharpen your focus, reduce your stress, and improve your sleep. More regular physical activity—over months or years—can contribute to a reduced risk of depression, heart disease, several types of cancer, dementia, type 2 diabetes, and obesity.

No matter our age or ability, the more that we can make regular physical activity and participation in sports a part of our lives, the better off both we and our Nation will be. Greater amounts of physical activity can have positive effects in every stage of life and lead to better overall health outcomes for both children and adults, including those with disabilities. The Department of Health and Human Services' Move Your Way campaign provides helpful tips to encourage children and adults to meet the recommendations from the *Physical Activity Guidelines for Americans*. The Centers for Disease Control and Prevention's Active People, Healthy Nation initiative provides a blueprint for building active communities to make it easier for all Americans to attain the physical activity they need, with a goal of getting 27 million more Americans physically active by 2027.

By transcending differences and uniting in celebration of physical activity, healthy competition, and shared enjoyment, sports are a fun and engaging way to stay active and keep fit for people of all ages. For our Nation's youth, playing sports can also help to build confidence on and off the field, while team sports foster the added virtues of service to common causes and communal responsibility—win or lose, every game offers the opportunity to learn something new or hone your skills. Every athletic challenge is an avenue to greater mental and physical resilience. While social distancing has made participation in organized sports challenging, we can use this time to renew our focus on fundamental skills and training in preparation for a return to play, especially for young athletes.

Our Nation can and must do more to make sure that every child has the opportunity to play sports and obtain the benefits that come with play, including greater physical fitness and better health. As we recover from the COVID-19 pandemic, it is more important than ever that we ensure equal access to sports and fitness activities for everyone. To that end, my Administration continues to promote programs that provide opportunities for all of our young people to play sports—regardless of their race, ethnicity, sex, sexual orientation, gender identity, religion, disability, or neighborhood—in support of the *National Youth Sports Strategy*.

I encourage every American to discover an enjoyable exercise activity that fits into their daily routine. It does not matter how you choose to be active—whether you are trying your hand at a new sport, exploring a local park, or going for a walk or a jog in your own neighborhood, physical activity holds the key to better health and wellness. During National Physical Fitness and Sports Month, let us all strive to be more active together.

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 May 2021 as National Physical Fitness and Sports Month. I call upon the people of the United States to make daily physical activity a priority, to support efforts to increase access to sports opportunities in their communities, and to pursue physical fitness as an essential part of healthy living.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of April, in the year of our Lord two thousand twenty-one, and of the Independence of the United States of America the two hundred and forty-fifth.

L. Beder. Ja

[FR Doc. 2021–09591 Filed 5–4–21; 8:45 am] Billing code 3295–F1–P

Proclamation 10195 of April 30, 2021

National Teacher Appreciation Day and National Teacher Appreciation Week, 2021

By the President of the United States of America

A Proclamation

As the proud husband of an educator who continues, as First Lady, to teach writing at a community college, I have seen firsthand the dedication, selflessness, and vision of our Nation's educators. They play so many different roles: They are mentors who guide with creativity and care; advocates who fight for students' needs; role models who help students dream and dare more boldly; and leaders who tirelessly support the families and communities that depend on them. Every day, with every student they reach, educators build the future of our country, and we are grateful for their commitment to our shared future. This National Teacher Appreciation Day and National Teacher Appreciation Week, we honor the service and passion and celebrate the immeasurable contributions of our Nation's educators in schools from coast to coast.

Throughout history, America's educators have risen to unprecedented challenges. Over the past year, with our country facing a cascade of crises, educators have risen to this challenge with care and creativity: overcoming disruptions in their own lives while offering unwavering support for their students' wellbeing and academic progress.

Educators served both as facilitators of learning and as the technology support for their students, getting them up and running with access to fully remote learning. They often worked late into the day to support hard-to-reach children, and took the extracurriculars their students love and adapted them for remote and hybrid learning. Our teachers even found new ways to leverage technology platforms to coordinate with parents as partners in learning, keep a close eye on the development of their students, and build community by moving music rehearsals and sports practices online.

As this pandemic has shined a bright light on the inequities that persist in our schools, educators have also fought for the tools and resources their schools need to bridge gaps and ensure all children have what they need to succeed. Other school staff and administrators have also stepped up in our time of need, with bus drivers bringing hotspots to areas with no wireless internet, food service staff preparing meals for students who might otherwise go hungry, and counselors helping students and parents cope with trauma.

When I took office, I vowed to support our educators by giving them the pay and dignity they deserve. I made a promise that they would not only have a voice as we work to rebuild and reimagine our education system, they would help us lead this effort. That is why my Administration is partnering with State and local leaders, educators and their unions, and families to ensure high-quality instruction, overcome the challenges of the instructional time we lost in the pandemic, address educational inequities, and meet students' physical, social, and emotional needs.

In early March, I prioritized early childhood through 12th grade educators and staff for vaccination, and I set a goal of getting all of these frontline essential workers at least one shot by the end of the month. On April

2nd, I announced that 80 percent of all teachers, school staff, and childcare workers across the country had received at least one dose of the COVID–19 vaccine. Since then, we have made even more progress in protecting our educators.

The American Rescue Plan is providing critical relief, including \$122 billion in relief for K–12 schools to get students back in the classroom quickly and safely and address the needs of students. In addition, the American Rescue Plan includes \$7.6 billion for special education, children and youth experiencing homelessness, Tribal educational agencies, Native Hawaiians, and Alaska Natives, emergency assistance to non-public schools, and the outlying areas of American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, and the U.S. Virgin Islands, as well as \$40 billion for higher education.

Education is the one field that makes all others possible. Every one of us has been shaped by someone who inspired our curiosity and helped us find our confidence, who guided us to think more clearly and pushed us to strive for better. On National Teacher Appreciation Day and during National Teacher Appreciation Week, we remember the tremendous debt of gratitude owed to educators everywhere who helped define us as individuals and as a country, and to all that they are doing to light the way forward for our families and our communities.

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 May 4, 2021, as National Teacher Appreciation Day and May 2 through May 8, 2021, as National Teacher Appreciation Week. I call upon all Americans to recognize the hard work and dedication of our Nation's teachers and to observe this day and this week by supporting teachers through appropriate activities, events, and programs.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of April, in the year of our Lord two thousand twenty-one, and of the Independence of the United States of America the two hundred and forty-fifth.

L. Beder. J.

Proclamation 10196 of April 30, 2021

Public Service Recognition Week, 2021

By the President of the United States of America

A Proclamation

In the face of unprecedented challenges this past year, America's dedicated public servants have risen to the moment—bringing strength, healing, and hope to their communities and to our Nation. Our public servants are a living reminder that, here in America, we take care of one another and leave no one behind. As we work to defeat the pandemic and rebuild our economy, it is more important than ever to recognize and reflect upon both our collective loss and our collective resilience. During Public Service Recognition Week, we celebrate and thank our public servants at the local, State, and Federal levels who exemplify dedication to the common good.

Public servants are the lifeblood of our democracy. They are our researchers and scientists, our front-line workers, our educators, our first responders, our election officials, and our military service members—among countless others. They are ordinary Americans who answer the call to do extraordinary things, giving their time—and, in some cases, risking or giving their lives—to make life better for all of us.

Throughout this week and beyond, my Administration will be shining a light on the individual and collective efforts of public servants at the local, State, Tribal, and Federal levels who unite us and help lead us through challenging times. In the toughest of circumstances and often at great personal sacrifice, our public servants tackle the most complex problems facing our communities. Whether developing public health guidance and working across agencies to safely reopen schools during the pandemic, partnering with the private sector to develop and distribute vaccines, keeping small businesses dreams alive, or combating natural disasters in their hometowns, public servants demonstrate their commitment to our Nation every day. It is our responsibility, in turn, to ensure that they are honored and protected.

Since taking office earlier this year, I have made it the policy of the United States to protect, empower, and rebuild the career Federal workforce. My Administration made employee safety a priority—directing agencies to create COVID—19 workplace safety plans and require mask-wearing, physical distancing, and other public health measures in Federal buildings and on Federal lands. I revoked several Executive Orders that undermined the foundations of civil service, worked to ensure the right of Federal employees to engage in collective bargaining, and created a new interagency task force to ensure that Federal employees engaged in scientific research and data collection are never subjected to political interference.

In addition, I have strengthened protections against discrimination for Federal employees, including discrimination on the basis of gender identity or sexual orientation. I have also asked the Director of the Office of Personnel Management to provide me with recommendations to promote a \$15 per hour minimum wage for Federal employees, as well as recommendations for expanding the Federal Government's policy of providing employees time off to vote. And this week, I signed an Executive Order that will increase the minimum wage for employees working on Federal contracts to \$15 per hour.

Together, as we strive to build, support, and continuously improve our public workforce, we recognize and celebrate the indispensable contributions our public servants make while protecting our communities, taking care of our neighbors, and helping us heal and build back better. It is the honor of my lifetime to serve our Nation alongside our public servants, who work tirelessly to improve the lives of Americans and people around the globe.

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 May 2 through May 8, 2021, as Public Service Recognition Week. I call upon all Americans to celebrate public servants and their contributions this week and throughout the year.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of April, in the year of our Lord two thousand twenty-one, and of the Independence of the United States of America the two hundred and forty-fifth.

L. Beder. Ja

[FR Doc. 2021–09593 Filed 5–4–21; 8:45 am] Billing code 3295–F1–P

Proclamation 10197 of April 30, 2021

Law Day, U.S.A., 2021

By the President of the United States of America

A Proclamation

In the many years I spent as a United States Senator and as Vice President, I logged hundreds of thousands of miles of travel, and had the opportunity to meet with foreign officials all over the world. Those experiences impressed upon me a truth about America: that what makes our Nation unique is the depth of our devotion to the rule of law.

Unlike so many of the Nations of the world, the United States wasn't built around an ethnicity, religion, or tribe—it was built around common ideals. The rule of law is central to those ideals. It is what limits the abuse of power in our Nation, whether by an individual or a mob. It reflects President John Adams' desire to establish "a government of laws and not of men." It is how Thomas Paine distinguished us from the rest of the world—declaring that, while in other Nations, the king is law, "in America, the law is king."

Many Nations around the world still struggle to capture what we have captured here in America—not only in the text of our founding documents, but in the character of our people: reverence for the law. That reverence is essential to our democracy. Without it, equality and justice cannot be advanced, human rights cannot be protected, democratic norms and values cannot be secured, and disagreements cannot be peaceably resolved. The rule of law has also been a critical vehicle for delivering the full promise of American democracy to all of our people, particularly those excluded in our Nation's founding. Today, on Law Day, we rededicate ourselves to furthering that promise and strengthening those ideals, and we renew our commitment to ensure that every American's constitutional rights are protected.

The theme of this year's Law Day, "Advancing the Rule of Law Now," is particularly fitting at this moment in our Nation's history. Recently, we were again called to recognize that democracy is precious and fragile. We have witnessed grave threats to our democratic institutions and to the rule of law itself. These tragic events have taught us once again that when we are united, we can overcome the greatest challenges and move our country forward—but it takes a commitment to law over demagoguery, and the enforcement of law free from political interference, to do so.

Previous generations of Americans have lived through civil war, economic depressions, the rise of fascism, and world wars—and today, too many Americans continue to face pervasive racism, xenophobia, nativism, and other forms of intolerance. This year, the United States marks the 100th anniversary of the Tulsa, Oklahoma, race massacre, in which a mob of white residents attacked and killed between 100 and 300 Black residents and destroyed more than 1,000 homes and businesses in a thriving community known as Black Wall Street. Today, a century later, we still face chilling echoes of those threats to equality, justice, and the rule of law in the form of rising political extremism, white supremacy, and domestic terrorism.

My Administration is committed to advancing the rule of law within the United States so that everyone is ensured equal justice under the law, an equal place in our democracy, and the opportunity to fulfill their potential

free from abuses of power. On my first day in office, I signed an historic Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, to advance equity and racial justice and redress systemic racism across a comprehensive sweep of Federal policies, laws, and programs. I also signed a memorandum on Condemning and Combating Racism, Xenophobia, and Intolerance Against Asian Americans and Pacific Islanders in the United States, stating that the Federal Government has a responsibility to prevent racism, xenophobia, and intolerance against anyone in the United States-particularly, today, against Asian Americans who have spent the last year enduring unconscionable and un-American harassment and attacks—as well as an additional Executive Order on Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation. I have directed Federal agencies to facilitate access to voting using their existing legal authority, and my Administration supports further legislation to protect the sacred right to vote and make it more equitable and accessible for all Americans to exercise that right.

We are also working to advance the rule of law across the world by rebuilding global alliances; confronting authoritarianism; and reengaging with other governments, civil society organizations, and multilateral organizations, such as the United Nations. We must ensure that we are able to lead not by the example of our power, but by the power of our example. As I have said on many occasions, our diplomacy must be rooted in America's most cherished democratic values: defending freedom, championing opportunity, upholding universal rights, respecting the rule of law, and treating every person with dignity.

On this Law Day, U.S.A., I urge my fellow Americans to join me in recommitting ourselves to promoting and advancing the rule of law and delivering freedom and equality for all.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, in accordance with Public Law 87–20, as amended, do hereby proclaim May 1, 2021, as Law Day, U.S.A. I call upon all Americans to acknowledge the importance of our Nation's legal and judicial systems with appropriate ceremonies and activities, and to display the flag of the United States in support of this national observance.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of April, in the year of our Lord two thousand twenty-one, and of the Independence of the United States of America the two hundred and forty-fifth.

L. Beder. Je

Proclamation 10198 of April 30, 2021

Loyalty Day, 2021

By the President of the United States of America

A Proclamation

On Loyalty Day, we celebrate our allegiance to the project of this great Nation and the democratic ideals woven into the fabric of our Constitution. As Americans, we do not command loyalty, but seek to earn it through our actions—including by living up to the principles enshrined in our Constitution and respecting the will of the people as reflected in the democratic process. Drawn together by the promise of equality, freedom, and justice, we are a Nation of shared ideals and strong, resilient people. Here in America, loyalty does not mean fealty to any one leader or political party, nor does it mean unthinking praise or willful ignorance of our shortcomings—it means loyalty to our common ideals, and to one another. It means standing united as one people, even as we cherish our differences and respect dissent.

Our country is a diverse tapestry of many cultures, heritages, religions, and languages, brought together around the values and ideals we all share as Americans. Together, we celebrate our differences and draw strength from our common commitment to perfecting our Union. No matter what challenges come our way, our Nation holds strong together—bound by our Constitution and the rule of law, uplifted by individual liberties and promises of justice we have worked hard in each generation to secure and expand, and consecrated by those who have sacrificed to preserve, defend, and care for our Nation.

We see loyalty in the members of our Armed Forces, who selflessly serve in harm's way; in their families, who, in the timeless words of the poet John Milton, "also serve who only stand and wait;" in our educators, who dedicate their lives to nurturing young minds; in our first responders, who put their lives on the line to save others; in all those who have the courage to call out our Nation's imperfections when we fall short, and who continue to push our society to live up to its founding promise of freedom, justice, and equality for all. May 1 is also International Workers' Day, and we honor the workers whose service and sacrifice has helped turn the tide against the COVID–19 pandemic. On this day, we show our gratitude to our essential workers—and to all of the workers who have organized and fought to improve our Nation and create a fairer and more just society for all.

To acknowledge the American ethos of patriotism and the sacrifices so many of our fellow citizens have made, the Congress, by Public Law 85–529, as amended, has designated the 1st day of May each year as Loyalty Day. On this day, let us reaffirm our commitment to the values that bind us together and honor all those who have defended our freedom.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, do hereby proclaim May 1, 2021, as Loyalty Day. This Loyalty Day, I call upon the people of the United States to join in this national observance, display the United States flag and pledge allegiance to the Republic for which it stands.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of April, in the year of our Lord two thousand twenty-one, and of the Independence of the United States of America the two hundred and forty-fifth

R. Beder. fr

[FR Doc. 2021–09595 Filed 5–4–21; 8:45 am] Billing code 3295–F1–P

Rules and Regulations

Federal Register

Vol. 86, No. 85

Wednesday, May 5, 2021

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.

SMALL BUSINESS ADMINISTRATION

13 CFR Part 126

RIN 3245-AH66

HUBZone Program: Extending Map Freeze

AGENCY: U.S. Small Business

Administration.

ACTION: Direct final rule.

SUMMARY: This direct final rule extends the HUBZone map freeze mandated by the National Defense Authorization Act for Fiscal Year 2018 (NDAA 2018) from December 31, 2021, to June 30, 2023. The NDAA 2018 requires that certain certified HUBZone small business concerns shall maintain their HUBZone status until the HUBZone map is updated in accordance with the results of the 2020 census. SBA previously issued a rule to implement this provision and "freeze" the HUBZone map until December 31, 2021. However, SBA has learned that the data necessary to update the HUBZone map to reflect the 2020 census results will not be available to SBA until December 2022. Thus, SBA must extend the HUBZone "freeze" through June 30, 2023, which will permit SBA to process the data, update the HUBZone map, and provide adequate notice to the HUBZone small business community. This amendment is necessary to avoid public confusion about when certain HUBZone designations will be expiring.

DATES: This rule is effective on June 21, 2021 without further action, unless significant adverse comment is received by June 4, 2021. If significant adverse comment is received, SBA will publish a timely withdrawal of the rule in the **Federal Register**.

ADDRESSES: You may submit comments, identified by RIN: 3245–AH66, by any of the following methods:

• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail or Hand Delivery/Courier:
 Laura Maas, HUBZone Program, 409
 Third Street SW, Washington, DC
 20416.

SBA will post all comments on http:// www.regulations.gov. If you wish to submit confidential business information (CBI), as defined in the User Notice at http://www.regulations.gov. please submit the information to Laura Maas, HUBZone Program, 409 Third Street SW, Washington, DC 20416, 202-205-7341, or send an email to hubzone@sba.gov. Highlight the information that you consider to be CBI and explain why you believe SBA should hold this information as confidential. SBA will review the information and make the final determination on whether it will publish the information.

FOR FURTHER INFORMATION CONTACT: Laura Maas, HUBZone Program, 409 Third Street SW, Washington, DC 20416, 202–205–7341, hubzone@ sba.gov.

SUPPLEMENTARY INFORMATION: Section 1701(i) of the National Defense Authorization Act for Fiscal Year 2018 (NDAA 2018), Public Law 115-91, December 12, 2017, provides that certain certified HUBZone small business concerns shall maintain their HUBZone status until the HUBZone map is updated in accordance with the results of the 2020 census. To implement this provision, on November 26, 2019, SBA published a final rule "freezing" the HUBZone map until the map could be updated based on the results of the 2020 census. 84 FR 65222. In the preamble to the final rule, SBA explained:

In enacting section 1701(i), Congress intended for small businesses located in expiring redesignated areas to retain their HUBZone eligibility until the date on which SBA updates the HUBZone maps in accordance with the broader changes described in section 1701. In other words, firms that were certified HUBZone small business concerns as of the date of enactment of the NDAA 2018 (December 12, 2017), and that had principal offices located in redesignated areas set to expire prior to January 1, 2020, shall remain certified HUBZone small business concerns until SBA updates the HUBZone maps after the 2020 decennial census . . . SBA notes that to implement this change, SBA will 'freeze' the HUBZone maps with respect to qualified census tracts, qualified non-metropolitan counties, and redesignated areas. As a result,

for all redesignated areas in existence on December 12, 2017, the expiration of their HUBZone treatment has been extended until December 31, 2021. SBA selected this date because SBA estimates that the HUBZone maps will have been updated to incorporate the results of the 2020 census and to reflect the broad changes mandated by section 1701 by that time, and selecting a specific date provides stability to program participants. SBA did not receive any comments on the proposed definition of 'HUBZone small business concern' and is implementing the changes as proposed. (84 FR 65222, 65226).

In the time since the publication of this final rule, SBA has learned that the datasets necessary for SBA to update the HUBZone map based on the results of the 2020 census will not be available to SBA until approximately December 2022. These datasets include the Department of Housing and Urban Development's designation of qualified census tracts. Consequently, SBA must extend the HUBZone map freeze beyond December 31, 2021. SBA has determined that the map freeze should be extended through June 30, 2023, which will permit SBA to process the data, update the HUBZone map, and provide adequate notice to the HUBZone small business community.

In order to extend the map freeze through June 30, 2023, SBA must amend the date set forth in the definitions of the terms HUBZone small business concern or certified HUBZone small business concern and Redesignated area contained in § 126.103 of the HUBZone regulations. This amendment is necessary to avoid public confusion about when certain HUBZone designations will be expiring.

Compliance With Executive Orders 12866, 12988, 13132, 13175, 13563, the Congressional Review Act (5 U.S.C. 801–808), the Paperwork Reduction Act (44 U.S.C. Ch. 35), and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Administrative Procedure Act, 5 U.S.C. 553

Executive Order 12866

The Office of Management and Budget (OMB) has determined that this direct final rule does not constitute a significant regulatory action under Executive Order 12866 (Regulatory Planning and Review).

Executive Order 12988

This action meets applicable standards set forth in sections 3(a) and

3(b)(2) of Executive Order 12988 (Civil Justice Reform), to minimize litigation, eliminate ambiguity, and reduce burden. The action does not have retroactive or preemptive effect.

Executive Order 13132

For the purposes of Executive Order 13132 (Federalism), SBA has determined that this direct final rule will not have substantial, direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, for the purpose of Executive Order 13132, SBA has determined that this direct final rule has no federalism implications warranting preparation of a federalism assessment. If you believe this direct final rule has implications for federalism, please call or email the person listed in the FOR FURTHER **INFORMATION CONTACT** section.

Executive Order 13175

SBA has determined that this direct final rule would not have tribal implications under Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments) because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this direct final rule has implications for Indian tribes, please call or email the person listed in the FOR **FURTHER INFORMATION CONTACT** section.

Executive Order 13563

Executive Order 13563 (Improving Regulation and Regulatory Review) reaffirms the principles of Executive Order 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. Executive Order 13563 also requires that regulations be based on the open exchange of information and perspectives among state and local officials, affected stakeholders in the private sector, and the public as a whole. SBA has developed this rule in a manner consistent with these requirements. While developing this

rule, SBA responded to specific inquiries from government officials and the public regarding the extension of the HUBZone map freeze.

Paperwork Reduction Act, 44 U.S.C., Ch. 35

SBA has determined that this direct final rule does not impose additional reporting or recordkeeping requirements under the Paperwork Reduction Act, 44 U.S.C., Chapter 35.

Regulatory Flexibility Act, 5 U.S.C. 601–612

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601, requires administrative agencies to consider the effect of their actions on small entities, small nonprofit enterprises, and small local governments. Pursuant to the RFA, when an agency issues a rulemaking, the agency must prepare a regulatory flexibility analysis which describes the impact of the rule on small entities. However, section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities. Within the meaning of RFA, SBA certifies that this direct final rule will not have a significant economic impact on a substantial number of small entities because it will directly impact only certified HUBZone small business concerns with principal offices located in Redesignated Areas.

Justification for Direct Final Rule

SBA is publishing this rule as a direct final rule because SBA views this as a non-controversial administrative action because it merely changes a date in SBA's regulations to reflect updated information about when the 2020 Census results will be incorporated into the Department of Housing and Urban Development's designation of qualified census tracts. This rule will be effective on the date shown in the DATES section unless SBA receives any significant adverse comments on or before the deadline for comments set forth in the **DATES** section. Significant adverse comments are comments that provide strong justifications why the rule should not be adopted or for changing the rule. SBA does not expect to receive any significant adverse comments because section 1701(i) of the 2018 NDAA requires SBA to maintain the HUBZone status of certain certified HUBZone small business concerns until the HUBZone maps can be updated to reflect the results of the 2020 census. Implementation of this change will benefit the public by allowing the

HUBZone small business community to plan for the update of the maps on July 1, 2023, rather than January 1, 2022. If SBA receives any significant adverse comments, SBA will publish a notice in the **Federal Register** withdrawing this rule before the effective date. If SBA receives no significant adverse comments, SBA will publish a document in the **Federal Register** confirming the effective date.

Congressional Review Act, 5 U.S.C. 801–808

Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (codified at 5 U.S.C. 801-808), also known as the Congressional Review Act (CRA), 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. SBA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States. Additionally, the CRA provides that a major rule under the CRA cannot take effect until 60 days after it is published in the **Federal Register**: however, the Office of Information and Regulatory Affairs has determined that this rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 13 CFR Part 126

Administrative practice and procedure, Government procurement, Small businesses.

Accordingly, for the reasons stated in the preamble, SBA amends 13 CFR part 126 as follows:

PART 126—HUBZONE PROGRAM

■ 1. The authority for 13 CFR part 126 continues to read as follows:

Authority: 15 U.S.C. 632(a), 632(j), 632(p), 644 and 657a; Pub. L. 111–240, 24 Stat. 2504.

§126.103 Amended

- 2. Amend § 126.103 as follows:
- a. Amend the definition of the term *HUBZone small business concern or certified HUBZone small business concern* by removing the date "December 31, 2021" and adding in its place the date "June 30, 2023"; and
- b. Amend the definition of the term *Redesignated area* by removing the date

"December 31, 2021" and adding in its place the date "June 30, 2023".

Isabella Casillas Guzman,

Administrator.

[FR Doc. 2021–09397 Filed 5–4–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 53

[TD 9938]

RIN 1545-BO99

Tax on Excess Tax-Exempt Organization Executive Compensation; Correction

AGENCY: Internal Revenue Service (IRS),

ACTION: Correcting amendments.

SUMMARY: This document contains corrections to final regulations (Treasury Decision 9938) that were published in the Federal Register on Tuesday, January 19, 2021. The Treasury Decision provided final regulations implementing an excise tax on remuneration in excess of \$1,000,000 and any excess parachute payment paid by an applicable tax-exempt organization to any covered employee.

DATES: *Effective date:* These final regulation corrections are effective on May 5, 2021.

FOR FURTHER INFORMATION CONTACT:

William McNally at (202) 317–5600 or Patrick Sternal at (202) 317–5800 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9938) that are the subject of this correction are issued under section 4960 of the Internal Revenue Code.

Need for Correction

As published on January 19, 2021 (86 FR 6196) the final regulations (TD 9938) contain errors that need to be corrected.

List of Subjects in 26 CFR Part 53

Excise taxes, Foundations, Investments, Lobbying, Reporting and recordkeeping requirements.

Correction of Publication

Accordingly, 26 CFR part 53 is corrected by making the following correcting amendments:

PART 53—FOUNDATION AND SIMILAR EXCISE TAXES

■ Paragraph 1. The authority citation for part 53 continues to read in part as follows:

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

■ Par. 2. Section 53.4960–0 is amended by revising the entry for § 53.4960–1(b)(3) to read as follows:

§53.4960-0 Table of contents.

§ 53.4960-1 Scope and definitions.

(b) * * *

(3) [Reserved]

Crystal Pemberton,

Senior Federal Register Liaison, Legal Processing Division, Associate Chief Counsel, (Procedure and Administration).

[FR Doc. 2021-09425 Filed 5-4-21; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG-2021-0151]

Special Local Regulations: Miami Beach Air and Sea Show, Atlantic Ocean, Miami Beach, FL

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a special local regulation for the Miami Beach Air and Sea Show from Friday May 28, 2021 to Sunday May 30, 2021, from 9 a.m. to 5 p.m. to provide for the safety of life on navigable waterways during this event. During the enforcement periods, the operator of any vessel in the regulated area must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

DATES: The regulation in 33 CFR 100.725 will be enforced from Friday

DATES: The regulation in 33 GFR 100.725 will be enforced from Friday May 28, 2021, to Sunday May 30, 2021, from 9 a.m. to 5 p.m.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of

enforcement, call or email Petty Officer Robert M. Olivas, Sector Miami Waterways Management Division, U.S. Coast Guard; telephone 305–535–4317, email Robert.M.Olivas@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce a special local regulation in 33 CFR 100.725 for the

Miami Beach Air and Sea Show to provide for the safety of life on navigable waterways during the event. Our regulation for the Miami Beach Air and Sea Show, § 100.725, specifies the location of the regulated area which encompasses a portion of the Atlantic Ocean east of Miami Beach. During the enforcement periods, if you are the operator of a vessel in the regulated area you must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners and marine information broadcasts.

Dated: April 29, 2021.

J.F. Burdian,

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

[FR Doc. 2021-09469 Filed 5-4-21; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2021-0304]

Safety Zone; Commencement Bay, Tacoma, WA

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

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a safety zone for the Tacoma Freedom Fair Air Show on Commencement Bay from 2 p.m. on July 3 through 12:30 a.m. on July 4, 2021. This action is necessary to ensure the safety of the public from inherent dangers associated with the annual aerial displays. During the enforcement periods, no person or vessel may enter or transit this safety zone unless authorized by the Captain of the Port Puget Sound (COTP) or their designated representative.

DATES: The regulations in 33 CFR 165.1305 will be enforced each day from 2 p.m. on July 3 through 12:30 a.m. on July 4, 2021.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email Lieutenant Peter J. McAndrew, Sector Puget Sound Waterways Management Division, U.S. Coast Guard; telephone 206–217–6045, email SectorPugetSoundWWM@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone in 33 CFR 165.1305 for the Tacoma Freedom Air Show on Commencement Bay from 2 p.m. on July 3 through 12:30 a.m. on July 4, 2021. This action is being taken to provide for the safety of life on navigable waterways during the aerial demonstrations above the waterway. The safety zone resembles a rectangle protruding from the shoreline along Ruston Way and will be marked by the event sponsor. The specific coordinates of the safety zone location are listed in 33 CFR 165.1305.

As specified in § 165.1305(c), during the enforcement period, no vessel may transit the regulated area without approval from the COTP or a COTP designated representative. The COTP may be assisted by other federal, state, and local law enforcement agencies in enforcing this regulation.

In addition to this notice of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners, marine information broadcasts during the day of the event. If the COTP determines that the safety zone need not be enforced for the full duration stated in the notice of enforcement, they will use a Broadcast Notice to Mariners or Local Notice to Mariners to grant general permission to enter the regulated area.

Dated: April 29, 2021.

P.M. Hilbert,

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

[FR Doc. 2021–09501 Filed 5–4–21; 8:45 am]

BILLING CODE 9110-04-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 20-343; FCC 21-43; FRS 23867]

FCC Adopts 10-Application Limit for NCE FM New Station Applications in Upcoming 2021 Filing Window

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document the Commission adopts a limit of 10 applications filed by any party during the upcoming 2021 window for new noncommercial educational (NCE) FM radio stations. The application cap is designed to provide a meaningful opportunity for applicants to file for new NCE FM stations and expand NCE

service while, at the same time, deter speculative applications and procedural delays.

DATES: Effective June 4, 2021.

FOR FURTHER INFORMATION CONTACT:

James Bradshaw, James.Bradshaw@fcc.gov; Lisa Scanlan, Lisa.Scanlan@fcc.gov; or Amy Van de Kerckhove, Amy.Vandekerckhove@fcc.gov, of the Media Bureau, Audio Division, (202) 418–2700. Direct press inquiries to Janice Wise, Janice.Wise@fcc.gov, (202) 418–8165.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's document, FCC 21–43, adopted and released April 21, 2021. The full text of this document is available for download at the FCC's Electronic Document Management System (EDOCS) website at https://www.fcc.gov/edocs or via the FCC's Electronic Comment Filing System (ECFS) website at https://www.fcc.gov/ecfs by using the search function for MB Docket No. 20–343 (Documents will be available electronically in ASCII, Microsoft Word, and/or Adobe Acrobat.)

Synopsis

1. Introduction. The Commission recently announced the intention to open a 2021 filing window for FM reserved band (channels 201–220) applications for new noncommercial educational (NCE) FM radio stations and sought comment on a proposed limit of 10 applications filed by any party during the upcoming window. This document adopts the proposed 10-application cap on NCE FM new station applications.

2. Background. In 2007, before the first NCE FM filing window opened, the Commission sought comment on an application cap and subsequently established a limit of 10 NCE FM new station applications filed by any party during the October 2007 filing window. This application limit helped foster the goals of localism and diversity as reflected in the NCE FM point system, while also restricting the number of speculative or mutually exclusive (MX) applications. This, in turn, minimized the delay caused by processing complicated application chains. The 10application cap also allowed the Commission to expeditiously process and grant thousands of applications to a wide range of local and diverse applicants, therefore promoting the rapid expansion of new NCE FM service throughout the country. In the October 2020 Cap Comment Notice (published at 85 FR 70569 on Nov. 5, 2020), the Commission tentatively concluded that it should also establish a 10-application

limit for the upcoming 2021 NCE FM filing window.

- 3. In the Cap Comment Notice, the Commission sought comment on whether 10 applications is the appropriate limit to enable the efficient processing of applications and initiation of new NCE FM service. Although the commenters addressing the proposed cap agree that some limit is advisable, they were not in agreement on what specific limit would be most appropriate and beneficial. Specifically, while National Public Radio, Inc. (NPR) endorses the Commission's proposed 10-application cap, REC Networks (REC) proposes a lower five-application limit, and Educational Media Foundation (EMF) recommends allowing parties to file more than 10 applications if the additional applications are for areas outside the home counties of Nielsen Audio markets.
- 4. Discussion. The Commission adopts the proposal from the Cap Comment Notice to establish a limit of 10 NCE FM new station applications filed by any party during the upcoming filing window. The Commission finds a 10-application cap will best deter speculative filings, permit the expeditious processing of the applications filed in the window, and provide interested parties with a meaningful opportunity to file for and obtain new NCE FM station licenses.
- 5. The document acknowledges that REC's proposed five-application cap could theoretically curb the number of MX applications, and therefore, have the benefit of simplifying and expediting the processing of applications. The Commission finds, however, that this benefit is outweighed by the fact that a five-application limit will also curtail the expansion of new NCE FM service, and therefore, disserve the public interest. The last NCE FM filing window was over 13 years ago, and accordingly, there is pent-up demand for new NCE FM channels, which is unlikely to be satisfied with a lower five-application cap.
- 6. The document acknowledges EMF's novel proposal, but concludes that the logistical and administrative challenges of implementing EMF's two-tiered approach are simply too cumbersome and create the potential for extraordinary procedural delays and the ultimate delay of new NCE FM service to the public. The Commission finds that adopting EMF's approach is not administratively feasible at this time. The time required to further revise the Commission's rules and forms to adopt the EMF proposal would significantly delay the initiation of the filing window

and service to the public and outweigh any benefit from the EMF proposal.

7. The document recognizes EMF's claim that its proposal would increase NCE FM service to rural areas and allow parties to file more applications to upgrade FM translators serving rural areas to protected full-power stations. The Commission notes, however, that EMF's proposal, which was not endorsed by any of the commenters, also has the drawback of increasing the potential for more MX groups, created by the secondary application filings, larger MX groups, and complicated application chains, which could lead to processing delays, and ultimately, delay the initiation of new NCE FM service to the public.

8. The Commission finds that the proven 10-application cap strikes the best balance of its multiple objectives of providing a meaningful opportunity for applicants to file for new NCE FM stations and expanding service while, at the same time, deterring speculative applications and procedural delays. The 10-application cap, employed during the 2007 NCE FM filing window, has proven, in practice, to be very effective.

9. The document adopts the proposal that an applicant may file no more than a total of 10 applications in the 2021 NCE FM filing window. Under existing precedent, this means that a party to an application filed in the 2021 NCE FM filing window may hold attributable interests in no more than a total of 10 applications filed in the window. If it is determined that any party to an application has an attributable interest in more than 10 applications, the Media Bureau will retain the 10 applications that were filed first—based on the date of application receipt—and dismiss all other applications.

Procedural Matters

10. Regulatory Flexibility Analysis. As required by the Regulatory Flexibility Act of 1980 (RFA), as amended, an Initial Regulatory Flexibility Analysis was incorporated in the initial Public Notice, FCC Seeks Comment on Proposed Application Limit for NCE FM New Station Applications in Upcoming 2021 Window, FCC 20-145. The Commission sought written public comment on the proposal in the document, including comment on the IRFA. The Commission received no comments specifically directed toward the IRFA. This Final Regulatory Flexibility Analysis (FRFA) conforms to the RFA.

11. Need for, and Objectives of, the 10-Application Limit. The document adopts a limit of 10 NCE FM radio station applications filed by any party

during the upcoming 2021 filing window. The Commission has determined that, absent a limit on the number of applications that a party may file in the upcoming filing window, some parties may file a large number of speculative applications, including applications that are mutually exclusive with each other, resulting in procedural delays and the delay of new NCE FM service to the public. The Commission has concluded that a limit of 10 applications for new NCE FM construction permits in the filing window is an appropriate procedural safeguard to deter speculation and permit the expeditious processing of the NCE FM applications while still allowing applicants meaningful opportunities to expand NCE FM service. The Commission believes that the adopted limit will benefit small entities.

12. Summary of Significant Issues Raised by Public Comments in Response to the IRFA. There were no comments to the IRFA filed.

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

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

15. NCE FM Radio Stations. The application limit applies to potential licensees of the NCE FM radio service. This Economic Census category "comprises establishments primarily engaged in broadcasting aural programs

by radio to the public." The SBA has created the following small business size standard for this category: Those having \$41.5 million or less in annual receipts. Census data for 2012 show that 2,849 firms in this category operated in that year. Of this number, 2,806 firms had annual receipts of less than \$25 million, and 43 firms had annual receipts of \$25 million or more. Because the Census has no additional classifications that could serve as a basis for determining the number of stations whose receipts exceeded \$41.5 million in that year, the Commission concludes that the majority of radio broadcast stations were small entities under the applicable SBA size standard. In addition, the Commission has estimated the number of NCE FM radio stations to be 4,195. NCE stations are non-profit, and therefore considered to be small entities.

16. Description of Projected
Reporting, Recordkeeping, and Other
Compliance Requirements. The
Commission anticipates that none of the
changes adopted as a result of the
document will result in an increase to
the reporting and recordkeeping
requirements of broadcast stations or
applicants for NCE FM authorizations.

17. Steps Taken to Minimize Significant Impact on Small Entities, and Significant Alternatives Considered. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.

18. The Commission is directed under law to describe any alternatives it considered, including alternatives not explicitly listed above. The adopted 10application limit is intended to benefit all small NCE entities seeking to establish a new NCE FM service on a local or regional basis by preventing mass filings of speculative applications. This limit should benefit all applicants by expediting the review and processing of applications filed during the window. Based on the record in this proceeding, the Commission concludes that a lower limit would not effectively meet the demand for new NCE FM channels, whereas a higher limit would impose

unacceptable processing delays on all applicants, overriding any potential benefits to the few applicants interested in filing more than 10 applications in this window. The adopted limit does not impose any significant compliance or reporting requirements because it would merely set a limit on the number of applications for new NCE FM authorizations that a party could file during the window. Accordingly, the Commission is not aware of any alternatives that would benefit small entities.

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

Paperwork Reduction Act

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

Congressional Review Act

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

List of Subjects in 47 CFR Part 73

Radio, Reporting and recordkeeping requirements

Federal Communications Commission. **Marlene Dortch**,

Secretary.

Final Rule

For the reasons set forth in the preamble, the Federal Communications Commission amends part 73 of chapter 1 of title 47 of the Code of Federal Regulations as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 155, 301, 303, 307, 309, 310, 334, 336, 339.

■ 2. Section 73.503 is amended by adding paragraph (g) to read as follows:

§ 73.503 Licensing requirements and service.

* * * * *

(g) Application limit. An applicant may file no more than a total of 10 applications in the 2021 NCE FM filing window. A party to an application filed in the 2021 NCE FM filing window may hold attributable interests, as defined in § 73.7000, in no more than a total of 10 applications filed in the window. If it is determined that any party to an application has an attributable interest in more than 10 applications, the Media Bureau will retain the 10 applications that were filed first—based on the date of application receipt—and dismiss all other applications. *

[FR Doc. 2021–09508 Filed 5–4–21; 8:45 am]

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 21-446; FRS 24122]

Radio Broadcasting Services; Various Locations

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document amends the FM Table of Allotments, of the Commission's rules, by reinstating certain vacant FM allotments. These FM allotments are considered vacant because of the cancellation of the associated authorizations and licenses, or the dismissal of long-form auction applications. Theses vacant FM allotments have previously undergone notice and comment rule making. Reinstatement of the vacant allotments is merely a ministerial action to effectuate licensing procedures. Therefore, we find for good cause that further notice and comment are unnecessary.

DATES: Effective May 5, 2021.

FOR FURTHER INFORMATION CONTACT:

Rolanda F. Smith, Media Bureau, (202) 418–2700.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Order, adopted April 19, 2021 and released April 20, 2021. The full text of this Commission decision is available online at http://apps.fcc.gov/ecfs/. This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. The Commission will not send a copy of the Order in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, see 5 U.S.C. 801(a)(1)(A) because the Order is a ministerial action.

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

Federal Communications Commission. **Nazifa Sawez**,

Assistant Chief, Audio Division, Media Bureau.

Final Rules

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 155, 301, 303, 307, 309, 310, 334, 336, 339.

- 2. In § 73.202, the table in paragraph (b) is amended by adding in alphabetical order the following entries:
- i. Under California, "Visalia";
- ii. Under Colorado, "Yampa";
- iii. Under New Mexico, "Carrizozo";
- iv. Under North Dakota, "Beulah"; and
- v. Under Texas, "Girard" and "Kermit".

The additions read as follows:

§ 73.202 Table of Allotments.

* * * * *

(b) * * *

TABLE 1 TO PARAGRAPH (b)
[U.S. States]

		Char	Channel No.	
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/isalia				241A

TABLE 1 TO PARAGRAPH (b)—
Continued
[U.S. States]

			Cha	nnel No.
*	*	*	*	*
	C	OLORADO		
*		*	*	
				277C3
*	*	*	*	*
	N	EW MEXICO		
*	*	*	*	*
Carrizozo				261C2
*	*	*	*	*
	NO	RTH DAKOT	A	
Beulah				250A
*	*	*	*	*
		TEXAS		
*	*	*	*	*
Girard				248C3
*	*	*	*	*
Kermit	289C3			
*	*	*	*	*

[FR Doc. 2021–09399 Filed 5–4–21; 8:45 am]

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS-R8-ES-2021-0009; FF09E21000 FXES11110900000 212]

Endangered and Threatened Wildlife and Plants; Three Salamander Species Not Warranted for Listing as Endangered or Threatened Species

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notification of findings.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce findings that three salamander species, the Samwel salamander (*Hydromantes samweli*), Shasta salamander, (*H. shastae*), and Wintu salamander (*H. wintu*), are not warranted for listing as endangered or threatened species under the Endangered Species Act of 1973, as amended (Act). However, we ask the public to submit to us at any time any

new information relevant to the status of any of the three species or their habitats. **DATES:** The findings in this document were made on May 5, 2021.

ADDRESSES: Detailed descriptions of the bases and supporting information for these findings is available on the internet at http://www.regulations.gov at Docket No. FWS-R8-ES-2021-0009 or by contacting the person specified under FOR FURTHER INFORMATION CONTACT. Please submit any new information, materials, comments, or questions concerning this finding to the appropriate person specified under FOR FURTHER INFORMATION CONTACT.

FOR FURTHER INFORMATION CONTACT:

Jenny Ericson, Field Supervisor, U.S. Fish and Wildlife Service, Yreka Fish and Wildlife Office, 1829 S Oregon St., Yreka, CA 96097; telephone 530–841–3115. If you use a telecommunications device for the deaf (TDD), please call the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Background

Under section 4(b)(3)(B) of the Act (16 U.S.C. 1531 *et seq.*), we are required to make a finding whether or not a petitioned action is warranted within 12 months after receiving any petition for which we have determined contains substantial scientific or commercial information indicating that the petitioned action may be warranted ("12-month finding"). We must make a finding that the petitioned action is: (1) Not warranted; (2) warranted; or (3) warranted but precluded. We must publish a notice of these 12-month findings in the **Federal Register**.

Summary of Information Pertaining to the Five Factors

Section 4 of the Act (16 U.S.C. 1533) and the implementing regulations at part 424 of title 50 of the Code of Federal Regulations (50 CFR part 424) set forth procedures for adding species to, removing species from, or reclassifying species on the Lists of Endangered and Threatened Wildlife and Plants (Lists). The Act defines "species" as including any subspecies of fish or wildlife or plants, and any distinct population segment of any species of vertebrate fish or wildlife which interbreeds when mature (16 U.S.C. 1532(16). The Act defines "endangered species" as any species that is in danger of extinction throughout all or a significant portion of its range (16 U.S.C. 1532(6)), and "threatened species" as any species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range (16 U.S.C. 1532(20)). Under section 4(a)(1) of the Act, a species may be determined to be an endangered species or a threatened species because of any of the following five factors:

- (A) The present or threatened destruction, modification, or curtailment of its habitat or range;
- (B) Overutilization for commercial, recreational, scientific, or educational purposes;
 - (C) Disease or predation;
- (D) The inadequacy of existing regulatory mechanisms; or
- (E) Other natural or manmade factors affecting its continued existence.

These factors represent broad categories of natural or human-caused actions or conditions that could have an effect on a species' continued existence. In evaluating these actions and conditions, we look for those that may have a negative effect on individuals of the species, as well as other actions or conditions that may ameliorate any negative effects or may have positive effects.

We use the term "threat" to refer in general to actions or conditions that are known to or are reasonably likely to negatively affect individuals of a species. The term "threat" includes actions or conditions that have a direct impact on individuals (direct impacts), as well as those that affect individuals through alteration of their habitat or required resources (stressors). The term "threat" may encompass—either together or separately—the source of the action or condition or the action or condition itself. However, the mere identification of any threat(s) does not necessarily mean that the species meets the statutory definition of an "endangered species" or a "threatened species." In determining whether a species meets either definition, we must evaluate all identified threats by considering the expected response by the species, and the effects of the threats—in light of those actions and conditions that will ameliorate the threats—on an individual, population, and species level. We evaluate each threat and its expected effects on the species, then analyze the cumulative effect of all of the threats on the species as a whole. We also consider the cumulative effect of the threats in light of those actions and conditions that will have positive effects on the species, such as any existing regulatory mechanisms or conservation efforts. The Secretary determines whether the species meets the definition of an "endangered species" or a "threatened species" only after conducting this cumulative analysis and describing the

expected effect on the species now and in the foreseeable future.

The Act does not define the term "foreseeable future," which appears in the statutory definition of "threatened species." Our implementing regulations at 50 CFR 424.11(d) set forth a framework for evaluating the foreseeable future on a case-by-case basis. The term "foreseeable future" extends only so far into the future as the Service can reasonably determine that both the future threats and the species' responses to those threats are likely. In other words, the foreseeable future is the period of time in which we can make reliable predictions. "Reliable" does not mean "certain"; it means sufficient to provide a reasonable degree of confidence in the prediction. Thus, a prediction is reliable if it is reasonable to depend on it when making decisions.

It is not always possible or necessary to define foreseeable future as a particular number of years. Analysis of the foreseeable future uses the best scientific and commercial data available and should consider the timeframes applicable to the relevant threats and to the species' likely responses to those threats in view of its life-history characteristics. Data that are typically relevant to assessing the species' biological response include speciesspecific factors such as lifespan, reproductive rates or productivity, certain behaviors, and other demographic factors.

In conducting our evaluation of the five factors provided in section 4(a)(1) of the Act to determine whether the Samwel salamander (Hvdromantes samweli), Shasta salamander, (H. shastae), or Wintu salamander (H. wintu) (together referred to as the Shasta Complex salamanders) meet the definition of "endangered species" or "threatened species," we considered and thoroughly evaluated the best scientific and commercial information available regarding the past, present, and future threats for the three species. We reviewed the petition, information available in our files, and other available published and unpublished information. Our evaluation included information from recognized experts as well as Federal and State government resource and land management

We developed a species status assessment (SSA) (Service 2021a, entire) for the Shasta Complex salamanders that contains more detailed biological information, species' needs information, and information on the threats facing the three species and their habitat now and into the future. We also developed a species assessment form (Service

2021b, entire) that contains our analysis of the listing factors and documents our determination that these species do not meet the definition of an endangered species or a threatened species. This supporting information can be found on the internet at http://www.regulations.gov under Docket No. FWS-R8-ES-2021-0009. The following is an informational summary of the finding for the Shasta Complex salamanders and information found in the SSA and species assessment form for the three species. Please see those documents for additional information.

Previous Federal Actions

On July 11, 2012, we received a petition from the Center for Biological Diversity to list 53 species of reptiles and amphibians, including the Shasta salamander (Hydromantes shastae), as endangered or threatened under the Act (Center for Biological Diversity 2012, entire). On September 18, 2015, we published in the Federal Register (80 FR 56423) our 90-day finding that the petition presented substantial scientific or commercial information indicating that listing the Shasta salamander as endangered or threatened may be warranted based on impacts to the species' habitat (Factor A) and other natural or humanmade factors (Factor E). On April 23, 2018, the petitioners (Center for Biological Diversity 2018, entire) supplied us with a publication regarding a taxonomic split of the Shasta salamander into three separate species (Samwel salamander (Hydromantes samweli), Shasta salamander (H. shastae), and Wintu salamander (H. wintu) (Bingham et al. 2018, entire)), and requested that we consider this information in our status review. On November 29, 2018, we received a complaint for not completing the 12-month finding. Per a court approved settlement agreement, we agreed to deliver a 12-month finding for the Shasta salamander to the Federal Register by April 30, 2021. This document complies with the settlement agreement.

Species Description

The Shasta salamander was first described in 1953, as a single species (Gorman and Camp 1953, entire). Since that time the scientific community has determined that the Shasta salamander is made up of three separate individual species (Bingham et al. 2018, entire). The three species are identified as the Samwel salamander (Hydromantes samweli), Shasta salamander (H. shastae), and Wintu salamander (H. wintu). We refer to the three species in the species assessment form (Service

2021b, entire), the SSA (Service 2021a, entire), and this document as the Shasta Complex salamanders. The three salamanders are lungless web-footed salamanders that breathe through their skin and the mucous membrane in their mouth and throat. The three species are very similar except that the Shasta salamander has a longer third digit on the pes (rear foot). The approximate length of the three species is approximately 2 to 2.5 inches (51 to 64 millimeters). The three species have short, strongly tapered, generally blunttipped tails and broad, flattened heads.

Taxonomy and Genetic Information

From 1953 to 2018, the Shasta salamander was recognized as a single species (Gorman and Camp 1953, entire; Gorman 1964, entire; Rovito 2010, entire). However, a high degree of variation in genetic structure and genetic divergence was found after both mitochondrial and nuclear DNA studies of the species were completed (Wake et al. 1978, entire; Wake and Papenfuss 2005, entire; Bingham 2007, entire). As such, and as noted above, in 2018 the Shasta salamander was split into three separate species (Bingham et al. 2018, entire). Based on this study, there are three divergent lineages made up of five genetic clades (a group of organisms that evolved from a common ancestor) (Bingham et al. 2018, pp. 403, 407). Hydromantes shastae and H. wintu make up two of the clades, with H. samweli having three genetic clades (Bingham et al. 2018, p. 408). This information has been published and the split of the Shasta salamander has been accepted by the scientific community. After review of this information, we have determined that the three species are listable entities under the Act.

Habitat/Life History

The three species are strictly terrestrial for their entire lives and must remain moist in order for individuals to absorb oxygen through their skin. Consequently, the three salamanders are surface active only when it is moist and cool. Historically, the three species were thought to occur only in and around limestone rock outcrops or within limestone caves. In the last 25 years, the three species have been found in a broader range of habitats away from limestone, including other types of rock outcrops, and even habitats with no rock outcrop associations, such as areas with thick vegetative litter (Lindstrand 2000, pp. 259-261; Nauman and Olson 2004, pp. 35-38; Lindstrand et al. 2012, pp. 236-241).

Range/Distribution

The historical range of the three species is restricted to unglaciated and non-volcanized forested areas within the lower McCloud River, Pit River, Sacramento River, and Squaw Creek watersheds in Shasta County, California, with Samwel salamander extending slightly further west. The absence of glaciation and volcanic activity has maintained the limestone and other rock outcrops and subsurface characteristics of the area occupied by the three species. Although current survey efforts have identified the distribution of the three species within their respective ranges, the exact distribution and abundance of the three species within the larger range of suitable geologic habitat around and near Shasta Lake is unknown, as surveys in such areas are difficult to obtain given the physical restrictions of accessing the terrain and difficulty of detecting individuals. The current range of the three species is similar to their historical range with likely some loss due to the construction of Shasta Dam and subsequent inundation from Shasta Lake in the 1950s.

Evaluation of Status

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats to the Samwel salamander, Shasta salamander, and Wintu salamander, and we evaluated all relevant factors under the five listing factors, including any regulatory mechanisms and conservation measures addressing these threats and the cumulative impact of these threats. Our analysis identified the threats from habitat loss, degradation, and modification due to vegetation management and wildfire (Factor A) and the effects of increased temperature and reduced moisture from climate change (Factor E) as the main threats currently facing the three species. We also identified the additional threat of the proposed action of raising Shasta Dam and the subsequent removal and inundation of habitat for the three species (Factor E).

Existing conservation measures for the species and their habitats include State and Federal protections and conservation measures. The Shasta salamander was listed by the State of California as a threatened species under the California Endangered Species Act (CESA) before it was split into three separate species. The State has not officially recognized the split; however, the State listing provides measures to protect and conserve all three species.

For example, any road construction or maintenance actions associated with timber harvest plans or other roadways managed by Caltrans, the counties, or other private landowners undergo environmental compliance review with the State under CESA and the California Environmental Quality Act, to ensure that impacts to species listed as threatened by the State are mitigated. The three species are also managed by the U.S. Forest Service and Bureau of Land Management as sensitive species and currently receive protection through conservation measures and best management practices under the Northwest Forest Plan's Survey and Manage program and Sensitive Species programs. These measures reduce or eliminate impacts to rock outcrops, limestone areas, and known salamander occurrence sites during road construction and maintenance activities as well as any vegetation management actions.

After review of the threats identified above and cumulative effects facing the species, as well as existing conservation measures, we conclude that habitat loss or disturbance from various threats (e.g., vegetation management activities, wildfire, climatic changes) within the range of the Samwel, Shasta, and Wintu salamanders have likely impacted individuals of each species. However, the magnitude and extent of these impacts up to the present time have not impacted the resiliency, representation, or redundancy for each species or resulted in a decline in the overall distribution or general demographic condition of any of the three species such that they are in danger of extinction now throughout all of their

In determining potential future threats facing the three species, we evaluated various climate change projections using downscaled data for interior northern California, which includes the ranges of the three species. Our timeframe for review looked out approximately 15, 30, and 50 years based on the threat information identified below and climate change data. This was our timeframe for our threats analysis of future conditions for the three species to determine if they were likely to become endangered within the foreseeable future (i.e., if they meet the Act's definition of "threatened species") throughout all of their ranges.

In our analysis of potential future conditions, we analyzed the future conditions related to vegetation management, future wildfire conditions, and projected climate change effects such as variability of precipitation events and timing, increased

temperatures, reduced snowpack, and prolonged drought. We also identified the additional threat of the proposed action of raising Shasta Dam and the subsequent removal and inundation of habitat for the three species.

We anticipate that vegetation management activities and wildfire will have a similar degree of impact into the future as they do currently, and that they will not result in impacts to the three species at a level such that they would meet the Act's definition of "threatened species." Although the potential raising of Shasta Dam would affect individuals and inundate or remove additional habitat for the three species, the extent of the potential loss of known detection sites and habitat areas that can support individuals is very limited relative to the overall number of detection sites and remaining available suitable habitat in each species' range.

We expect that existing regulatory mechanisms and conservation measures will continue to help ameliorate or reduce impacts of threats to the species and will protect Shasta Complex salamanders and their habitats now and into the foreseeable future (50 years) such that their resiliency, representation, and redundancy will support their ability to sustain populations in the wild over time.

We also reviewed whether there were any significant portions of the three species' ranges that may meet the definition of endangered or threatened. In our analysis, we did not find any portion of the Samwel, Shasta, or Wintu salamanders' ranges where the threats identified above are currently acting on the three species at a biologically meaningful scale such that the species may be endangered, or are likely to act on the species into the future such that they may be threatened. Therefore, no portion of the three species' ranges can provide a basis for determining that any one of the three species is in danger of extinction now or likely to become so in the foreseeable future in a significant portion of its range.

Finding

Our review of the best available scientific and commercial information indicates that the Samwel salamander, Shasta salamander, and Wintu salamander do not meet the definition of an endangered species or a threatened species in accordance with sections 3(6) and 3(20) of the Act. Therefore, we find that listing the Samwel salamander, Shasta salamander, and Wintu salamander as endangered or threatened species under the Act is not warranted at this time. A detailed discussion of the

basis for this finding can be found in the SSA (Service 2021a, entire) and species assessment form (Service 2021b, entire).

Request for New Information

We request that you submit any new information concerning the taxonomy of, biology of, ecology of, status of, or threats to the Samwel salamander, Shasta salamander, or Wintu salamander to the Yreka Fish and Wildlife Office (see FOR FURTHER **INFORMATION CONTACT**), whenever it becomes available. New information will help us monitor these three species and make appropriate decisions about their conservation and status. We encourage Federal, State, and local agencies and stakeholders to continue cooperative monitoring and conservation efforts for the three species.

References Cited

A list of the references cited in this petition finding is available on the internet at http://www.regulations.gov at Docket No. FWS-R8-ES-2021-0009 or upon request from the person specified under FOR FURTHER INFORMATION CONTACT.

Authors

The primary authors of this document are the staff members of the Species Assessment Team, Ecological Services Program.

Authority

The authority for this action is section 4 of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Martha Williams,

Principal Deputy Director, Exercising the Delegated Authority of the Director, U.S. Fish and Wildlife Service.

[FR Doc. 2021–09489 Filed 5–4–21; 8:45 am] BILLING CODE 4333–15–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 200505-0127; RTID 0648-XB031]

Fisheries Off West Coast States; Modifications of the West Coast Commercial and Recreational Salmon Fisheries; Inseason Actions #10 Through #16

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

ACTION: Inseason modification of 2021 management measures.

SUMMARY: NMFS announces seven inseason actions in the 2021 ocean salmon fisheries. These inseason actions modified the commercial salmon fisheries in the area from the U.S./ Canada border to the U.S./Mexico border.

DATES: The effective dates for the inseason actions are set out in this document under the heading Inseason Actions.

FOR FURTHER INFORMATION CONTACT: Christina Iverson at 360–742–2506, Email: Christina.iverson@noaa.gov.

SUPPLEMENTARY INFORMATION:

Background

In the 2020 annual management measures for ocean salmon fisheries (85 FR 27317, May 8, 2020), NMFS announced management measures for the commercial and recreational fisheries in the area from U.S./Canada border to the U.S./Mexico border, effective from 0001 hours Pacific Daylight Time (PDT), May 6, 2020, until the effective date of the 2021 management measures, as published in the Federal Register. NMFS is authorized to implement inseason management actions to modify fishing seasons and quotas as necessary to provide fishing opportunity while meeting management objectives for the affected species (50 CFR 660.409). Inseason actions in the salmon fishery may be taken directly by NMFS (50 CFR 660.409(a)—Fixed inseason management provisions) or upon consultation with the Chairman of the Pacific Fishery Management Council (Council) and the appropriate State Directors (50 CFR 660.409(b)—Flexible inseason management provisions). The state management agencies that participated in the consultations described in this document were: The Washington Department of Fish and Wildlife, the Oregon Department of Fish and Wildlife (ODFW) and the California Department of Fish and Wildlife (CDFW).

Management Areas

Management of the salmon fisheries is generally divided into two geographic areas: North of Cape Falcon (NOF) (U.S./Canada border to Cape Falcon, OR) and south of Cape Falcon (SOF) (Cape Falcon, OR, to the U.S./Mexico border). The actions described in this document affected both NOF and SOF

fisheries as set out under the heading Inseason Actions.

Reason and Authorization for SOF Inseason Actions #10-#14

The fisheries affected by the inseason actions described below were authorized in the final rule for 2020 annual management measures for ocean salmon fisheries (85 FR 27317, May 8, 2020). At its March 10, 2021 meeting, the Council's Salmon Technical Team (STT) presented updated stock abundance forecasts for salmon stocks managed under the Pacific Coast Salmon Fishery Management Plan (FMP). Based on the STT's report, SOF ocean salmon fisheries will be constrained in 2021 by the low abundance forecast for Klamath River fall-run Chinook salmon (KRFC), which was determined to be overfished under the Magnuson-Stevens Fishery Conservation and Management Act (MSA) in 2018. The forecast of potential spawner abundance for KRFC in 2021 is 42,098 natural area spawners; which is below the 2020 potential spawner forecast of 48,274, and is 31 percent of the average forecast of potential KRFC spawners over the previous 9 years (2012-2020). To reduce ocean salmon fishery impacts on KRFC, NMFS took 9 inseason actions concurrent with the March Council meeting to restrict some fisheries that were previously scheduled to open prior to May 16, 2021 (86 FR 16540, March 30, 2021). At its April 6-15, 2021 meeting, the Council finalized development of its recommended 2021 ocean salmon management measures.

NMFS took additional inseason actions, described below, to manage and conserve SOF ocean salmon fishery impacts on overfished KRFC by reducing impacts in spring fisheries through closure or shortened fisheries in areas that impact KRFC consistent with its forecasted abundance in 2021 and conservation goals.

The NMFS West Coast Regional Administrator (RA) considered the abundance forecasts for Chinook salmon stocks and the impacts of the SOF ocean salmon fisheries, as modeled by the STT, and determined that the inseason actions, described below, were necessary to meet management and conservation goals set preseason. These inseason actions modify boundaries under 50 CFR 660.409(b)(1)(v) and fishing seasons under 50 CFR 660.409(b)(1)(i).

Consultation under 50 CFR 660.409(b) on these inseason actions occurred on April 15, 2021. Representatives from NMFS, ODFW, CDFW, and Council staff participated in this consultation.

Reason and Authorization for NOF Inseason Actions #15–#16

The fisheries affected by the inseason actions described below were authorized in the final rule for 2020 annual management measures for ocean salmon fisheries (85 FR 27317, May 8, 2020). At the April 6–15, 2021 meeting, the Council finalized development of its recommended 2021 ocean salmon management measures. This included final model runs of exploitation rates based on a Chinook salmon retention size for NOF commercial fisheries of 27 inches. The results as modeled did not indicate a change in the exploitation rates previously modeled with the 28 inch retention size, and would continue to meet conservation objectives.

NMFS is taking these inseason actions to provide consistency between fisheries authorized under the 2020 management measures and fisheries adopted at the April Council meeting for 2021, which NMFS is expected to enact by May 16, 2021.

The NMFS West Coast Regional Administrator (RA) considered the abundance forecasts for Chinook salmon stocks and the impacts of the NOF ocean salmon fisheries, as modeled, and determined that the inseason actions, described below, were necessary to meet management and conservation goals set preseason. These inseason actions modify fishing seasons under 50 CFR 660.409(b)(1)(i).

Consultation under 50 CFR 660.409(b) on these inseason actions occurred on April 20, 2021. Representatives from NMFS, ODFW, WDFW, and Council staff participated in this consultation.

Inseason Actions

Inseason Action #10

Description of the action: Inseason action #10 closes the commercial ocean salmon fishery from Cape Falcon to Heceta Bank Line fishery from May 6–May 9, 2021. This fishery is now scheduled to be open March 20–May 5, 2021, and May 10–May 15, 2021.

Effective dates: Inseason action #10 took effect on April 15, 2021, and remains in effect until superseded.

Inseason Action #11

Description of the action: Inseason action #11 supersedes inseason action #3 which delayed the opening of the commercial ocean salmon fishery from the Heceta Bank Line to Humbug Mountain previously scheduled to open March 15, 2021. This fishery is now scheduled to be open May 1–5, 2021, and May 10–15, 2021.

Effective dates: Inseason action #11 took effect on April 15, 2021, and remains in effect until superseded.

Inseason Action #12

Description of the action: Inseason action #12 closes the commercial ocean salmon fishery from Humbug Mountain to the Oregon/California border (Oregon Klamath Management Zone) from May 6–May 9, 2021. This fishery is now scheduled to be open March 20–May 5, 2021, and May 10–May 15, 2021.

Effective dates: Inseason action #12 took effect April 15, 2021, and remains in effect until superseded.

Inseason Action #13

Description of the action: Inseason action #13 delayed the opening date of the commercial ocean salmon fishery from Point Arena to Pigeon Point (San Francisco management area) which was previously scheduled to open May 1, 2021. This fishery is now scheduled to be open June 16–June 30, 2021.

Effective dates: Inseason action #13 took effect April 15, 2021, and remains in effect until superseded.

Inseason Action #14

Description of the action: Inseason action #14 modifies the commercial ocean salmon fishery from Pigeon Point to the U.S./Mexico border (Monterey management area) which was previously scheduled to open May 1–May 12, 2021, and May 18–May 30, 2021. This fishery is now scheduled to be open May 1–May 12, 2021.

Effective dates: Inseason action #14 took effect April 15, 2021, and remains in effect until superseded.

Inseason Action #15

Description of the action: Inseason action #15 modifies the Chinook salmon minimum size limit in the commercial ocean salmon fishery from the U.S./ Canada border to Cape Falcon, OR. The Chinook salmon minimum size limit in this fishery was 28 inches (71.1 cm) total length, inseason action #15 changes the minimum size limit to 27 inches (68.6 cm) total length.

Effective dates: Inseason action #15 takes effect April 20, 2021, and remains in effect until superseded.

Inseason Action #16

Description of the action: Inseason action #16 revised the quota and subarea catch limits for the commercial salmon fishery from the U.S./Canada border that opens May 1, 2021. The May–June quota increased from 13,820 Chinook salmon to 15,375 Chinook salmon, no more than 5,680 of which may be caught in the area between the

U.S./Canada border and the Queets River, and no more than 4,195 of which may be caught in the area between Leadbetter Pt. and Cape Falcon.

Effective dates: Inseason action #16 took effect April 20, 2021, and remains

in effect until superseded.

All other restrictions and regulations remain in effect as announced for the 2020 ocean salmon fisheries (85 FR 27317, May 8, 2020) and as modified by previous inseason actions (85 FR 31707, May 27, 2020; 85 FR 55784, September 10, 2020; 86 FR 13824, March 11, 2021; and 86 FR 16540, March 30, 2021).

The RA determined that these inseason actions were warranted based on the best available information on Pacific salmon abundance forecasts and anticipated fishery effort. The states manage the fisheries in state waters adjacent to the areas of the U.S. exclusive economic zone consistent with these Federal actions. As provided by the inseason notice procedures at 50 CFR 660.411, actual notice of the described regulatory action was given, prior to the time the action was effective, by telephone hotline numbers 206-526-6667 and 800-662-9825, and by U.S. Coast Guard Notice to Mariners broadcasts on Channel 16 VHF-FM and 2182 kHz.

Classification

NMFS issues these actions pursuant to section 305(d) of the MSA. These actions are authorized by 50 CFR 660.409, which was issued pursuant to section 304(b), and is exempt from review under Executive Order 12866—Regulatory Planning and Review.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on these actions, as notice and comment would be impracticable and contrary to the public interest. Prior notice and opportunity for public comment on these actions was impracticable because NMFS had insufficient time to provide for prior notice and the opportunity for public comment between the time Chinook salmon abundance, catch, and effort information was developed and fisheries impacts were calculated, and the time the fishery modifications had to be implemented in order to ensure that fisheries are managed based on the best available scientific information, ensuring that conservation objectives and limits for impacts to overfished salmon stocks are not exceeded. As previously noted, actual notice of the regulatory action was provided to fishers through telephone hotline and radio notification. This action complies with the requirements of the annual management measures for ocean salmon fisheries (85 FR 27317, May 8, 2020), the FMP, and regulations implementing the FMP under 50 CFR 660.409 and 660.411.

There is good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay in

effective date, as a delay in effectiveness of these actions would allow fishing at levels inconsistent with the goals of the FMP and the current management measures.

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

Dated: April 29, 2021.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service. [FR Doc. 2021–09427 Filed 4–30–21; 4:15 pm]

BILLING CODE 3510-22-P

Proposed Rules

Federal Register

Vol. 86, No. 85

Wednesday, May 5, 2021

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

DEPARTMENT OF ENERGY

10 CFR Part 431

[EERE-2020-BT-TP-0032]

RIN 1904-AE53

Energy Conservation Program: Test Procedure for Commercial & Industrial Pumps

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Request for information; extension of public comment period.

SUMMARY: On April 16, 2021, the U.S. Department of Energy ("DOE") published a request for information ("RFI") pertaining to the test procedure for commercial and industrial pumps ("pumps"). The notice provided an opportunity for submitting written comments, data, and information by June 1, 2021. On April 19, 2021, DOE received a request from Price Pump Company ("Price Pump"), and on April 20, 2021, DOE received requests from Grundfos and the Hydraulic Institute ("HI") to extend the public comment period by 90 days. DOE has reviewed these requests and is granting a 30-day extension of the public comment period to allow public comments to be submitted until July 1, 2021.

DATES: The comment period for the RFI published on April 16, 2021 (86 FR 20075) is extended. DOE will accept comments, data, and information regarding this RFI received no later than July 1, 2021.

ADDRESSES: Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at http://www.regulations.gov. Follow the instructions for submitting comments. Alternatively, interested persons may submit comments, identified by docket number EERE–2020–BT–TP–0032 by any of the following methods:

1. Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

2. Email: To Pumps2020TP0032@ ee.doe.gov. Include docket number EERE-2020-BT-TP-0032 in the subject line of the message.

No telefacsimilies ("faxes") will be accepted.

Although DOE has routinely accepted public comment submissions through a variety of mechanisms, including postal mail and hand delivery/courier, the Department has found it necessary to make temporary modifications to the comment submission process in light of the ongoing Covid–19 pandemic. DOE is currently suspending receipt of public comments via postal mail and hand delivery/courier. If a commenter finds that this change poses an undue hardship, please contact Appliance Standards Program staff at (202) 586-1445 to discuss the need for alternative arrangements. Once the Covid-19 pandemic health emergency is resolved, DOE anticipates resuming all of its regular options for public comment submission, including postal mail and hand delivery/courier.

Docket: The docket for this activity, which includes Federal Register notices, comments, and other supporting documents/materials, is available for review at http://www.regulations.gov. All documents in the docket are listed in the http://www.regulations.gov index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available.

The docket web page can be found at: http://www.regulations.gov/docket? D=EERE-2020-BT-TP-0032. The docket web page contains instructions on how to access all documents, including public comments, in the docket.

FOR FURTHER INFORMATION CONTACT: Mr. Jeremy Dommu, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–2J, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–9870. Email: ApplianceStandards Questions@ee.doe.gov.

Mr. Michael Kido, U.S. Department of Energy, Office of the General Counsel, GC-33, 1000 Independence Avenue SW, Washington, DC 20585-0121. Telephone: (202) 586-8145. Email: Michael.Kido@hq.doe.gov.

For further information on how to submit a comment or review other

public comments and the docket contact the Appliance and Equipment Standards Program staff at (202) 287– 1445 or by email: ApplianceStandards Questions@ee.doe.gov.

SUPPLEMENTARY INFORMATION: On April 16, 2021, DOE published a RFI seeking data and information regarding whether amended test procedures would more accurately or fully comply with the requirement that the test procedure produces results that measure energy use during a representative average use cycle for pumps without being unduly burdensome to conduct, or that reduce testing burden. 86 FR 20075. Interested parties in the matter, Price Pump (on April 19, 2021), HI (on April 20, 2021), and Grundfos (on April 20, 2021), requested a 90-day extension of the public comment period for the RFI. (Price Pump, No. 10 at p. 1; HI, No. 11 at p. 1; Grundfos, No. 12, at p. 1).1 Grundfos and Price Pump commented that the June 1, 2021 deadline does not provide sufficient time to collect the requested data and information requested in the RFI. (Price Pump, No. 10 at p. 1; Grundfos, No. 12 at p. 1 HI commented that it has developed a committee to review and respond to DOE's requests for comment, and requires additional time to develop and review member surveys and coordinate a response. (HI, No. 11, p.1)

DOE has reviewed the requests and is extending the comment period to allow additional time for interested parties to submit comments. As noted, the RFI was issued as part of the preliminary stages of rulemaking to consider amendments to the test procedure for pumps. If DOE determines that amended test procedures may be appropriate, additional notices will be published (e.g., a notice of proposed rulemaking) providing interested parties with an additional opportunity to submit comment. As such, DOE has determined that a 30-day extension is sufficient for this preliminary stage. Therefore, DOE is extending the comment period to July 1, 2021.

¹ The parenthetical reference provides a reference for information located in DOE's test procedure rulemaking docket. (Docket No. EERE-2020-BT-TP-0032, which is maintained at http://www.regulations.gov/#!docketDetail;D=EERE-2020-BT-TP-0032). The references are arranged as follows: (Commenter name, comment docket ID number, page of that document).

Signing Authority

This document of the Department of Energy was signed on April 27, 2021, by Kelly Speakes-Backman, Principal Deputy Assistant Secretary and Acting Assistant Secretary for Energy Efficiency and Renewable Energy, 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 April 28, 2021.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2021-09274 Filed 5-4-21; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary of Transportation

14 CFR Chapters I, II, and III

23 CFR Chapters I, II, and III

46 CFR Chapter II

48 CFR Chapter 12

49 CFR Chapters I, II, III, V, VI, VII, VIII, X, and XI

[Docket No. DOT-OST-2021-0036]

Notification of Regulatory Review

AGENCY: Office of the Secretary of Transportation (OST); U.S. Department of Transportation (DOT).

ACTION: Regulatory review.

SUMMARY: As directed by Executive Order 13990, "Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis," and Executive Order 13992, "Revocation of Certain Executive Orders Concerning Federal Regulation," the U.S. Department of Transportation (Department or DOT) is currently reviewing its existing regulations and other agency actions to determine whether they are consistent with the policies and National objectives set

forth in these executive orders. As part of this review, the Department invites the public to provide input on existing rules and other agency actions for the Department's consideration regarding consistency with the policies and objectives of these executive orders.

DATES: Comments should be received on or before June 4, 2021. Late-filed comments will be considered to the extent practicable.

ADDRESSES: You may file comments identified by the docket number DOT–OST–2021–0036 by any of the following methods:

Federal eRulemaking Portal: Go to http://www.regulations.gov and follow the online instructions for submitting comments.

Mail: Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Ave. SE, Room W12–140, Washington, DC 20590–0001.

Hand Delivery or Courier: The Docket Management Facility is located on the West Building, Ground Floor, of the U.S. Department of Transportation, 1200 New Jersey Ave. SE, Room W12–140, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Fax: 202-493-2251.

Instructions: You must include the Docket Number DOT–OST–2021–0036 at the beginning of your comment. All comments received will be posted without change to http://www.regulations.gov, including any personal information provided.

Privacy Act: DOT posts public comments, without edit, to www.regulations.gov, as described in the system of records notice, DOT/ALL-14 FDMS, accessible through www.dot.gov/privacy. To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Regardless of whether commenters identify themselves, timely comments will be considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

Docket: For access to the docket to read background documents or comments received, go to http://www.regulations.gov or to the street address listed above. Follow the online instructions for accessing the docket.

FOR FURTHER INFORMATION CONTACT: Elizabeth Kohl, Attorney-Advisor, U.S. Department of Transportation, 1200 New Jersey Ave. SE, Washington, DC 20590, 202–366–7523 (phone), elizabeth.kohl@dot.gov (email). SUPPLEMENTARY INFORMATION: On January 20, 2021, the President issued Executive Order (E.O.) 13990, "Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis" (86 FR 7037; Jan. 25, 2021), and E.O. 13992, "Revocation of Certain Executive Orders Concerning Federal Regulation" (86 FR 7049; Jan. 25, 2021).

In E.O. 13990, the President acknowledged the Nation's "abiding commitment to empower our workers and communities, promote and protect our public health and the environment; and conserve our national treasures and monuments, places that secure our national memory." The President also set forth the policy of the Administration to "listen to the science: to improve public health and protect our environment; to ensure access to clean air and water; to limit exposure to dangerous chemicals and pesticides; to hold polluters accountable, including those who disproportionately harm communities of color and low-income communities; to reduce greenhouse gas emissions; to bolster resilience to the impacts of climate change; to restore and expand our national treasures and monuments; and to prioritize both environmental justice and the creation of the well-paying union jobs necessary to deliver on these goals." To that end, the President directed the heads of all executive departments and agencies, including DOT, to immediately review and, as appropriate and consistent with applicable law, address the promulgation of Federal regulations and other actions that conflict with these important national objectives, as well as to immediately commence work to confront the climate crisis." E.O. 13990 specifically directed the Secretary of Transportation to review and consider publishing for notice and comment a proposed rule suspending, revising, or rescinding: "The Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule Part One: One National Program," and "The Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule for Model Years 2021-2026 Passenger Cars and Light Trucks." In a Fact Sheet issued by the President simultaneously with E.O. 13990, the President also directed DOT to review "Hazardous Materials: Liquefied Natural Gas by Rail" (https:// www.whitehouse.gov/briefing-room/ statements-releases/2021/01/20/factsheet-list-of-agency-actions-for-review/).

In E.O. 13992, the President set forth the Administration's policy "to use available tools to confront the urgent challenges facing the Nation, including the coronavirus disease 2019 (COVID— 19) pandemic, economic recovery, racial

justice, and climate change." The President stated that "[t]o tackle these challenges effectively, executive departments and agencies . . . must be equipped with the flexibility to use robust regulatory action to address national priorities." E.O. 13992 revoked certain executive orders issued prior to January 20, 2021 and directed the Director of the Office of Management and Budget and the heads of agencies, including DOT, to promptly take steps to rescind any orders, rules, regulations, guidelines, or policies, or portions thereof, implementing or enforcing these revoked executive orders, as appropriate and consistent with applicable law.

To respond to the President's direction in E.O. 13990 and E.O. 13992, the Department seeks input from the public on existing regulations or other agency actions for the Department's consideration regarding consistency with the policies and objectives of these executive orders. In recognition of the fact that safety is the Department's highest priority, DOT also seeks comment on those existing regulations or other agency actions that the Department can address without compromising, or to further improve, safety. The Department welcomes public comment on any of its regulations and other agency actions to achieve the goals of E.O. 13990 and E.O.

Content of Comments: The Department will review comments submitted timely to the docket associated with this regulatory review, DOT-OST-2021-0036. To maximize the usefulness of comments, the Department encourages commenters to provide the following information:

- 1. Specific reference. A specific reference to the regulation or other agency action that the commenter believes the Department should consider with respect to the goals of E.O. 13990 and E.O. 13992. This should be a citation to the Code of Federal Regulations, a guidance document number, or an internet link. A specific reference will assist the Department in identifying the regulation or other agency action, the original source of the action, and relevant documentation that may describe the history and effects of the action.
- 2. Description of effects. A description of the effects of the identified regulation or other agency action. A comment that describes the relationship between the regulation or other agency action and the goals of E.O. 13990 and E.O. 13992 is more useful than a comment that merely asserts that the action is either consistent or inconsistent with the

executive orders. Comments that reflect knowledge of or an understanding of the effects and provide data or other information describing those effects are more creditable than comments that do not provide such information.

Verifiable, quantifiable data describing the effects are more useful than anecdotal descriptions.

- 3. Description of potential alternative actions. If the commenter believes that a regulation or other agency action may be developed that achieves the goals of E.O. 13990 and E.O. 13992, the commenter should describe that regulation or action in detail. Likewise, if the commenter believes that a regulation or other agency action currently meets the goals of one or both executive orders, the commenter should provide that explanation.
- 4. Examples of affected entities or projects. Commenters may provide examples of entities that are, have been, or will be negatively affected by the identified regulation or other agency action, and examples of entities that will benefit if DOT acts to address the negative effects of the regulation or other agency action. A comment listing specific entities is more useful because it will assist the Department in investigating any negative effects and how DOT may most effectively address these effects.

Scope of Comments: The Department is interested in comments on any DOT regulation or other agency action for consideration regarding consistency, with the policies and objectives of E.O. 13990 and E.O. 13992.

Dated: April 28, 2021.

John E. Putnam,

Acting General Counsel. [FR Doc. 2021–09239 Filed 5–4–21; 8:45 am] BILLING CODE P

DEPARTMENT OF THE TREASURY

United States Mint

31 CFR Part 100

Exchange of Coin

AGENCY: United States Mint, Department of the Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: The United States Mint proposes to revise its regulations relating to the exchange of uncurrent, bent, partial, fused, and mixed coins. The proposed revisions will enhance the integrity of the redemption process for bent and partial United States coins and prevent fraud.

DATES: Send comments on or before July 6, 2021.

ADDRESSES: The United States Mint invites comments on all aspects of this proposed revision. You may send comments by any of the following methods:

- Federal eRulemaking Portal: www.regulations.gov. Follow the instructions for sending comments.
- Mail: Submit all written comments to Mutilated Coin Redemption Program; Manufacturing Directorate; United States Mint, 801 9th Street NW, Washington, DC 20220.
- Hand Delivery/Courier: Same as mail address.

Instructions: All submissions received must include the agency name for this rulemaking. All comments received will be posted without change to regulations.gov, including any personal information provided.

FOR FURTHER INFORMATION CONTACT:

Apryl Whitaker, Senior Legal Counsel, Office of the Chief Counsel, United States Mint, at (202) 354–7938 or rulemaking@usmint.treas.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Treasury Regulations appearing at 31 CFR part 100, subpart C, are promulgated under 31 U.S.C. 5120, and relate to the exchange of uncurrent, bent, partial, fused, and mixed coins. The last amendment to 31 CFR part 100, subpart C, was on December 20, 2017. Since then, the United States Mint has identified additional portions of the regulations in need of revision to further enhance the integrity of the redemption process for bent and partial United States coins.

For many years, the United States Mint has redeemed bent and partial coins for full face value. The policy's objective was always to maintain public confidence in United States coinage and protect the integrity of the currency by removing coins that were unfit for circulation through general wear and tear. However, in recent years, the volume of coins submitted for possible redemption has greatly increased. Additionally, the condition of many coins submitted for examination precludes effective authentication. Rather than removing damaged coins from general domestic coin circulation, as was the intended purpose, many participants are seeking to submit large quantities of coins that, in some cases, have already been removed from general circulation (e.g., recovered from scrap or trash processing), or in other cases, are extremely difficult to authenticate due to their condition and volume. Finally,

there are indicators of current counterfeit coin fraud schemes aimed at the Mutilated Coin Redemption Program, which the revisions are specifically designed to deter. The United States Mint has hired additional staff and developed improved authentication procedures and testing methodology for coin redemptions to ensure that only genuine U.S. coins are accepted for redemption.

II. This Proposed Rule

The first category of proposed revisions would update and improve the efficiency and security of the redemption process for bent and partial coins. These revisions would provide notice that the United States Mint will establish weight and shipment limits for at a maximum of 1,000 lbs. of coins per month per participant. To implement improved testing and authentication methods for determining the genuineness of coins, the United States Mint will process all future redemptions at its Philadelphia location, which has new equipment and staff capable of performing detailed analyses of coins submitted for redemption. Previously, the United States Mint directed approved bulk redeemers to ship submissions directly to authorized recyclers. Large shipments sent to our recyclers created storage and material control issues during the time necessary for sampling and authentication before melting. A 1,000 lb. limit is necessary to ensure effective controls so that each submission may be carefully reviewed to ensure that only genuine U.S. coinage is redeemed. Under these limits, participants are not guaranteed the right to submit 1,000 lbs. per month. The United States Mint Philadelphia facility's capacity to process mutilated coins is limited by physical storage capacity, caseload complexity, submission size, and workload. Improved authentication procedures extend the time required for sampling and evaluation, and the amount of time needed to properly authenticate and then process each submission varies. Given the intent of the program, which is to allow for the removal of bent or partial coins from circulation (and not recycling recovered coin from scrap or trash), the proposed weight limit and scheduling restrictions propose a reasonable balance between a discretionary service offered to the public to redeem bent or partial coins received in good faith in commerce and protection against fraud.

The second category of proposed revisions would prohibit redemption if a submission contains coins imported from outside of the United States. The

United States Mint has learned of fraud schemes where large amounts of counterfeit coins are manufactured overseas in an attempt to defraud the Government. A high percentage of counterfeits have been identified in imported coins intercepted by law enforcement, as well in as several large submissions to the Mutilated Coin Redemption Program. It is extremely difficult to trace and verify the chain of custody of coins imported from outside of the United States given that the majority of coins coming from abroad are represented to have been found in scrap that has been processed and sold multiple times over. Another consideration is that such coins have been effectively removed from the domestic coin circulation for which the redemption program aims to replace bent or partial coins. A prohibition on imported coins reduces the risk of fraud on the program. The proposed revisions also clarify that coins damaged in industrial processes (such as shredders, burnishers, incinerators, exposure to elevated temperatures), or coins that have been drilled, punctured, ground, polished, etched, or chemically treated by any industrial or recycling process, are not eligible for redemption. Such coins present a high risk of being counterfeit because they are difficult and time-consuming to evaluate and require increased resources to determine whether they are genuine. The regulations already require coins to be readily and clearly identifiable as to genuineness and denomination. The proposed revisions seek to provide examples from the United States Mint's experience of coins that by their nature are difficult to evaluate and cannot be "readily and clearly identifiable" as genuine.

The third category of proposed revisions clarifies the roles and responsibilities of the United States Mint and participants. For example, the proposed revisions clarify under what circumstances a participant will have the opportunity to retrieve a rejected shipment, and under what circumstances an entire submission will be turned over to law enforcement authorities. The purpose is to clearly put members of the public on notice of the potential consequences of submitting coins for examination that are prohibited from redemption. For example, if a submission contains counterfeit coins, the United States Mint will turn the entire submission over to law enforcement.

III. Procedural Analysis

Regulatory Planning and Review

The Office of Management and Budget has determined that this proposed rule does not constitute a "significant regulatory action" under Executive Order 12866 or Executive Order 13771.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) (PRA), the United States Mint is seeking approval for a new information collection of data and reporting requirements applicable to participants seeking to redeem bent or partial coins. The proposed collection of information described in this notice of proposed rulemaking has been submitted to the Office of Management and Budget (OMB) for review in accordance with the PRA under OMB No. 1525–NEW.

Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, or via email to *OIRA_*Submission@omb.eop.gov, with copies to Mutilated Coin Redemption Program; Manufacturing Directorate; United States Mint, 801 9th Street NW, Washington, DC 20220. Comments on the collection of information should be received by July 6, 2021.

In accordance with 5 CFR 1320.8(d)(1), the Department of the Treasury is soliciting comments from members of the public concerning this collection of information to:

- (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information;
- (3) Enhance the quality, utility, and clarity of the information to be collected; and
- (4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated collection techniques or other forms of information technology.

The form for OMB No. 1525–NEW proposed in the information collection rulemaking is as follows:

United States Mint Mutilated Coin Redemption Program Instructions and Application Form, Mint Form MF 6006: The burden of the information collections in this proposed rule is estimated as follows:

Estimated total annual reporting and/ or recordkeeping burden: 200 hours. Estimated average annual burden per respondent: 1 hour.

Estimated number of respondents: 200.

Estimated annual frequency of responses: Annually.

Under the PRA, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

Regulatory Flexibility Act Analysis

It is hereby certified that the proposed revisions will not have a significant economic impact on a substantial number of small entities. First and foremost, the regulations do not directly regulate any entities. The redemption of uncurrent, bent, or partial coins is a discretionary service offered to the public; participation is voluntary.

Second, the number of entities tendering significant quantities of coins for redemption is small. A large number of entities redeeming coins are individuals. A wide variety of businesses, such as municipal entities, recyclers, coin processors, amusement parks, auto shops, and waste management companies, also have applied for coins to be redeemed in the past. With the proposed limit of 1,000 lbs. per month, that is, at most, equivalent to \$240,000 a year. In Fiscal Years (FY) 2014, 2013, and 2012, the United States Mint paid only nine entities more than \$240,000. In FY 2011. there were 14, and FY 2010 there were 12. With respect to the proposed ban on coins imported from outside the United States, about 20 applicants listed "overseas" as the source of their coins on their applications submitted from 2018 to 2019. With respect to the proposed ban on coins that have been through industrial processes, about 20 applicants listed "recycling" as the source of their coins on their applications submitted from 2018 to

Even if each entity qualified as a "small entity" within the meaning of 5 U.S.C. 605(b), based on a review of past applications as described above, the United States Mint does not believe that the proposed revisions are likely to have a significant economic impact. The proposed rule does not change the redemption rates. Moreover, the regulations already require coins to be readily and clearly identifiable as to genuineness and denomination. The

proposed revisions seek to provide guidance from the United States Mint's experience of coins that by their nature are difficult to evaluate and cannot be "readily and clearly identifiable" as genuine. Notwithstanding this certification, the United States Mint invites comments on the impacts this rule may have on small entities.

IV. Request for Comment

Before the proposed revisions to the Treasury Regulations at 31 CFR part 100, subpart C, are adopted as final regulations, the United States Mint will consider any comments that are submitted to the bureau as prescribed in this preamble under the DATES and **ADDRESSES** sections. The United States Mint and the Department of the Treasury request comments on all aspects of the proposed revisions to these regulations, including the effects on stakeholders of the 1,000 lb. monthly limit and suggestions for alternative ways to achieve a balance between providing for the removal of bent or partial coins, cost, and prevention of fraud.

List of Subjects in 31 CFR Part 100

Coins.

Words of Issuance

For the reasons set forth in the preamble, the United States Mint proposes to amend 31 CFR part 100 as follows:

PART 100—EXCHANGE OF PAPER CURRENCY AND COIN

■ 1. The authority for part 100 continues to read as follows:

Authority: 31 U.S.C. 321.

■ 2. Subpart C is revised to read as follows:

Subpart C—Request for Examination of Coin for Possible Redemption

Sec.

100.10 Request for examination of uncurrent coin for possible redemption.
100.11 Request for examination of bent or partial coin for possible redemption.
100.12 Exchange of fused or mixed coin.
100.13 Notices.

§ 100.10 Request for examination of uncurrent coin for possible redemption.

(a) Definition. Uncurrent coins are whole U.S. coins that are merely worn or reduced in weight by natural abrasion yet are readily and clearly recognizable as to genuineness and denomination and which are machine countable.

(b) Redemption process. The United States Mint will not accept uncurrent coins for redemption. Members of the public wishing to redeem lawfully held uncurrent coins must deposit the uncurrent coins with a bank or other financial institution that will accept them, or with a depository institution that has established a direct customer relationship with a Federal Reserve Bank. A Federal Reserve Bank will redeem uncurrent coins, based on the policies described in the Federal Reserve's Operating Circular 2.

(c) Criteria for acceptance. Depository institutions that redeem uncurrent coins must sort the coins by denomination into packages in accordance with the Federal Reserve's Operating Circular 2. The Federal Reserve Banks have the right to reject any shipment containing objects that are not U.S. coins or any contaminant that could render the uncurrent coins unsuitable for coinage metal.

(d) Redemption sites. The Federal Reserve Banks and branches listed in § 100.17 are the only authorized redemption sites at which a depository institution that has established a direct customer relationship with a Federal Reserve Bank may redeem uncurrent coins.

§ 100.11 Request for examination of bent or partial coin for possible redemption.

- (a) General. Lawfully held bent or partial coins of the United States may be submitted to the United States Mint for examination in accordance with the provisions in this subpart. Any submission under this subpart shall be deemed an acceptance of all provisions of this subpart.
- (b) *Definitions*. (1) *Bent coins* are U.S. coins that are bent or deformed so as to preclude normal machine counting but which are readily and clearly identifiable as to genuineness and denomination.
- (2) Partial coins are U.S. coins that are not whole; partial coins must be readily and clearly identifiable as to genuineness and denomination.
- (3) Participants are individuals or businesses that submit coins through the redemption process.
- (c) Redemption process. (1)
 Depending on submission amount and frequency, participants may be subject to a certification process by the United States Mint. The established annual weight threshold and details about the participant certification process will be published on the United States Mint's website. If certification is required, it must be completed prior to submission.
- (2) All submissions for review shall include an estimate of the value of the coins and an explanation of how the submission came to be bent or partial. The submission should also contain the

- bank account number and routing number for a checking or savings account at a bank or other financial institution (such as a mutual fund, brokerage firm, or credit union) in the United States.
- (3) Participants will be required to provide information for how the participant came into custody of the bent or partial coins. The United States Mint reserves the right to request additional information.
- (4) The United States Mint reserves the right to test samples from any submission to authenticate the genuineness of the coins. The size of the sample will be limited to the amount necessary for authentication. Testing may result in partial or complete destruction of the sample.
- (5) The United States Mint reserves the right to conduct site visits to verify information provided to the United States Mint.
- (6) Each participant is limited to submitting no more than 1,000 lbs. of coins per month.
- (7) No redemption will be made when:
- (i) A submission contains any counterfeit coins;
- (ii) A submission demonstrates a pattern of systematic or intentional mutilation or demonstrates an attempt to defraud the United States;
- (iii) A submission appears to be part of, or intended to further, any criminal activity;
- (iv) A submission contains a material misrepresentation of facts;
- (v) Material presented is not identifiable as United States coins;
- (vi) A submission contains any contaminant that could render the coins unsuitable for coinage metal or contains hazardous materials;
- (vii) A submission contains more than a nominal amount of uncurrent coins;
- (viii) A submission contains coins imported from outside of the United States; or
- (ix) A submission, contains coins damaged in industrial or recycling processes (such as shredders, burnishers, incinerators, exposure to elevated temperatures), or coins that have been drilled, punctured, ground, polished, etched, or chemically treated.
- (8) If redemption is denied on the basis of paragraph (c)(7)(i), (ii), (iii), or (iv) of this section, the entire submission will be turned over to law enforcement authorities. Counterfeit coins and the entire submission may be subject to forfeiture under 18 U.S.C. 492.
- (9) If redemption is denied on the basis of paragraph (c)(7)(v), (vi), (vii), (viii), or (ix) of this section, the

- participant will be notified to retrieve the entire submission, at the participant's sole expense, within 30 days. If the submission is not retrieved in a timely manner, the entire submission will be treated as voluntarily abandoned property, pursuant to 41 CFR 102–41.80, and will be retained or disposed of by the United States Mint.
- (10) The Director of the United States Mint, or designee, shall have final authority with respect to all aspects of redemptions of bent or partial coin submissions.
- (d) Redemption rates—(1) Generally. Participants shall separate bent or partial coins by denomination in lots of at least one pound for each denomination category. The United States Mint will redeem bent or partial coins on the basis of their weight and denomination at the following rates:
- (i) One-Cent Coins: \$1.4585 per pound.
 - (ii) 5-Cent Coins: \$4.5359 per pound. (iii) Dime, Quarter-Dollar, and Half-
- (111) Dime, Quarter-Dollar, and Half-Dollar Coins: \$20.00 per pound.
 - (iv) \$1 Coins: \$20.00 per pound.
- (2) Exceptions. (i) The United States Mint will redeem one-cent coins inscribed with a year after 1982 at the rate set forth at paragraph (d)(1)(i) of this section unless such one-cent coins are presented unmixed from one-cent coins inscribed with a year before 1983. The United States Mint will redeem unmixed one-cent coins inscribed with a year after 1982 at a rate of \$1.8100 per pound.
- (ii) The United States Mint will redeem \$1 coins inscribed with a year after 1978 at the rate set forth at paragraph (d)(1)(iv) of this section unless such \$1 coins are presented unmixed from \$1 coins inscribed with a year before 1979. The United States Mint will redeem unmixed \$1 coins inscribed with a year after 1978 at a rate of \$56.00 per pound.
- (e) Redemption sites. Coins are shipped at the sender's risk of loss and expense.
- (1) Bent and partial coins submitted in quantities less than or equal to a threshold established annually by the United States Mint will be redeemed only at the United States Mint at Philadelphia, P.O. Box 400, Philadelphia, PA 19105.
- (2) Bent and partial coins submitted in quantities greater than a threshold established annually should be scheduled with the United States Mint, and the participant may be required to send the shipment directly to the authorized recycler(s) of the United States Mint.

§ 100.12 Exchange of fused or mixed coin.

- (a) *Definitions*. (1) *Fused coins* are U.S. coins that are melted to the extent that they are bonded together.
- (2) Mixed coins are U.S. coins of several alloy categories that are presented together, but are readily and clearly identifiable as U.S. coins.
- (b) Fused and mixed coins. The United States Mint will not accept fused coins for redemption. The United States Mint will not accept mixed coins for redemption, except as provided for in § 100.11(d)(2).

§100.13 Notices.

- (a) Additional information and procedures about the United States Mint's redemption of bent or partial coins can be found on the United States Mint's website.
- (b) Criminal penalties connected with the defacement or mutilation of U.S. coins are provided in 18 U.S.C. 331.
- (c) Notwithstanding any other provision of this subpart, the Director of the United States Mint may provide information pertaining to any bent or partial coin submissions, or turn over the entire submission, to law enforcement officials or other third parties for purposes of investigating related criminal activity or for purposes of seeking a civil judgment.
- (d) Whoever intentionally files a false claim seeking reimbursement for uncurrent, bent, or partial coins may be held criminally liable under a number of statutes including 18 U.S.C. 287 and 18 U.S.C. 1341 and may be held civilly liable under 31 U.S.C. 3729, et seq.

John F. Schorn,

Chief Counsel, United States Mint. [FR Doc. 2021–09338 Filed 5–4–21; 8:45 am] BILLING CODE 4810–37–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2020-0033]

RIN 1625-AA09

Drawbridge Operation Regulation: Rainy River, Rainy Lake and Their Tributaries, Rainier, MN

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to authorize the Canadian National Railroad Bridge, mile 85.0, across the Rainy River to operate remotely. The

request was made by the bridge owner. The bridge will continue to open on signal.

DATES: Comments and related material must reach the Coast Guard on or before July 6, 2021.

ADDRESSES: You may submit comments identified by docket number USCG—2020–0033 using Federal e-Rulemaking Portal at http://www.regulations.gov.

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

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or email Mr. Lee D. Soule, Bridge Management Specialist, Ninth Coast Guard District; telephone 216–902–6085, email Lee.D.Soule@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
OMB Office of Management and Budget
NPRM Notice of Proposed Rulemaking
(Advance, Supplemental)
§ Section
U.S.C. United States Code

II. Background, Purpose and Legal Basis

Rainy River and Rainy Lake serve as the border between the United States of America and Canada. This bridge is a single leaf, bascule type railroad bridge that provides a horizontal clearance of 125 feet. The water level on Rainy Lake and under the bridge is controlled by a hydro-electric dam facility at International Falls, Minnesota, thus charted datum is based on the water level surface of Rainy Lake when the gauge at Fort Frances, Canada reads 1107.0 feet resulting in a variable vertical clearance of 6 to 10 feet in the closed position. The railroad bridge carries significant train traffic across the international border. Rainer, Minnesota is a customs port-of-entry.

III. Discussion of Proposed Rule

On April 8, 2020, we published a Temporary Deviation with request for comments in FR 2020–06822 and we did not receive any comments.

IV. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This NPRM has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB) and pursuant to OMB guidance; it is exempt from the requirements of Executive Order 13771.

This proposed rule intends to allow the bridge to be operated remotely. All other conditions in 33 CFR 117.664 shall remain.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601-612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. While some owners or operators of vessels intending to transit the bridge may be small entities, for the reasons stated in section IV.A above this proposed rule would not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see ADDRESSES) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the FOR FURTHER INFORMATION CONTACT. The Coast Guard will not retaliate against small entities that

question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

Also, this proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this proposed rule has implications for federalism or Indian tribes, please contact the person listed in the FOR FURTHER INFORMATION **CONTACT** section.

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning Policy COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321– 4370f). The Coast Guard has determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule promulgates the operating regulations or procedures for drawbridges. Normally such actions are categorically excluded from further review, under paragraph L49, of Chapter 3, Table 3–1 of the U.S. Coast Guard Environmental Planning Implementation Procedures.

Neither a Record of Environmental Consideration nor a Memorandum for the Record are required for this rule. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

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

V. Public Participation and Request for Comments

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

We encourage you to submit comments through the Federal eRulemaking Portal at https://www.regulations.gov. If your material cannot be submitted using https://www.regulations.gov, contact the person in the FOR FURTHER INFORMATION CONTACT section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to https://www.regulations.gov and will include any personal information you have provided. For more about privacy and submissions in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

Documents mentioned in this NPRM as being available in this docket and all public comments, will be in our online docket at https://www.regulations.gov and can be viewed by following that

website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

List of Subjects in 33 CFR Part 117

Bridges.

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

PART 117—DRAWBRIDGE OPERATION REGULATIONS

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

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; DHS Delegation No. 0170.1.

■ 2. Revise § 117.664 to read as follows:

§ 117.664 Rainy River, Rainy Lake and their tributaries.

The draw of the Canadian National Bridge, mile 85.0, at Rainer, may operate remotely, and shall open on signal; except that, from October 16 to April 30, the draw shall open on signal if at least 12-hours advance notice is provided. The commercial phone number to provide advance notice shall be posted on the bridge so that it is plainly visible to vessel operators approaching the up or downstream side of the bridge. The owners of the bridge shall provide and keep in good legible condition two board gauges painted white with black figures to indicate the vertical clearance under the closed draw at all water levels. The gauges shall be so placed on the bridge that they are plainly visible to operators of vessels approaching the bridge either up or downstream. The bridge shall operate and maintain a VHF-FM Marine Radio.

Dated: April 2, 2021.

D.L. Cottrell,

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

[FR Doc. 2021-09003 Filed 5-4-21; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS-R8-ES-2020-0074; FF09E22000 FXES11130900000 201]

RIN 1018-BE73

Endangered and Threatened Wildlife and Plants; Removing Five Species From San Clemente Island From the Federal Lists of Endangered and Threatened Wildlife and Plants

AGENCY: Fish and Wildlife Service,

Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service or USFWS), propose to remove the San Clemente Bell's sparrow (Artemisiospiza belli clementeae) (formerly known as the San Clemente sage sparrow, Amphispiza belli clementeae), San Clemente Island bush-mallow (Malacothamnus clementinus). San Clemente Island paintbrush (Castilleja grisea), San Clemente Island lotus (Acmispon dendroideus var. traskiae), and San Clemente Island larkspur (Delphinium variegatum ssp. kinkiense) from the Federal Lists of Endangered and Threatened Wildlife and Plants (Lists). The bird species and four plant species occur only on San Clemente Island, one of the Channel Islands off the southern coast of California. The proposed delistings are based on our evaluation of the best available scientific and commercial information, which indicates that the species' statuses have improved and threats to the species have been eliminated or reduced to the point that the species have recovered and no longer meet the definitions of either endangered or threatened species under the Endangered Species Act of 1973, as amended (Act). If this proposal is finalized, these species will be removed from the Lists.

DATES: We will accept comments received or postmarked on or before July 6, 2021. We must receive requests for public hearings, electronically, using the Federal eRulemaking Portal (see **ADDRESSES**, below) by June 21, 2021.

ADDRESSES: You may submit comments by one of the following methods:

(1) Electronically: Go to the Federal eRulemaking Portal: http://www.regulations.gov. In the Search box, enter FWS-R8-ES-2020-0074, which is the docket number for this rulemaking. Then, click on the Search button. On the resulting page, in the Search panel on the left side of the screen, under the

Document Type heading, check the Proposed Rule box to locate this document. You may submit a comment by clicking on "Comment Now!" Comments submitted electronically must be received by 11:59 p.m. Eastern Time on the closing date.

(2) By hard copy: Submit by U.S. mail to: Public Comments Processing, Attn: FWS-R8-ES-2020-0074, U.S. Fish and Wildlife Service, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041-3803.

We request that you send comments only by the methods described above. We will post all comments on http://www.regulations.gov. This generally means that we will post any personal information you provide us (see Public Comments, below, for more information).

Document availability: This proposed rule and supporting documents, including the recovery plan, draft post-delisting monitoring plan, and species status assessment (SSA) reports, are available at https://ecos.fws.gov/ecp/ and at https://eww.regulations.gov under Docket No. FWS-R8-ES-2020-0074.

FOR FURTHER INFORMATION CONTACT:

Scott Sobiech, Field Supervisor, Carlsbad Fish and Wildlife Office, 2177 Salk Avenue, Suite 250, Carlsbad, CA 92008; telephone 760–431–9440. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Act, a species may warrant removal from the Federal Lists of Endangered and Threatened Wildlife and Plants (i.e., "delisting") if it no longer meets the definition of an endangered species or a threatened species. Delisting a species can only be completed by issuing a rule.

What this document does. We propose to remove San Clemente Bell's sparrow (Artemisiospiza belli clementeae) (formerly known as the San Clemente sage sparrow, Amphispiza belli clementeae), San Clemente Island bush-mallow (Malacothamnus clementinus), San Clemente Island paintbrush (Castilleja grisea), San Clemente Island lotus (Acmispon dendroideus var. traskiae), and San Clemente Island larkspur (Delphinium variegatum ssp. kinkiense) from the Federal Lists of Endangered and Threatened Wildlife and Plants (Lists).

The basis for our action. Under the Act, we may determine that a species is an endangered or threatened species because of any of five factors: (A) The present or threatened destruction,

modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. We have determined that the threats to each of these species have been reduced or eliminated so that the species are no longer in danger of extinction now or in the foreseeable future and, therefore, do not meet the definitions of endangered species or threatened species under the Act.

These species occur only on San Clemente Island, one of the Channel Islands off the southern coast of California. The entire island is owned and managed by the U.S. Department of the Navy (Navy). Historically, nonnative herbivores (goats, sheep, pigs, cattle, mule deer) severely degraded habitat on San Clemente Island, leading to the decline of endemic species. Since removal of these nonnative herbivores, the plant communities on San Clemente Island have been recovering. Removal of nonnative herbivores, along with restoration and management actions by the Navy, have led to the recovery of these five species to the point that they no longer require protections under the Act.

Information Requested

We intend that any final action resulting from this proposed rule will be based on the best scientific and commercial data available and be as accurate and as effective as possible. Therefore, we request comments or information from other concerned governmental agencies, Native American tribes, the scientific community, industry, or any other interested parties concerning this proposed rule.

We particularly seek comments concerning:

- (1) Reasons we should or should not remove (delist) any of these species from the Lists.
- (2) New information on the historical and current status, genetics, range, distribution, and population size of these species.
- (3) New information on the known and potential threats to the species, including fire and changes in precipitation.
- (4) New information regarding the life history, ecology, and habitat use of the species.
- (5) The extent of protection and management that would be provided by the Navy to the five species if the

protections of the Act (16 U.S.C. 1531 *et seq.*) are removed.

(6) Current or planned activities within the geographic range of these species that may have adverse or beneficial impacts on the species.

(7) Any planned change in military training, infrastructure needs, or land use on San Clemente Island that may affect the species.

(8) Considerations for post-delisting monitoring, including monitoring protocols and length of time monitoring is needed, as well as triggers for reevaluation.

Please include sufficient information with your submission (such as scientific journal articles or other publications) to allow us to verify any scientific or commercial information you include.

Please note that submissions merely stating support for, or opposition to, the action under consideration without providing supporting information, although noted, do not provide substantial information necessary to support a determination. Section 4(b)(1)(A) of the Act directs that determinations as to whether any species is an endangered species or a threatened species must be made "solely on the basis of the best scientific and commercial data available."

Because we will consider all comments and information we receive during the comment period, our final determinations may differ from this proposal. Based on the new information we receive (and any comments on that new information), we may conclude that one or more of the species should remain listed as endangered or threatened instead of being removed from the Lists, we may conclude that one or more of the species should be reclassified from an endangered species to a threatened species, or we may conclude that one or more of the species should be reclassified from a threatened to an endangered species.

You may submit your comments and materials concerning this proposed rule by one of the methods listed in ADDRESSES. We request that you send comments only by the methods described in ADDRESSES.

If you submit information via http://www.regulations.gov, your entire submission—including any personal identifying information—will be posted on the website. If your submission is made via a hardcopy that includes personal identifying information, 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. We will post all hardcopy submissions on http://www.regulations.gov.

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on http://www.regulations.gov.

Public Hearing

Section 4(b)(5) of the Act provides for a public hearing on this proposal, if requested. Requests must be received by the date specified in **DATES**. Such requests must be sent electronically, using the Federal eRulemaking Portal (see ADDRESSES, above). We will schedule a public hearing on this proposal, if requested, and announce the date, time, and place of the hearing, as well as how to obtain reasonable accommodations, in the Federal **Register** and local newspapers at least 15 days before the hearing. For the immediate future, we will provide public hearings using webinars that will be announced on the Service's website,

in addition to the **Federal Register**. The use of virtual public hearings is consistent with our regulations at 50 CFR 424.16(c)(3).

Supporting Documents

Species status assessment (SSA) reports for the five species were prepared by Texas A&M Natural Resources Institute, in cooperation with the Service's San Clemente Island SSA team and the Navy. The SSA reports represent a compilation of the best scientific and commercial data available concerning the status of these species, including the impacts of past, present, and future factors (both negative and beneficial) affecting the species.

In accordance with our July 1, 1994, peer review policy (59 FR 34270; July 1, 1994), our August 22, 2016, Director's Memo on the Peer Review Process, and the Office of Management and Budget's December 16, 2004, Final Information

Quality Bulletin for Peer Review (revised June 2012), we solicited independent scientific reviews of the information contained in each of the SSA reports. Table 1, below, indicates the number of independent peer reviewers we sent each SSA report to and the number of responses we received. You may view the peer review responses we received at http:// www.regulations.gov under Docket No. FWS-R8-ES-2020-0074. The SSA reports were also submitted to our Federal and State partners for scientific review, but we did not receive any comments. The Navy helped with development of the SSAs and, therefore, did not comment on the drafts. We incorporated the results of the peer reviews in the final SSA reports, as appropriate, which are the foundation for this proposed rule.

TABLE 1—NUMBER OF PEER REVIEWS REQUESTED AND RESPONSES

Species	Number peer reviews requested	Number peer review responses received
San Clemente Bell's sparrow	5	4
San Clemente Island paintbrush	3	2
San Clemente Island lotus	3	1
San Clemente Island larkspur	4	2
San Clemente Island bush-mallow	5	3

Previous Federal Actions

All five species were originally listed under the Act on August 11, 1977 (42 FR 40682). The four plant species were listed as endangered species, while the sparrow was listed as a threatened species. No critical habitat has been designated for any of the five species.

The taxonomies of the species have undergone revisions since the species were first listed, so that some are now referred to by different scientific and common names. Table 2, below, indicates the scientific and common names under which the species were originally listed as well as their currently accepted scientific names. These taxonomic and nomenclatural revisions have not altered the definition.

distribution, or range of any of these species from what it was at the time of listing. In the remainder of this proposed rule, we will refer to the species by their currently accepted common names.

The Recovery Plan for Endangered and Threatened Species of the California Channel Island, which included the five species that are the subject of this proposed rule, was finalized in 1984 (USFWS 1984, pp. 1–165). Five-year status reviews were completed for each of these taxa and recommended reclassification from endangered to threatened species for all four of the plant taxa (USFWS 2007a, USFWS 2007b, USFWS 2007c, USFWS 2008).

On May 18, 2010, we received a petition from the Pacific Legal Foundation requesting that the Service delist or downlist six species, including San Clemente Island paintbrush, San Clemente Island lotus, and San Clemente Island bush-mallow. The subsequent status reviews resulted in downlisting the San Clemente Island paintbrush and San Clemente Island lotus from endangered to threatened (78 FR 45406; July 26, 2013) as indicated below in Table 2. San Clemente Island bush-mallow was not reclassified at the time because of uncertainty regarding the status of several occurrences that made up a large proportion of its range (77 FR 29078; May 16, 2012).

We published notices of initiation of periodic status reviews for the five species required under section 4(c)(2) of the Act in 2019 and 2020 (84 FR 36116,

July 26, 2019; 85 FR 4692, January 27, 2020); this document serves as completion of those status reviews. The referenced documents and additional

details can be found using the Service's Environmental Conservation Online System (ECOS): https://ecos.fws.gov/.

Table 2—Summary of Previous Federal Actions

[An *indicates the common and scientific names of these taxa as they currently appear on the Lists at 50 CFR 17.11 and 17.12.]

Species						
Common and scientific names at time of listing (1977).	San Clemente sage sparrow. (Amphispiza belli clementae)*.	San Clemente Island indian paintbrush. (Castilleja grisea)	San Clemente broom. (<i>Lotus scoparius</i> ssp. <i>traskiae</i>).	San Clemente Island larkspur. (Delphinium kinkiense).	San Clemente Island bushmallow (Malacothamnus clementinus)	
Original listing status	T	È	E	E	E	
5-Year status review date and recommendation.	August 13, 2009; No change.	September 24, 2007; downlist to threatened.	September 24, 2007; downlist to threatened.	March 31, 2008; downlist to threat- ened.	September 28, 2007; downlist to threatened	
12-month findings and reclassifications.		Final downlisting: July 26, 2013 (78 FR 45406).	Final downlisting: July 26, 2013 (78 FR 45406).		12-month finding, not warranted for reclassification: May 16, 2012 (77 FR 29078)	
Currently accepted common and scientific names.	San Clemente Bell's sparrow. (Artemisiospiza belli clementeae).	San Clemente Island paintbrush. (Castilleja grisea)*	San Clemente Island lotus. (Acmispon dendroideus var.	San Clemente Island larkspur. (Delphinium variegatum ssp.	San Clemente Is- land bush-mallow (Malacothamnus clementinus)*	
Current listing status	Т	Т	<i>traskiae</i>) *.	kinkiense)*.	E	

Proposed Delisting Determinations Background

Overview of San Clemente Island

The five species addressed in this proposed rule are endemic to San Clemente Island, the southernmost island of the California Channel Islands, located 64 miles (mi) (103 kilometers (km)) west of San Diego, California. The island is approximately 56 square mi (145 square km, 36,073 acres (ac), or 14,598 hectares (ha)) (Junak and Wilken 1998, p. 2) and is long and narrow: 21 mi (34 km) long by 1.5 mi (2.4 km) wide at the north end, and 4 mi (6.4 km) wide at the south end (USFWS 1984, p. 5). The island consists of a relatively broad open plateau that slopes gently to the west. Conspicuous marine terraces line the western slope of the island, while steep escarpments drop precipitously to the rocky coastline on the eastern side along the southern 75 percent of its coastline. Many canyons, some of which are up to 500 feet (ft) (152 meters (m)) deep, dissect the southern part of the island. Mount Thirst, the highest point on the island, rises to approximately 1,965 ft (599 m) (Navy 2013a, p. 1.4).

San Clemente Island is located in a Mediterranean climatic regime with a significant maritime influence. Average monthly temperatures range from 58 degrees Fahrenheit (°F) (14 degrees Celsius (°C)) to 66 °F (19 °C), with a monthly maximum temperature of 72 °F (27 °C) in August and a monthly minimum of 51 °F (10 °C) in December

(Navy 2013a, p. 3.11). Average monthly relative humidity varies from 54 to 86 percent depending on location and time of year, and the island experiences dramatic fluctuations in annual rainfall, averaging 6.6 inches (in) (16.8 centimeters (cm)) (Navy 2013a, pp. 3.11, 3.13). Precipitation is received mainly from November through April, with little from May through October. In addition to precipitation, fog drip during the typical dry season is a vital source of moisture to the San Clemente Island (SCI) ecosystem (Navy 2013a, pp. 3.9, 3.13). The central plateau is characterized mainly by native and nonnative grassland communities. Marine terraces on the western side of the island support maritime desert scrub communities, and the steep eastern escarpment supports grassland and sagebrush communities. Deep canyons that incise both the east and the west sides of the island support limited canyon woodland communities.

San Clemente Bell's Sparrow

A thorough review of the taxonomy, life history, and ecology of the San Clemente Bell's sparrow is presented in the SSA report (USFWS 2020a). The San Clemente Bell's sparrow (Artemisiospiza belli clementeae; Chesser et al. 2012), formerly called the San Clemente sage sparrow, is a nonmigratory subspecies of Bell's sparrow endemic to San Clemente Island, California. It is a grayish-brown colored sparrow with a small dark breast spot,

complete white eye rings, and distinctive white and black malar stripes. It is approximately 5.1–5.9 in (13–15 cm) long, and weighs, on average, 0.59 ounces (16.8 grams) (Martin and Carlson 1998, p. 2; Turner et al. 2005, p. 27).

The San Ĉlemente (SC) Bell's sparrow has been close to extinction, with a low of 38 individual adults reported in 1984 (Hyde 1985, p. 30). The population was estimated to be 316 in 1981, 38 in 1984, and 294 in 1997 (Beaudry et al. 2003, pp. 1–2). Some of this population fluctuation may be related to differences in survey methods and areas surveyed (Kaiser et al. 2008, pp. 31-33). In order to more accurately estimate distribution and population size, SC Bell's sparrow breeding season surveys were redesigned in 2012 (Meiman et al. 2019, pp. 3-4) and implemented island-wide in 2013, resulting in an island-wide estimate of 4,534 adult sparrows (2,267 pairs). The population estimates have consistently been over 4,000 adults since 2013 (4,194-7,656) (USFWS 2020a, p. 25).

At listing, the SC Bell's sparrow was primarily distributed within the lower marine terraces along the northwestern portion of SCI, in the maritime desert scrub plant communities, mostly dominated by boxthorn (Willey 1997, p. 219). However, the SC Bell's sparrow has more recently been found widely across the island, bringing recent estimates of potential available habitat from approximately 4,196 ha (10,369)

acres) in 2009 (USFWS 2009, p. 8) to approximately 13,132 ha (32,449 acres, almost 90 percent of the island) (Meiman *et al.* 2018, p. 5). As the native habitats recovered following the removal of the nonnative grazing and browsing animals, the distribution of SC Bell's sparrow expanded on SCI

(Meiman *et al.* 2019, pp. 2–4). It is likely that sparrows used boxthorn as a refuge and started using other substrates before we recognized them as nesting habitat. While the SC Bell's sparrow is now distributed widely across the island (see Figure 1, below), its density varies greatly spatially and among vegetation

types. While sparrows may be found in some habitat strata mapped as grasslands, many grassland areas do not support SC Bell's sparrow, likely due in part to the lack of shrub cover.

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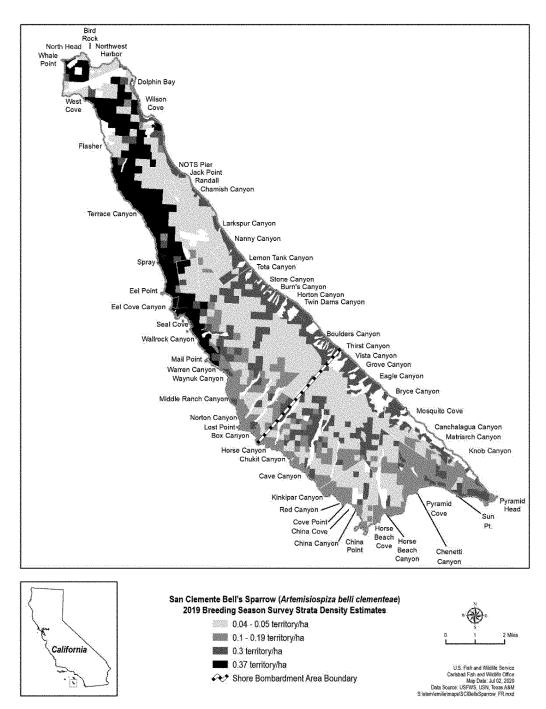


Figure 1. Map showing distribution of San Clemente Bell's sparrow.

Boxthorn habitat is still considered high-quality habitat, although moderate to high population densities are also found in sagebrush and shrub habitat near canyons and along the steep eastern slope. SC Bell's sparrows are present in significantly lower densities in mixed shrub, cactus, and grassland (grass/herb) habitats along the central plateau (Meiman et al. 2018, p. 18). The west shore boxthorn habitat, where the species was originally described, remains densely occupied and is thus important to the species.

SC Bell's sparrows inhabit most plant communities on SCI, including Maritime Desert Scrub in Lycium (boxthorn) phase, Opuntia (prickly pear) phase, and Cylindropuntia (cholla) phase; Maritime sage scrub; canyon shrubland/woodland; and grasslands (USFWS 2020a, pp. 20–21). Within these plant communities, SC Bell's sparrows show an affinity for areas dominated by shrubs and cacti (Opuntia spp.). SC Bell's sparrows demonstrate a positive association with structural shrub cover (Meiman et al. 2015a, p. 33), as they typically use shrubs for nesting substrate and use the gaps between and area underneath shrubs for foraging. The abundance of shrubs, including boxthorn, has been positively correlated with sparrow density (Turner 2009, pp. 53-54). High grass cover has been correlated with lower sparrow densities and larger territory sizes, which may indicate that grasses are not likely important resources during the

The SC Bell's sparrow is a ground gleaner and eats available insects and spiders, and also seeds taken from the ground and low vegetation. During the winter, SC Bell's sparrows feed on prickly pear and cholla cactus fruit and on moths (Hyde 1985, p. 24). The initiation of breeding activity and the length of the nesting season appear to be tied to precipitation patterns (Kaiser et al. 2007, pp. 48-49; Meiman et al. 2018, p. 36). Breeding activity usually peaks in March and April, and lasts through late June or July. Clutch size ranges from 1 to 5 eggs, with asynchronous hatching after 12 to 13 days of incubation conducted mostly by the female (Martin and Carlson 1998, p. 9). SC Bell's sparrows are able to breed their first vear, and multiple clutches per year have been recorded, with most pairs producing multiple successful broods in favorable years (Martin and Carlson

nesting season (Turner 2009, pp. 53-54).

1998, p. 9; Kaiser *et al.* 2008, p. 36). SC Bell's sparrows express site fidelity each nesting season, and juveniles disperse from the natal area during their first winter.

Amounts and distribution of rainfall affect the timing and extent of vegetation growth and flowering. During drought years, SC Bell's sparrows may not reproduce at all or a subset of the population may suppress breeding (Kaiser et al. 2007, p. iv; Stahl et al. 2010, p. 48; Meiman et al. 2019, p. 35), which can, but does not always, result in depressed populations following drought years. SC Bell's sparrows appear to respond to favorable precipitation patterns and resulting conditions by producing multiple clutches, which typically drive population numbers up in years that follow "good" precipitation years (Kaiser et al. 2007, p. iv; Stahl et al. 2010, p. 50). However, while there is a relationship between reproductive output and rainfall, the impacts of droughts of varying duration and severity on the population are unclear, and the mechanisms driving these relationships are unknown (USFWS 2020a, pp. 58–63).

San Clemente Island Bush-Mallow

A thorough review of the taxonomy, life history, and ecology of the San Clemente Island bush-mallow is presented in the SSA report (USFWS 2020b). San Clemente Island bushmallow (Malacothamnus clementinus) is a rounded shrub in the Malvaceae (mallow family) (Slotta 2012; 77 FR 29078, May 16, 2012, p. 29080). Plants are generally 2.3 to 3.3 ft (0.7 to 1 m) tall with numerous hairy branched stems arising from the base of the plant (Munz and Johnston 1924, p. 296; Munz 1959, pp. 122-125; Bates 1993, p. 752). Flowers are clustered in the uppermost leaf axils, forming interrupted spikes 3.9 to 7.9 in (10 to 20 cm) long (Munz 1959, p. 125). Flowers are bisexual and variously described as having pink or white and fading lavender petals (Munz and Johnston 1924, p. 296; Bates 1993, p. 752).

The historical range and distribution of SCI bush-mallow on SCI is unknown because botanical studies were not conducted on the island prior to the introduction of ungulates beginning in the 1800s (Kellogg and Kellogg 1994, p. 4). At the time of listing, one site at Lemon Tank Canyon on the eastern side

of the island and two additional locations of two to three small plants in China Canvon on the southern end of the island were known (42 FR 40682, August 11, 1977, p. 40683; USFWS 1984, p. 48). Since listing, new locations of SCI bush-mallow have been discovered among the generally southwesterly facing coastal terraces and their associated escarpments in the southern and middle regions of SCI (Junak and Wilken 1998, pp. 1-416, Geographic Information System (GIS) data; Junak 2006, pp. 1-176, GIS data; Tierra Data Inc. 2008, pp. 1-24, appendices and GIS data; San Diego State University Soil Ecology and Restoration Group (SERG) 2010a and 2010b, GIS data). Most of the known locations occur throughout the southwestern region of the island. The main southern distribution of SCI bushmallow is disconnected from the Lemon Tank Canyon locality by approximately 4 mi (6.4 km). Many of these new locations have been documented since feral mammals were removed, suggesting that plants may have reemerged from underground stems that survived grazing by feral herbivores (Junak 2006, pers. comm. in 77 FR 29078, May 16, 2012, p. 29086), although experts doubt that rhizomes would be able to store enough energy to sprout after a long period of dormancy without sending up shoots in the interim (Munson 2019, pers. comm.; Rebman 2019, pers. comm.; Morse 2020, pers. comm.).

The current abundance and distribution of SCI bush-mallow is estimated to total approximately 5,611 individuals at 222 locations occupying 15 watersheds (see Figure 2, below) (USFWS 2020b, pp. 29-31). Because distinguishing genetically distinct individuals among groups of stems is difficult, counts or estimates of individuals have most often been used collectively to refer to both genetically distinct individuals (genets) and clones (ramets) (USFWS 2020b, p. 26). In the current estimate, individuals refer to individual plants and not necessarily to genetically distinct individuals. Because of access restrictions due to risk of unexploded ordnances, occurrences within areas subject to bombardment have not been assessed recently enough to be included in this estimate, but are likely still extant.

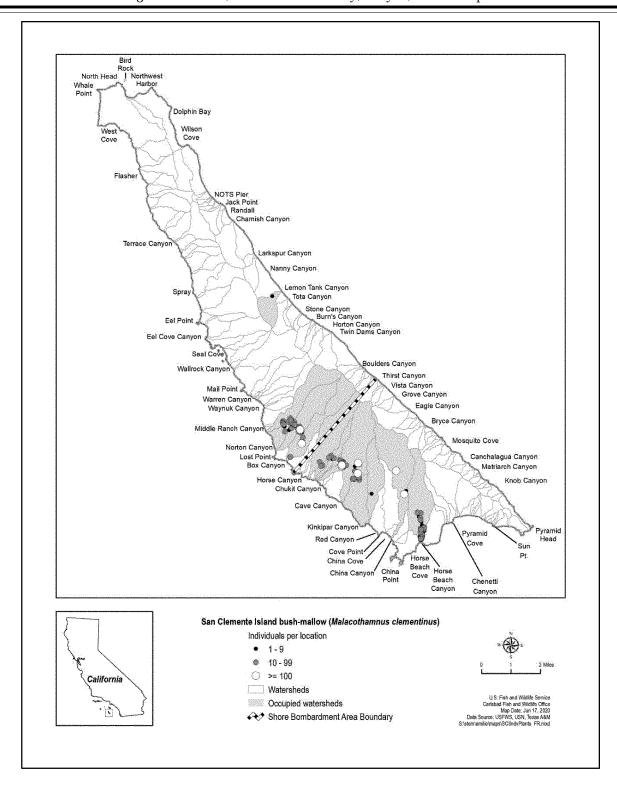


Figure 2. Map showing distribution of San Clemente Island bush-mallow.

SCI bush-mallow occurs in a variety of habitats on SCI. Historically, it was observed on rocky canyon walls and ridges, presumably because foraging goats did not browse those areas. Since removal of nonnative feral ungulates, SCI bush-mallow has been found at the base of escarpments between coastal terraces on the western side of the island within maritime cactus scrub (Navy 2002, pp. D–19, D–20), and it can also occur on low canyon benches and in rocky grasslands. Moisture that collects in rock crevices and at the base

of canyon walls and escarpments may provide favorable conditions for this species (Junak 2006, pers. comm. in 77 FR 29078, May 16, 2012, p. 29094). Based on its habitat range on the island and the ease of cultivating the plant, SCI bush-mallow appears to tolerate a broad range of soil types (USFWS 1984, p. 50). It is often associated with maritime cactus scrub vegetation on coastal flats at the southwestern end of the island (Junak and Wilken 1998, p. 256).

SCI bush-mallow flowers in the spring and summer, typically from March to August (Kearney 1951, p. 115; California Native Plant Society 2011). It is generally thought that SCI bush-mallow is pollinated by insects; potential pollinators incidentally observed in the wild include wasps and butterflies (USFWS 2007, p. 9). Although no specific pollinator for this species is known, the shape of the flowers suggest that it is not limited to a specific pollinator and instead can be pollinated by different pollinators (Muller and Junak 2011, p. 33).

While each plant is capable of making large numbers of seeds, recorded seed production in natural occurrences of SCI bush-mallow has been very low (Helenurm 1997, p. 51; Helenurm 1999, p. 39; Junak and Wilken 1998, p. 291). Germination rates in seed trials are also low, only 4 to 35 percent (Evans and Bohn 1987, p. 538; Junak and Wilken 1998, p. 291). Hypotheses for low seed set and germination rates include low pollinator visitation rates, reduced pollinator diversity, partial selfincompatibility (i.e., plants need to be pollinated by a non-closely related individual), limited survey efforts, and that seed germination may be stimulated by fire (USFWS 2020b, pp. 22-23).

However, it is difficult to determine the

cause of the apparent low reproductive

output is still an issue currently, and

output noted, whether low reproductive

whether fire assists germination. SCI bush-mallow can reproduce vegetatively, or clonally, by sprouting from rhizomes (Evans and Bohn 1987, p. 538), as well as sexually by seeds, although sexual recruitment is likely low. The ability to spread vegetatively by underground rhizomes results in patches of spatially separate but genetically identical individuals (Evans and Bohn 1987, p. 538). Occurrences are likely a mix of both genetically unique individuals (genets) and clonal individuals (ramets) that are connected underground. Although difficult to discern between ramets and genets in the field, most groups of plants are comprised of ramets from an unknown

number of genets, consistent with other plant species exhibiting strong clonal growth. Although growth and spread of the population has been thought to be mostly clonal (Muller and Junak 2011, p. 50), seedlings have on occasion been identified in the field by the presence of cotyledons (embryonic leaf in seedbearing plants) (Munson 2019, pers. comm.). While the distribution of SCI bush-mallow is much greater than was known at the time of listing, difficulty and confusion with discerning between ramets and genets and low reproductive output create uncertainty about whether it is reproducing sexually or only clonally.

Two different studies of population genetics have been conducted (Helenurm 1997; Helenurm 1999). These genetic assessments along with field observations indicate that overall genetic diversity is low, but there is some genetic diversity within and among patches of SCI bush-mallow (i.e., based on these studies, not all individuals are clones in each area). However, due to the limitations of techniques, neither study is conclusive. Genetic diversity is presumed to have declined since the introduction of feral browsers and grazers, but we do not know historical or current levels of genetic diversity or normal rates of sexual versus asexual reproduction, so no comparisons can be made. Overall, genetic diversity within SCI bushmallow is still very low compared with other island endemic plant taxa (Helenurm 1999, p. 40).

This species may be subject to drought stress to some extent (from 25 to 89 percent of individuals sampled), which may reduce flowering (Muller and Junak 2011, p. 58). This species may be drought deciduous as is a closely related species of bush-mallow, *Malacothamnus fasciculatus*, but there are no physiological studies to support this conjecture; the similar phenology of SCI bush-mallow and its habitat attributes support the suggestion (Muller and Junak 2011, p. 32).

Although there is no information regarding the fire tolerance of SCI bushmallow, other species in the same genus are fire-tolerant and able to adapt (Rundel 1982, p. 86). Seed germination in other species in the genus is stimulated by fire, and there is evidence

that fire may also have a positive effect on SCI bush-mallow. Because of its ability to resprout from rhizomes and the adaptation of other species in the genus to fire, it is thought that SCI bushmallow is likely resistant to fire and that its seeds may even respond positively to fire (USFWS 2008b, p. 77).

San Clemente Island Paintbrush

A thorough review of the taxonomy, life history, and ecology of the San Clemente Island paintbrush is presented in the SSA report (USFWS 2020e).

San Clemente Island paintbrush (Castilleja grisea) is a highly branched perennial subshrub in the broomrape family (Orobanchaceae) endemic to SCI (Chuang and Heckard 1993, p. 1021) and is the only representative of the genus Castilleja found on the island (Helenurm et al. 2005, p. 1222). SCI paintbrush is typically 11.5 to 31.5 in (29 to 80 cm) in height and covered with dense white, wooly hairs. Most Castilleja species have bisexual flowers disposed in terminal spikes. The flowers of SCI paintbrush are yellow.

SCI paintbrush is thought to have been relatively common on SCI in the 1930s, and subsequently declined as a result of unchecked grazing by introduced feral herbivores (Helenurm et al. 2005, p. 1222). The complete historical range of SCI paintbrush on SCI is unknown because botanical studies were not completed before the plant's decline. Herbarium records documented the species on the south and east sides of the island before the time of listing (California Consortium of Herbaria 2019, records for *C. grisea*). By 1963, SCI paintbrush was reported as rare or occasional (Raven 1963, p. 337). Since the complete removal of feral ungulates from SCI by 1992, SCI paintbrush has been detected across the southern two-thirds of the island (Keegan et al. 1994, p. 58; Junak and Wilken 1998, pp. 1–416, GIS data; Junak 2006, pp. 1–176, GIS data; Tierra Data Inc. 2008, pp. 1–24, appendices and GIS data; SERG 2010a and 2010b, GIS data). The current abundance and distribution of SCI paintbrush is estimated to be comprised of 601 locations totaling 48,181 individuals occupying 87 watersheds (see Figure 3, below) (USFWS 2020e, pp. 27-29).

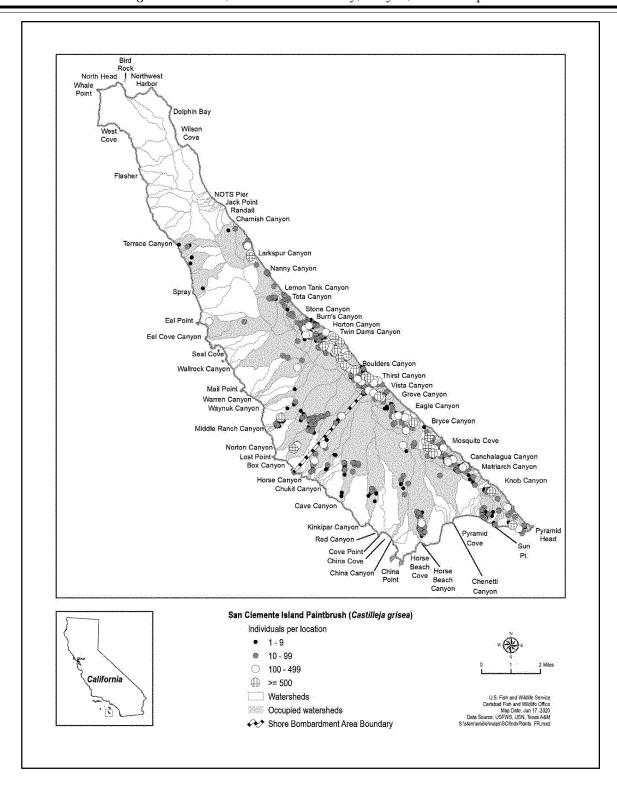


Figure 3. Map showing distribution of San Clemente Island paintbrush.

Over time, the range of SCI paintbrush has expanded, and it now occupies a broad range of habitats across the island. SCI paintbrush is often associated with two major vegetation types: Canyon woodland (which encompasses approximately 696 ac (282 ha)), and

maritime desert scrub (which encompasses approximately 6,228 ac (2,520 ha)). Aspect varies widely, but generally plants are found on flats and steep rocky slopes from 0–70 degrees (CNDDB 2019; Navy 2017, pp. 11–24; Vanderplank *et al.* 2019, p. 5), and the

species is found almost exclusively on non-clay soils and rocky outcrops (Vanderplank *et al.* 2019, p. 5). SCI paintbrush can colonize disturbed areas, and the species likely has the potential for further range expansion on SCI (Navy 2008a, p. 3.11–3.20; Vanderplank *et al.* 2019, p. 5).

All members of the genus Castilleja are considered hemiparasitic, meaning that its roots are capable of forming parasitic connections to roots of other plants (Heckard 1962, p. 27). Plants within the genus are capable of photosynthesis and can exist without a host, but they are able to derive water, nutrients, and photosynthates from a host plant if present (Heckard 1962, p. 25). Members of the genus Castilleja appear to form parasitic connections with a wide range of host plant species from a wide range of families (Heckard 1962, p. 28; Atsatt and Strong 1970, p. 280; Marvier 1996, p. 1399; Adler 2002, p. 2704; Adler 2003, p. 2086; Muller 2005, p. 4). Although studies to verify host-connections have not been done, numerous plant species are associated with SCI paintbrush (Junak and Wilken 1998, p. 82; R. N. Muller 2009, pers. comm., in 77 FR 29078, May 16, 2012, p. 29096). The generalist host-selection of *C. grisea* likely aided recovery of this species as the vegetation recovered following the removal of feral browsers and grazers (Muller and Junak 2012, pp. 16-17).

SCI paintbrush typically flowers between February and May, producing yellow bisexual flowers (Chuang and Heckard 1993, pp. 1016–1024; Navy 2013a, pp. 3-203). SCI paintbrush is likely self-incompatible (unable to produce viable seed through selffertilization), as observed in other species of the genus (Carpenter 1983, p. 218; Junak and Wilken 1998, p. 84). Results of a population genetic study were consistent with an outcrossing breeding system (Helenurm et al. 2005, p. 1225). SCI paintbrush is most closely related to, and shares floral traits with, other species in the genus primarily adapted for bee pollination (Chuang and Heckard 1991, p. 658), but both insect and hummingbird pollination of Castilleja have been reported (Grant 1994, p. 10409; Junak and Wilken 1998,

Although the lifespan of SCI paintbrush is unknown, its larger stature and woodier habit (general appearance or growth form) suggest it may be longer lived, which would be consistent with an estimated lifespan of 5–15 years based on observations made during repeat visits to occupied sites (Munson 2019, pers. comm.). Based on lifehistory, the persistence of interbreeding

groups of plants may depend upon frequent production of seed (Dunwidde et al. 2001, p. 161) as no evidence of clonal growth has been found (Muller and Junak 2010, p. 42). Population growth is primarily by recruitment from existing populations from plants that emerged from the soil seed-bank following removal of feral herbivores or from plants that survived those impacts (Muller and Junak 2010, p. 42). However, the increase in SCI paintbrush's range, along with the discovery of new individuals along trails or near buildings that people frequent (O'Connor 2019, pers. comm.), suggests that the establishment of new population centers may be relatively common. The degree of fire tolerance of SCI paintbrush is unknown. It is not specifically adapted to fire, but it is likely resilient to occasional fires and has been seen to persist in areas after fires, although severe fires can kill plants and reduce numbers of individuals in a location (Muller and Junak 2011, p. 16; US Navy 1996, pp. 5– 2; Tierra Data Inc. 2005, p. 80; Vanderplank et al. 2019, p. 13).

San Clemente Island Lotus (Acmispon dendroideus var. traskiae)

A thorough review of the taxonomy, life history, and ecology of the San Clemente Island lotus is presented in the SSA report (USFWS 2020d).

San Clemente Island lotus (*Acmispon dendroideus* var. *traskiae*) is a semiwoody, flowering subshrub in the legume or pea family (Fabaceae). It is endemic to SCI (Isely 1993, p. 619) and is one of five taxa in the genus *Acmispon* found on the island (Tierra Data Inc. 2005, p. C–8; Brouillet 2008, pp. 388–392).

SCI lotus is typically less than 4 ft (1.2 m) tall with slender erect green branches (Munz 1974, pp. 449–450; USFWS 1984, p. 59; Allan 1999, p. 82). Each leaf has three to five leaflets, each approximately 0.2 to 0.3 in (5 to 9 millimeters (mm)) long (USFWS 1984, p. 59; Allan 1999, p. 82). SCI lotus has small yellow flowers that are bisexual and arranged in one to five flowered clusters on stalks that arise from axils between the stem and leaf of terminal shoots (Junak and Wilken 1998, p. 256). Pistils are initially yellow, turning

(USFWS 1984, p. 59). The 1977 listing rule mentioned that SCI lotus occurred at Wilson Cove on the north end of the island, but no other

orange then red as the fruit matures

details were available (42 FR 40682, August 11, 1977, p. 40683). In the 1984 recovery plan, SCI lotus was considered to be restricted to six "populations" associated with rocky areas, with the largest number of plants growing in the Wilson Cove area (USFWS 1984, p. 59). Only a few herbarium specimens of SCI lotus exist, making historical distribution and condition difficult to assess. Based on herbarium records, California Natural Diversity Database (CNDDB) records, and the recovery plan, the historical range includes occurrences in the northern part of the island (Wilson Cove) down to the southern point (Pyramid Head). Since the final removal of all feral herbivores by 1992, the distribution of this taxon has steadily increased (77 FR 29078, May 16, 2012, p. 29110). By 1997, roughly 50 percent of documented occurrences of these plants were found in the vicinity of Wilson Cove and by 2004, 75 percent of the distribution of this taxon was found beyond this area and extended to the southern-most part of the island (USFWS 2007, pp. 4-5).

The most recent survey data show the distribution of SCI lotus spans the entire length of the island from Wilson Cove to the southern tip east of Pyramid Cove, a distance of approximately 19 mi (31 km) (Junak and Wilken 1998, p. 261; Junak 2006, Map A-C; Vanderplank et al. 2019, p. 27). The majority of locations tend to be clustered on northfacing slopes on the eastern side of the island (Vanderplank et al. 2019, p. 7). SCI lotus tends to occur in small groups of 10 to 50 individuals (Allan 1999, p. 84). The status of a number of historical locations are unknown because they occur in areas with restricted access, such as due to unexploded ordnances. Without repeated survey data in some of those locations, it is unknown whether individuals observed 40 years ago still persist, so for purposes of estimating current distribution and abundance, 15 historically occupied watersheds are no longer considered occupied (USFWS 2020d, p. 26). However, despite inconsistencies in the survey data, the data indicate that the number of individuals and the range of SCI lotus have increased over time, and SCI lotus's current distribution is estimated to be 249 locations within 58 watersheds totaling 21,251 individuals (see Figure 4, below) (USFWS 2020d, pp. 24–27).

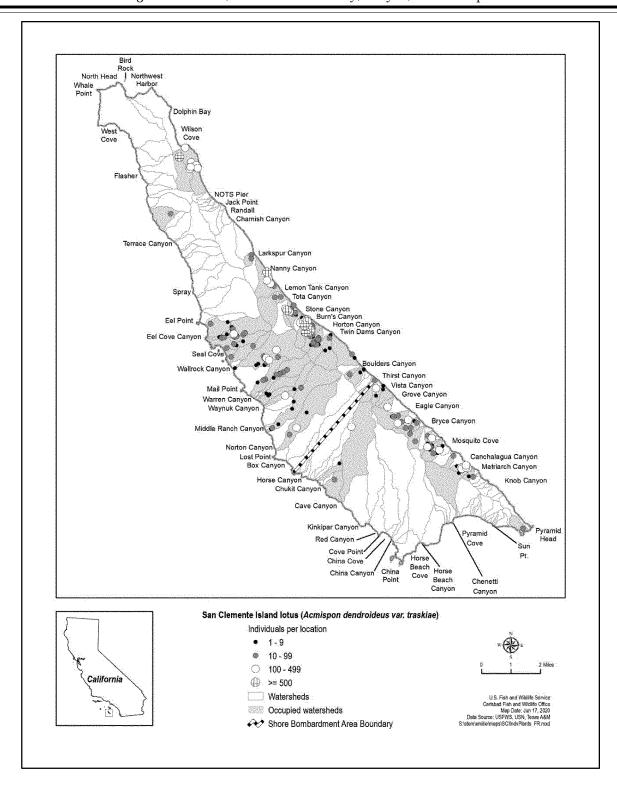


Figure 4. Map showing distribution of San Clemente Island lotus.

SCI lotus establishes on north- and east-facing slopes and ridges at elevations ranging from 25 to 1,400 ft (7.6 to 463 m) and is found in canyon bottoms or along ridgelines (Junak 2006, p. 125). It appears to preferentially establish and grow somewhat colonially

around rock outcrops and among large boulders situated in grassland areas and along the interface between grassland and maritime sage scrub (Allan 1999, p. 84; Navy 2002, p. D–9); SCI lotus also readily occupies disturbed sites and locations close to buildings, roads, and pipelines (Navy 2013b, p. 3–201). It occurs on well-drained soils where adequate soil moisture is available to the plant (Junak and Wilken 1998, p. 256; Navy 2002, p. D–9) and occurs mostly on clay to rocky soils (Vanderplank et al. 2019, p. 7). SCI lotus

is generally associated with two habitat types on the island: canyon woodland supported on approximately 696 ac (282 ha), and maritime desert scrub along the northeastern escarpment supported on approximately 6,228 ac (2,520 ha) (Navy

2002, pp. 3.57, 3.58).

SCI lotus is short-lived, with a reported lifespan of less than 5 years (USFWS 2008, p. 113); however, individuals near Wilson Cove have been observed to live longer than 6 years (Emily Howe 2017, pers. comm. in Vanderplank et al. 2019, p. 6). Like other legumes, the roots of plants in the genus *Acmispon* to which SCI lotus belongs are able to fix atmospheric nitrogen, making it available to plants in the form of ammonia, enriching the soil and making members of the genus Acmispon important post-fire colonizers (Sørensen and Sessitsch 2007 in Vanderplank *et al.* 2019, p. 4).

SCI lotus flowers between February and August, peaking from March to May (Junak and Wilken 1998, p. 256; USFWS 2008, p. 113), with halictid bees (a family of small solitary bees that typically nest in the ground), bumblebees, and small beetles observed foraging on the flowers (Junak and Wilken 1998, p. 257; Allan 1999, pp. 64, 85). A sister taxon (Acmispon glaber [syn. Lotus scoparius]) flowers in response to available moisture from fog and precipitation, primarily winter rainfall (Vanderplank and Ezcurra 2015, p. 16), which may also be true of SCI lotus. The taxon is self-compatible, meaning it is capable of selffertilization, and can self-pollinate (Allan 1999, pp. 85–86), but plants may also rely on insects for more effective pollination (Arroyo 1981, pp. 728-729).

On average, a single SCI lotus individual can produce approximately 36 to 64 flowering shoots, 118 to 144 flowers per shoot, and 4 to 6 seeds per fruit (Junak and Wilken 1998, p. 257). This information suggests that, under ideal conditions, an individual can produce a high volume of seeds (16,000 or more). Like most legumes, SCI lotus seeds require scarification (weakening or opening the seed coat to promote germination) or gradual seed coat degradation to germinate (Wall 2011, pers. comm. in 77 FR 29078, May 16, 2012, p. 29095). SCI lotus is thought to have high long-term survival in the seed bank. Germination rates for seed stored for 6 years only dropped from 80 percent to 76 percent; one seed lot displayed 65 percent germination after more than 30 years in storage (Cheryl Birker 2017, pers. comm. in Vanderplank et al. 2019, p. 6).

The majority (67 percent) of SCI lotus's genetic variability is found

among, rather than within, occurrences (Allan 1999, p. 61). However, more recent genetic work (McGlauglin et al. 2018, p. 754) has shown moderate levels of genetic diversity in the species, with gene flow between neighbor populations. The genetic diversity of SCI lotus is equal to or higher than that of the mainland variety of the same species, Acmispon dendroideus var. dendroideus, and SCI lotus also contains unique and highly divergent genotypes (Wallace et al. 2017, pp. 747-748). SCI lotus has hybridized with A. argophyllus var. argenteus in disturbed areas in Wilson Cove (Liston et al. 1990, pp. 239-240; Allan 1999, p. 86). Based on intermediate characteristics, the hybrid plants appear to be first generation (F1 generation) plants from a cross between the two varieties. It is not known whether these plants are capable of producing viable seeds by backcrossing between the hybrids or with the putative parent plants (Allan 1999, p. 86).

The fire tolerance of SCI lotus is not well understood. Based on SCI lotus's growth characteristics and occurrence increases in areas affected by fire, and the fire adaptations of related taxa, SCI lotus may be resilient to at least occasional fire. Because it is short-lived and likely relies on its seed bank for recruitment, fire may benefit this taxon by opening up areas of bare ground for seedling germination (USFWS 2007, p. 7). However, frequent fires could exceed its tolerance of fire severity and frequency and exhaust the seed bank in repeatedly burned areas (USFWS 2007, p. 11; USFWS 2020d, pp. 20–21).

San Clemente Island Larkspur

A thorough review of the taxonomy, life history, and ecology of the San Clemente Island larkspur is presented in the SSA report (USFWS 2020c). The San Clemente İsland larkspur (Delphiniumvariegatum ssp. kinkiense) is an herbaceous perennial in the buttercup family (Ranunculaceae). It grows 6 to 33 in (14 to 85 cm) in height but generally is less than 20 in (50 cm) tall (Koontz and Warnock 2012). The flowers are light blue to white in color and are bilaterally symmetrical with five petallike sepals and four smaller petals. The uppermost sepal is a straight or downcurved spur that is characteristic for the genus.

SCI larkspur is one of two subspecies of *Delphinium variegatum* that occur exclusively on SCI, the other being Thorne's larkspur (*Delphinium variegatum* spp. *thornei*). The island subspecies are currently distinguished primarily by flower color, with Thorne's larkspur generally having bright blue

(i.e., darker), slightly larger flowers than the SCI larkspur, which generally has white flowers, consistent with distinctions noted in earlier works (Dodd and Helenurm 2000, p. 125; Koontz and Warnock 2012). SCI larkspur occurs mostly in the northern portion of the island, and Thorne's larkspur occurs in the southern portion of the island. However, in the middle of the island (and on the far southern end), the two flower colors coexist in many locations, with varying proportions of each color, and flower colors ranging from pure white to dark purple. While ambiguity of the subspecies classifications, mostly within the central areas of the island, has caused some confusion regarding true range and distribution, the currently accepted taxonomic treatment recognizes the two subspecies and is followed in our assessment.

The historical range and distribution of SCI larkspur on SCI is unknown because botanical studies were not completed before the plant's decline. The final listing rule (42 FR 40682, August 11, 1977) did not provide specific information regarding the SCI larkspur's distribution and abundance. The 1984 recovery plan noted that the subspecies occurred in 6 or 7 locations (USFWS 1984, pp. 17, 35). The true range and distribution of SCI larkspur on SCI is somewhat unknown due to the ambiguity of the subspecies classifications, particularly in the central areas of the island where SCI larkspur and Thorne's larkspur cooccur, as do plants exhibiting characteristics intermediate between the two subspecies. While various delineations have been used to classify mixed occurrences (USFWS 2020c, p. 22), SCI larkspur is generally found mid-island on gentle slopes on the eastern side of the island, although the species has also been detected at higher elevations on the west side of the island (see Figure 5, below). Since grazing pressure was removed on SCI, both subspecies of Delphinium variegatum have been noted to have expanded dramatically (O'Brien 2019, pers. comm.). The species' ability to go dormant also contributes to difficulties in determining population counts. The current distribution and abundance estimate of SCI larkspur is 18,956 individuals within 22 watersheds (see Figure 5, below). Occupancy at two additional watersheds has been reported, but population counts are not available at these locations (USFWS 2020c, pp, v., 36).

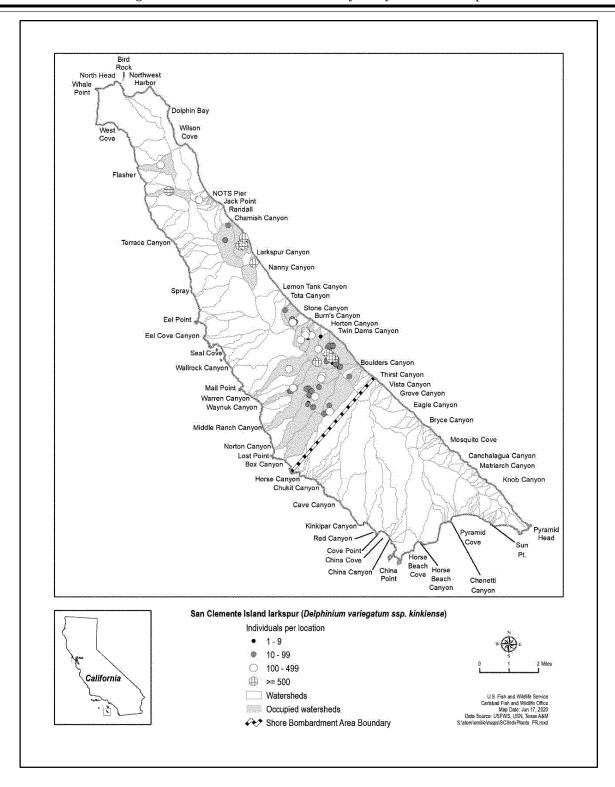


Figure 5. Map showing distribution of San Clemente Island larkspur.

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SCI larkspur was once associated with two main vegetation types: California Broadleaf woodlands and forests (which encompasses approximately 43.5 ac (17 ha), or 0.12 percent, of the island), and California perennial grassland (which encompasses approximately 2,213.5 ac (895 ha), or 6.3 percent, of the island) (Navy 2013). The species is now found in a broad range of habitats within the same general vegetation types and is widespread across the island. SCI larkspur is generally found within mid-

to high-elevation grasslands on the east side of the northern and central portions of the island where it occurs in clay, loam, and rocky soils with soil depths ranging from shallow to deep; however, it is more often associated with non-clay soils (Vanderplank *et al.*, in prep.).

Reported habitats have included coastal grasslands (Koontz and Warnock 2012), as well as grassy slopes and benches, open grassy terraces, and chaparral and oak woods (Warnock 1993 in USFWS 2008a). Currently, SCI larkspur occurs primarily on the east side of the island on gentle slopes with northern, northwestern, and eastern exposures. The higher-elevation plateau supports grasslands dominated by the native perennial bunch-grasses interspersed with annual forbs while the mid- and lower-elevation grasslands tend to be less floristically diverse and dominated by introduced annual grasses. They are primarily found within vegetation communities dominated by Artemisia californica, nonnative grasslands, and Baccharis pilularis (Vanderplank et al., in prep.).

Flower production in *Delphinium* can be highly variable and may be dependent upon quite localized weather conditions (Lewis and Epling 1959, p. 512) and soil moisture (Inouye *et al.* 2002, pp. 545, 549). Plants may not flower until reaching 2 to 3 years of age (*e.g.*, Waser and Price 1985, p. 1727 in

reference to *D. nelsonii*).

SCI larkspur generally flowers from March to April (California Native Plant Society 2001, in USFWS 2008a), but has been documented flowering from January to April (Koontz and Warnock 2012). Blue and white flowered Delphinium species are largely pollinated by bumblebees (Waser and Price 1983, p. 343; Waddington 1981, p. 154). Several different species of pollinators have been observed visiting SCI larkspur (USFWS 2020c, p. 28; Junak and Wilken 1998, p. 120; Munson 2019, pers. comm.; SERG 2015b, p. 13). Given the spur-length of San Clemente Island larkspur, bumblebees or hummingbirds may be the primary pollinators (Jabbour et al. 2009, p. 814). Successful outcrossing within island populations indicates that pollination is effective; therefore, populations of pollinators are likely to be ample.

Like most other California larkspurs, SCI larkspur can survive below ground when conditions are unfavorable and may remain dormant and not appear above-ground for one or more years. The species begins to go dormant shortly after flowering, remaining dormant until early in the rainy season. Although we have no information on the lifespan of SCI larkspur, based on information regarding other species of larkspurs, it is likely that the subspecies is relatively long-lived (USFWS 2020c, p. 28). Because of the species' ability to go dormant, and additionally because flower production in *Delphinium* can be highly variable and may be dependent

upon quite localized weather conditions, exact numbers of individuals are difficult to locate and count.

In comparison with other endemic plant species, Delphinium variegatum appears to be typical in its pattern of genetic diversity relative to its geographic range at both the population and taxon levels (Dodd and Helenurm 2002, p. 619). However, in comparison with other *Delphinium*, the genetic variation observed for the insular taxa of D. variegatum appears to be low. The data suggest that there is a higher level of gene flow among adjacent populations. If estimates of historical gene flow are indicative of current patterns, then gene flow among the 24 island populations studied appears to be high enough to prevent genetic differentiation among them. This is consistent with the general low level of genetic differentiation found among populations of other species in the genus *Delphinium* (Dodd and Helenurm 2002, pp. 619-620).

Little is known regarding the fire tolerance of SCI larkspur. However, its dormancy period (roughly May or June through November) and the fire season generally coincide (O'Connor 2019, pers. comm.; Navy 2009, p. 4.22). The possible benefits of fire to SCI larkspur include reduction in competitive shading and/or nutrient uptake, which would likely increase flowering and possibly visibility to pollinators.

Recovery Criteria

Section 4(f) of the Act directs us to develop and implement recovery plans for the conservation and survival of endangered and threatened species unless we determine that such a plan will not promote the conservation of the species. Recovery plans must, to the maximum extent practicable, include objective, measurable criteria which, when met, would result in a determination, in accordance with the provisions of section 4 of the Act, that the species be removed from the Lists.

Recovery plans provide a roadmap for us and our partners on methods of enhancing conservation and minimizing threats to listed species, as well as measurable criteria against which to evaluate progress towards recovery and assess the species' likely future condition. However, they are not regulatory documents and do not substitute for the determinations and promulgation of regulations required under section 4(a)(1) of the Act. A decision to revise the status of a species, or to delist a species, is ultimately based on an analysis of the best scientific and commercial data available to determine

whether a species is no longer an endangered species or a threatened species, regardless of whether that information differs from the recovery plan.

There are many paths to accomplishing recovery of a species, and recovery may be achieved without all of the criteria in a recovery plan being fully met. For example, one or more criteria may be exceeded while other criteria may not vet be accomplished. In that instance, we may determine that the threats are minimized sufficiently and that the species is robust enough that it no longer meets the definition of an endangered species or a threatened species under the Act. In other cases, we may discover new recovery opportunities after having finalized the recovery plan. Parties seeking to conserve the species may use these opportunities instead of methods identified in the recovery plan. Likewise, we may learn new information about the species after we finalize the recovery plan. The new information may change the extent to which existing criteria are appropriate for identifying recovery of the species. The recovery of a species is a dynamic process requiring adaptive management that may, or may not, follow all of the guidance provided in a recovery plan.

In 1984, we published the Recovery Plan for the Endangered and Threatened Species of the California Channel Islands (recovery plan) that addresses the five species addressed in this proposed rule, plus some additional species (USFWS 1984). The recovery plan preceded the 1988 amendments to the Act outlining required elements of recovery plans. As such, the recovery plan does not include recovery criteria, but followed guidance in effect at the time it was finalized. Rather than including specific criteria for determining when threats have been removed or sufficiently minimized, the recovery plan identifies six objectives to achieve recovery of the Channel Island species. Given the threats in common to the species addressed, the recovery plan is broad in scope and focuses on restoration of habitats and ecosystem function. The six objectives identified in the recovery plan are:

• *Objective 1:* Identify present adverse impacts to biological resources and strive to eliminate them.

• Objective 2: Protect known resources from further degradation by: (a) Removing feral herbivores, carnivores, and selected exotic plant species; (b) controlling erosion in sensitive locations; and (c) directing military operations and adverse

recreational uses away from biologically sensitive areas.

- Objective 3: Restore habitats by revegetation of disturbed areas using native species.
- Objective 4: Identify areas of San Clemente Island where habitat restoration and population increase of certain addressed taxa may be achieved through a careful survey of the island and research on habitat requirements of each taxon.
- Objective 5: Delist or downlist those taxa that achieve vigorous, self-sustaining population levels as the result of habitat stabilization, habitat restoration, and prevention or minimization of adverse human-related impacts.
- Objective 6: Monitor effectiveness of recovery effort by undertaking baseline quantitative studies and subsequent follow-up work (USFWS 1984, pp. 106–107).

The Navy has taken a variety of recovery actions to achieve the recovery plan's objectives. These include:

- Removal of all feral herbivores, which was achieved in 1992.
- Monitoring and control of the expansion of highly invasive, nonnative plant species on an ongoing basis since the 1990s (O'Connor 2019, pers. comm.).
- Implementing a nonnative wildlife program, which focuses on island-wide nonnative predator management, initiated by the Navy in 1992 (USFWS 2008, p. 172).
- Conducting and funding surveys, research, and monitoring to better understand the ecology and habitat requirements of sensitive species, and monitor their status and the effectiveness of recovery efforts.
- Conducting long-term vegetation monitoring studies.
- Conducting propagation and outplanting (transplant individuals from the greenhouse to vegetative communities) of native species through a contract with the San Diego State University Soil Ecology and Restoration Group (SERG) since 2001 (Howe 2009, pers. comm.; Munson 2013, pers. comm.). Although most of the restoration efforts were not specifically designed for the benefit of the species addressed in this proposed rule, restoration of the island's vegetation communities has helped to improve habitat suitability for the subject species by reducing the spread of invasive, nonnative plants and restoring ecological processes.
- Conducting annual reviews of fire management and fire occurrences, allowing for adaptive management to minimize the frequency and spread of

fires. For example, in 2017, after a large fire that burned part of the eastern escarpment had seemingly gone out, the fire restarted the next day and response was therefore delayed. This prompted a change in how the Navy monitors fires that are thought to be out (O'Connor 2019, pers. comm.).

• Addressing training-related erosion through development of an erosion control plan (Navy 2013b, entire). The Navy incorporates erosion control measures into all site feasibility studies to minimize impacts from erosion and avoid impacts to listed species.

Contributions to meeting the recovery objectives include adoption and implementation of the SCI Integrated Natural Resources Management Plan (INRMP). The Navy adopted the SCI INRMP in 2002 (Navy 2002, entire) and updated it again in 2013 (Navy 2013a, entire). An INRMP is intended to guide installation commanders in managing their natural resources in a manner that is consistent with the sustainability of those resources, while ensuring continued support of the military mission (Navy 2002, p. 1-1). The INRMP identifies goals and objectives for specified management units and their natural resources, including measures to protect, monitor, restore, and manage special status species and their habitats. The Navy identifies and addresses threats to special status species during the INRMP planning process. If possible, threats are ameliorated, eliminated, or mitigated through this procedure.

The SCI INRMP outlines management actions for invasive species control island-wide, including near listed species; biosecurity protocols; restoration of sites that support sensitive plants; habitat enhancement for sensitive and listed species; fuel break installation to minimize fire spread; and fire suppression to protect endangered, threatened, and other priority species. The Navy also developed and implements specific plans for some management issues, including: SCI Wildland Fire Management Plan; Erosion Control Plan; and the Naval Auxiliary Landing Field San Clemente Island Biosecurity Plan. For additional details on the Navy's implementation of recovery efforts, see "Conservation Actions and Regulatory Mechanisms,"

Interim progress on achieving the recovery objectives resulted in improvements in the status of SCI paintbrush and SCI lotus such that our 2007 5-year reviews recommended reclassification (USFWS 2007a, b), and both species were subsequently reclassified from endangered species to

threatened species (July 26, 2013; 78 FR 45406). We also recommended in our 2007 5-year review for SCI bush-mallow and 2008 5-year review for SCI larkspur that they be reclassified as threatened (USFWS 2007c; USFWS 2008).

While the recovery plan did not include specific metrics, the plan's objectives have largely been achieved for these five species through removal of nonnative herbivores and subsequent recovery of native plant communities, and through restoration and management actions implemented by the Navy to improve habitat and control threats related to erosion, invasive species, fire, and land use. As a result of these actions, habitat has been sufficiently restored and managed on the island and supports self-sustaining populations for each of these five taxa.

Regulatory and Analytical Framework

Regulatory Framework

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species is an "endangered species" or a "threatened species." The Act defines an endangered species as a species that is "in danger of extinction throughout all or a significant portion of its range," and a threatened species as a species that is "likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range." The Act requires that we determine whether any species is an "endangered species" or a "threatened species" because of any of the following

- (A) The present or threatened destruction, modification, or curtailment of its habitat or range;
- (B) Overutilization for commercial, recreational, scientific, or educational purposes;
 - (C) Disease or predation;
- (D) The inadequacy of existing regulatory mechanisms; or
- (E) Other natural or manmade factors affecting its continued existence.

These factors represent broad categories of natural or human-caused actions or conditions that could have an effect on a species' continued existence. In evaluating these actions and conditions, we look for those that may have a negative effect on individuals of the species, as well as other actions or conditions that may ameliorate any negative effects or may have positive effects. We consider these same five factors in reclassifying a species from an endangered species to a threatened species or removing a species from the Lists (50 CFR 424.11(c) through (e)).

We use the term "threat" to refer in general to actions or conditions that are known to or are reasonably likely to negatively affect individuals of a species. The term "threat" includes actions or conditions that have a direct impact on individuals (direct impacts), as well as those that affect individuals through alteration of their habitat or required resources (stressors). The term "threat" may encompass—either together or separately—the source of the action or condition itself.

However, the mere identification of any threat(s) does not necessarily mean that the species meets the statutory definition of an "endangered species" or a "threatened species." In determining whether a species meets either definition, we must evaluate all identified threats by considering the species' expected response and the effects of the threats—in light of those actions and conditions that will ameliorate the threats—on an individual, population, and species level. We evaluate each threat and its expected effects on the species, then analyze the cumulative effect of all of the threats on the species as a whole. We also consider the cumulative effect of the threats in light of those actions and conditions that will have positive effects on the species—such as any existing regulatory mechanisms or conservation efforts. The Secretary determines whether the species meets the definition of an "endangered species" or a "threatened species" only after conducting this cumulative analysis and describing the expected effect on the species now and in the foreseeable future.

The Act does not define the term "foreseeable future," which appears in the statutory definition of "threatened species." Our implementing regulations at 50 CFR 424.11(d) set forth a framework for evaluating the foreseeable future on a case-by-case basis. The term foreseeable future extends only so far into the future as we can reasonably determine that both the future threats and the species' responses to those threats are likely. In other words, the foreseeable future is the period of time in which we can make reliable predictions. "Reliable" does not mean "certain"; it means sufficient to provide a reasonable degree of confidence in the prediction. Thus, a prediction is reliable if it is reasonable to depend on it when making decisions.

It is not always possible or necessary to define foreseeable future as a particular number of years. Analysis of the foreseeable future uses the best scientific and commercial data available

and should consider the timeframes applicable to the relevant threats and to the species' likely responses to those threats in view of its life-history characteristics. Data that are typically relevant to assessing the species' biological response include speciesspecific factors such as lifespan, reproductive rates or productivity, certain behaviors, and other demographic factors. In our analyses presented below, we expect the Navy's current level of training as well as its management of natural resources on SCI to continue well into the future, including management of threats, such as minimizing impacts of training, and managing erosion, invasive species, and wildland fire. However, as described below (see Climate Change), uncertainty regarding effects of a changing climate increases after 20-30 years, making reliable predictions after this time period difficult. We used this 20-30 vear timeframe in developing our projections of future conditions in each of the species status assessments for the five species.

Analytical Framework

The SSA reports document the results of our comprehensive biological review of the best scientific and commercial data regarding the status of the species, including assessments of the potential threats to the species. The SSA reports do not represent our decisions on whether any of the species should be delisted or reclassified under the Act. They do, however, provide the scientific basis that informs our regulatory decisions, which involve the further application of standards within the Act and its implementing regulations and policies. The following is a summary of the key results and conclusions from the SSA reports; the full SSA reports can be found at Docket No. FWS-R8-ES-2020-0074 on http://www.regulations.gov.

To assess species viability, we used the three conservation biology principles of resiliency, redundancy, and representation (Shaffer and Stein 2000, pp. 306-310). Briefly, resiliency supports the ability of the species to withstand environmental and demographic stochasticity (for example, wet or dry, warm or cold years); redundancy supports the ability of the species to withstand catastrophic events (for example, droughts, large pollution events); and representation supports the ability of the species to adapt over time to long-term changes in the environment (for example, climate changes). In general, the more resilient and redundant a species is and the more representation it has, the more likely it is to sustain populations over time, even under changing environmental conditions. Using these principles, we identified the species' ecological requirements for survival and reproduction at the individual, population, and species levels, and described the beneficial and risk factors influencing the species' viability.

The SSA process can be categorized into three sequential stages. During the first stage, we evaluated individual species' life-history needs. The next stage involved an assessment of the historical and current condition of the species' demographics and habitat characteristics, including an explanation of how the species arrived at its current condition. The final stage of the SSA involved making predictions about the species' responses to positive and negative environmental and anthropogenic influences. Throughout all of these stages, we used the best available information to characterize viability as the ability of a species to sustain populations in the wild over time. We use this information to inform our regulatory decisions.

Summary of Biological Status and Threats

Below, we review the biological condition of the species and their resources, and the threats that influence the species' current and future condition, in order to assess the species' overall viability and the risks to that viability.

Each of the five SCI species occurs as a single population with no natural division in their ranges. However, for assessing species resilience and for monitoring and tracking the plant species in the future, we divided the species' ranges into watershed units to quantify threats across the range. Watersheds were suggested for use in delineation for monitoring purposes by the Navy (Vanderplank et al. 2019, pp. 6-7), as every point on the island can be easily assigned to a watershed, and watershed boundaries on SCI are not expected to change significantly during the 20- to 30-year time frame of this analysis. These units are not meant to represent "populations" in a biological sense; rather, these units were designed to subdivide the species' ranges in a way that facilitates assessing and reporting the variation in current and future resilience across the range. In the SSAs for the plant species, we assessed the species' ability to withstand stochastic events in each watershed, and how these occupied watersheds contribute to the viability of the entire island population (the species). Note that this way of delineating analysis units within which to measure

resiliency does not follow the methods used in the July 26, 2013, rule reclassifying SCI paintbrush and SCI lotus (78 FR 45406), and it is therefore not directly comparable. However, the watersheds that are represented correspond to the extant occurrences described in the July 26, 2013, reclassification rule (USFWS 2020d, pp. 82–85; USFWS 2020e, pp. 89–92).

In assessing species resilience for SC Bell's sparrow, we followed the approach for surveys of annual sparrow densities. Those annual surveys divide the island into eight vegetation strata. Because densities vary greatly among these strata each year, and because these strata are used for annual monitoring, we assess the resiliency of the subspecies within each of these strata in terms of the estimated population size, but then scale up from these strata to the resiliency of the subspecies. These vegetation strata are not meant to represent "populations" in a biological sense; as with the plant species, these units were designed to subdivide the species' range in a way that facilitates assessing and reporting the variation in current and future resilience across the range.

Species Needs

Our SSA framework generally includes identifying the species' ecological requirements for survival and reproduction at the individual, population, and species levels. However, population-level and specieslevel needs, such as number of individuals or reproductive success necessary to maintain an occurrence, level of gene flow or dispersal, etc., are not well understood for any of the five species. Where information is lacking or incomplete, we make certain scientific assumptions based on principles of conservation biology in order to conduct our analyses. In each of the plant SSAs, we make the assumption that, for the plant species, numbers of individuals within a watershed correlates with greater resilience and, conversely, watersheds with fewer individuals or with only one location within the watershed have lower resiliency. Similarly, for SC Bell's sparrow, our models in the SSA assume that density correlates with greater resilience, and that vegetative strata with greater densities have greater resilience.

Risk Factors for the San Clemente Island Species

We reviewed the potential risk factors (i.e., threats, stressors) that could be affecting the five SCI species now and in the foreseeable future. In this proposed rule, we will discuss only

those factors in detail that could meaningfully impact the status of the species. Those risks that are not known or unlikely to have effects on the status of the SCI species, such as disease or seed predation, are not discussed here, but are evaluated in the SSA reports. Many of the threats and risk factors are the same or similar for each of the species. Where the effects are expected to be similar, we present one discussion that applies to all species. Where the effects may be unique or different to one species, we address that species specifically. Many of the risk factors affect both habitat (quantity and quality) and individuals of the species (disturbance, injury, or mortality). The primary risk factors (i.e., threats) affecting all the SCI species are: (1) Past and current land use, including military training activities (Factors A and E from the Act); (2) erosion (Factor A); (3) invasive species (Factors A and E); (4) fire and fire management (Factors A and E); and (5) climate change (Factors A and E). Additional risk factors for some of the species include predation (Factor C), drought (Factors A and E), small population size (Factor E), and reduced genetic diversity (Factor E). Finally, we also reviewed the conservation efforts being undertaken for the species.

Past Land Use

The current habitat conditions for listed species on SCI are partly the result of historical land use practices. SCI was used legally and illegally for sheep ranching, cattle ranching, goat grazing, and pig farming (77 FR 29078, May 16, 2012, p. 29093; Navy 2013a, p. 2-3). Goats and sheep were introduced early by the Europeans, and cattle, pigs, and mule deer were introduced in the 1950s and 1960s (Navy 2013a, p. 3-185). These nonnative herbivores greatly changed the vegetation of SCI and were the main cause of the SCI species' decline (42 FR 40682, August 11, 1977, p. 40683). Persistent grazing and browsing defoliated large areas of the island, and the animals caused trampling and trail proliferation, which exacerbated erosion, altering plant communities on SCI and leading to severe habitat degradation and loss of suitable habitat that likely curtailed the range of endemic plants and animals on the island. Grazing and ranching on the island also facilitated the introduction and spread of nonnative plants (Navy 2002, p. 3-31).

All nonnative ungulates were removed by 1992 (Keegan *et al.* 1994, p. 58; 77 FR 29078, May 16, 2012, p. 29093). Since then, the vegetation on SCI has rebounded, and habitat conditions have improved, leading to

changes in the cover of native and nonnative plants on the island, further evidenced by the increases in endangered and threatened taxa since the feral animals were removed (Junak 2006a, pers. comm.; Uveda et al. 2019, pp. 6, 22, 30). While nonnative herbivores have been successfully removed and are no longer directly affecting native plant communities, continuing impacts include areas vulnerable to erosion that have not fully recovered, the presence of invasive species, and the interaction of nonnative grasses with fire. The past and continuing effects of erosion, invasive species, and fire are discussed further below.

Overview of Current Land Use

SCI is owned by the Navy, and is the primary maritime training area for the Pacific Fleet and Sea Air and Land Teams (77 FR 29078, May 16, 2012). The island also supports training by the Marine Corps, the Air Force, the Army, and other military organizations. As the westernmost training range in the eastern Pacific Basin, where training operations are performed prior to troop deployments, portions of the island receive intensive use by the military (Navy 2008a, p. 2.2).

Infrastructure, including runways, buildings, and associated development, is concentrated at the northern end of the island. The remainder of the island is largely devoid of infrastructure, except for the ridge road running along the spine of the island. In addition to existing infrastructure, various training activities occur within training areas on the island, and have the potential to affect the SCI species (see Table 3, below). Altogether, 34.8 percent of the island's area is located in one of these training areas, although training does not occur uniformly within each area. Military training activities within some of these training areas can involve the movement of vehicles and troops over the landscape and can include live munitions fire, incendiary devices, demolitions, and bombardment.

The Shore Bombardment Area (SHOBA) occupies roughly the southern third of the island and encompasses approximately 13,824 ac (5,594 ha) (Navy 2008a, p. 2–7, Navy 2009, p. 2–4). Areas of intensive use within SHOBA include two Impact Areas and three Training Areas and Ranges (TARs). Impact Areas support naval gun firing, artillery firing, and air-to-ground bombing (Navy 2008a, p. 2–7; Navy 2013a, p. 2–8). Much of the remainder of SHOBA serves as a buffer around Impact Areas; thus, 59 percent of SHOBA is not within intensive training

areas subject to direct training activities. Some areas, particularly the escarpment along the eastern coast, have limited training value because precipitous terrain hinders ground access.

Due to these various military training activities, land use has been considered a threat to listed species on SCI.

Training and other land use activities have multiple potential impacts, including trampling or crushing individuals or groups of plants; disturbance of nesting birds or injury or mortality of nestlings; and habitat impacts including disturbances to soil

and vegetation, spread of nonnative plant species, creation of road ruts and trails, compaction of soils, and fires (USFWS 2008b, pp. 96–99). Erosion, nonnative species, and fire are discussed separately from military training in this proposed rule.

TABLE 3—SUMMARY OF TRAINING AREAS, THEIR SIZE, USE, AND THE THREATS WITHIN EACH

Training area	Size (acres)	Percent of island *	Use	Threat/stressor
Assault Vehicle Maneuver Areas (AVMAs) (3).	1,060.5	2.9	Vehicular maneuvering	Soil erosion, trampling, devegetation (habitat removal); disturbance, injury, or mortality of individuals.
Infantry Operations Area	8,827.6	24.5	Dispersed foot traffic	Trampling, soil erosion; disturbance, injury, or mortality of individuals.
Training Areas and Ranges (TARs) (20).	1,968.2	5.5	Varies by TAR: demolition, small arms, combat, etc.	Varies by TAR, but limited to trampling, localized ground disturbance; disturbance, injury, or mortality of individuals.
Impact Areas (2)	3,399.7	9.4	Bombing, live fire	Devegetation (habitat removal), fires; disturbance, injury, or mortality of individuals.

^{*} Because several training areas overlap, percentages total more than the 34.8 percent of the island's area located in training areas.

Land Use for Military Training

Plants—Military training activities within training areas (primarily the Infantry Operations Area, TARs, and AVMAs) can entail the movement of vehicles and troops over the landscape and thus include the potential of trampling or crushing individuals or groups of plants, or removal of habitat. Naval gun firing, artillery firing, and airto-ground bombing occurs within the Impact Areas, and can result in the

destruction of habitat, injury or mortality of individual plants, and fires. Where the distributions of the plant taxa overlap with training areas, there is potential for impacts to individuals and to habitat. Table 4, below, details the number of locations, individuals, and percent of population of each of the plant taxa that occur within training areas. Percent of populations within training areas range from less than 1 percent to 13 percent. However, not all

of the land within each training area is used for training, and frequency and intensity of training vary among areas and uses, such that only a subset of individuals within any training area is likely to be affected. Additionally, some effects are minor, such as trampled leaves or broken branches (*i.e.*, injury but not mortality), and frequency of training impacts may allow sufficient time for individuals and habitats to recover.

TABLE 4—THE NUMBERS OF LOCATIONS AND TOTAL INDIVIDUALS OF PLANT TAXA THAT OCCUR WITHIN TRAINING AREAS [USFWS 2020b, p. 45; USFWS 2020c, p. 52; USFWS 2020d, p. 36; USFWS 2020e, p. 37]

Species	Locations	Watersheds	Individuals	Percent of population
SCI paintbrush SCI lotus	74 4	19	2,089 22	4.34 0.11
SCI larkspur	10 42	4	1,847 731	9.74 13

San Clemente Bell's sparrow—SC Bell's sparrows may be adversely affected in habitat within and surrounding training areas. Adverse effects include modification and degradation of habitat, as well as the disturbance, injury, or death of individual SC Bell's sparrows (more likely nestlings and fledglings), and loss of active SC Bell's sparrow nests, such as from trampling of nests or nestlings (USFWS 2008, p. 174). Currently, 4,788 ha (11,831 ac) of potential SC Bell's sparrow habitat falls within a training area. Based on the 2018 territory density estimates, this represents 25 percent of the total island population (USFWS 20202a, p. 49). Because training

activities in each area vary widely and SC Bell's sparrow density also varies, potential impacts vary by area. Because not all of the land within each training area is used for training, and frequency and intensity of training vary among areas and uses, only a subset of individuals within any training area is likely to be affected. Additionally, many effects are expected to be infrequent, temporary, or minor, such as flushing of birds. Monitoring from 2015 to 2018 of two TARs located within high-density SC Bell's sparrow habitat within boxthorn do not indicate major impacts to SC Bell's sparrow densities due to training in these TARs, and SC Bell's sparrows continue to inhabit these areas

(Meiman *et al.* 2019, pp. 9, 20–23, 38–39), indicating that impacts are limited or temporary.

Summary—While military training activities have the potential to impact all five SCI species, the majority of locations and habitats occur outside intensive training areas. Within training areas that overlap with the species' distributions, many effects are expected to be infrequent, minor, or temporary. Additionally, the Navy's INRMP (Navy 2013a) outlines measures for managing land and water resources on the island, including listed and sensitive species. The INRMP includes measures to avoid and minimize impacts, as well as to restore and manage habitat. Military

training activities are expected to continue into the future. Generally, training is expected to continue within the current footprint, but intensity of training could increase in the future. However, changes to training have and will be subject to environmental review under applicable laws and regulations, and impacts to federally listed and sensitive species will be evaluated (O'Connor 2019, pers. comm.). Projects and changes in training areas are subject to the Navy's Site Approval and Review Process, which includes identifying avoidance and minimization measures for plant communities and sensitive species, including measures that are recommended in the SCI INRMP (Navy 2013a, pp. 4-23, 4-28). Coupled with ongoing management of related threats (including wildland fire, soil erosion, invasive species) under the SCI INRMP, it is highly unlikely that future changes in military training on SCI will impede or reverse advances in the recovery of these five species (O'Conner 2019, pers. comm.).

Invasive and Nonnative Species

Along with the introduction of feral, nonnative herbivores, many other nonnative species have been introduced to the island. While nonnative, feral grazers have been completely removed from SCI, other nonnative species have become established and have the potential to negatively affect species and their habitats. These include feral cats (Felis catus), black rats (Rattus rattus), and many species of nonnative plants, especially nonnative annual grasses. Feral cats and black rats can prey on eggs, chicks, and adult SC Bell's sparrows. Nonnative plant species may alter ecological processes and habitats, while also directly competing with native plant species.

Predation by black rats and feral cats—Since listing, predation on SC Bell's sparrow by introduced black rats and feral cats, and by native predators, has been documented (USFWS 2020a, p. 57). While total population sizes of feral cats and black rats on the island are unknown and have not been estimated, the Navy conducts management activities for both on the island. Nonnative wildlife management implemented through the INRMP focuses on control of feral cats throughout the island and rodent control near San Clemente loggerhead shrike (Lanius ludovicianus mearnsi) nest sites (Meiman et al. 2013, p. 2). This program, while unlikely to completely eradicate feral cats and black rats, affords some protection to the SC Bell's sparrow, primarily through cat removal. Black rats remain commonly

recorded nest predators (Meiman et al. 2017, pp. 35–36; Meiman et al. 2018, p. 26). Despite the persistence of and current inability to eradicate black rats, the SC Bell's sparrow population expanded over the past two decades, increasing in abundance and distribution.

Nonnative plants—Contemporaneous with and likely aided by feral grazing animals, a large number of invasive, nonnative plant species have become naturalized on SCI and are now widespread (USFWS 2020b, pp. 47–49; USFWS 2020c, pp. 57-58; USFWS 2020d, pp. 40-41; USFWS 2020e, p. 43). Nonnative plants can alter habitat structure and ecological processes such as fire regimes, nutrient cycling, hydrology, and energy budgets, and they can directly compete with native plants for water, space, light, and nutrients (77 FR 29078, May 16, 2012, p. 29117). In addition to altering habitat, potential impacts of nonnative plants on the four SCI plant species include precluding germination (i.e., competitive exclusion) and reducing or preventing pollination (e.g., by growing densely around plants and thereby making them less obvious or less accessible to pollinators). The invasion of nonnative annual grasses on the island may have caused the greatest structural changes to habitat, especially on the coastal terraces and in swales (USFWS 2007, pp. 4-5). Annual grasses vary in abundance with rainfall, potentially changing the vegetation types from shrublands to grasslands and increasing the fuel load in wet years and interacting with fire (Battlori et al. 2013, p. 1119). The effects of fire are discussed separately below.

While nonnative plants, especially nonnative annual grasses, have the potential to adversely affect the listed plant species, nonnative grasses are present but not a dominant component of the plant communities at the majority of occurrences of the four SCI plant species. SCI paintbrush and SCI lotus are often associated with vegetation types where nonnative grasses are present but not a dominant component of the plant community (Tierra Data Inc. 2005, pp. 29-42; Junak and Wilken 1998, p. 261; USFWS 2007, pp. 6-7; Vanderplank et al. 2019, p. 12). Surveys conducted in 2011 and 2012 found just four occurrences (170 individuals) of SCI paintbrush in communities dominated by invasive grasses and no SCI lotus in communities dominated by nonnative grasses (Vanderplank et al. 2019, p. 12). Nonnative grasses do not occur densely within canyons, where SCI bush-mallow occurs, and it does not appear as if grasses are expanding,

although they have been present for many decades.

SČI larkspur occurs within grasslands that have experienced a proliferation of nonnative plant species, especially annual grasses. Surveys conducted between 2011 and 2017 found 13 of 74 locations of SCI larkspur in communities dominated by invasive grasses (Navy, unpublished data; Vanderplank et al., in prep).

While nonnative plant species, including nonnative annual grasses, are extensively distributed across SCI both as a result of post-grazing colonization of weedy species in highly disturbed habitat and accidental introduction of new weeds through human activities, they do not seem to be impeding recovery. Since the removal of feral grazers, all vegetation communities have been recovering, and naturalized grasslands (the most fire-prone of nonnative vegetation communities) constitute a small proportion of the island at this time, approximately 10.6 percent of the island area (US Navy 2013a, p. 3.59). In addition, the island now has more intact habitats, reduced erosion, and a stronger suite of native competitor species, making the conditions less favorable to invasion. The Navy makes significant efforts to control highly invasive, nonnative perennial grasses and nonnative forbs to preclude their expansion into habitat areas and areas in which weed control would be difficult due to terrain and access challenges, and the Navy has monitored and controlled the expansion of highly invasive, nonnative plant species on an ongoing basis since the 1990s (O'Connor 2019, pers. comm.). Many conservation measures to limit the introduction and spread of nonnative plants are included in the INRMP (Navy 2013a, pp. 3.289-3.290). The recently completed Biosecurity Plan (Navy 2016, entire) will also more effectively control the arrival of potentially invasive propagules. The plan contains actions recommended to avoid introduction of new invasive species and works to prevent and respond to new introductions of nonnative species and bio-invasion vectors. Despite the existence of nonnative plants on SCI, the four SCI plant species have expanded in distribution and abundance since listing (42 FR 40682; August 11, 1977).

Erosion

Degradation of the vegetation due to the browsing of feral goats and rooting of feral pigs modified the island's habitat significantly and resulted in increased erosion and soil loss over much of the island, especially on steep slopes where denuded soils could be quickly washed away during storm events (Johnson 1980, p. 107; Tierra Data Inc. 2007, pp. 6-7; Navy 2013a, pp. 3.32-3.33). Since the feral animals were removed, much of the vegetation has recovered, and natural erosion on the island has decreased significantly (Navy 2013a, p. 3-33, Vanderplank et al. 2019, p. 15). Erosion problems currently are limited to localized areas, and because of topography and soil characteristics, there always will be the potential for localized erosion to occur at sites across the island. Periods of heavy rainfall can cause localized erosion, but these areas are difficult to predict.

In addition to erosion caused by past land uses, military training activities and the existing road network could lead to erosion that could impact species and their habitats. Erosion is a primary concern associated with use of the Assault Vehicle Maneuver Corridor (AVMC). To address this concern, the Navy is implementing the San Clemente Island Erosion Control Plan (Navy 2013b, entire), which includes best management practices to prevent, minimize, and restore impacts to sensitive resources within the AVMC. Implementation of this plan has resulted in prioritization of low-erosion areas within the AVMAs for assault vehicle use, and establishment of routes within the AVMAs, to reduce loss of vegetation cover and allow for better control of erosion (Vanderplank et al. 2019, p. 16).

The existing road network on SCI includes Ridge Road and approximately 188 linear miles of dirt and paved roadways. These roads can concentrate water flow, causing incised channels and erosion of slopes (Forman and Alexander 1998, pp. 216-217). Increased erosion near roads could potentially degrade habitat, especially along the steep canyons and ridges. On occasion after particularly heavy rainfall events, localized areas of high erosion stemming from roadways have been noted; however, regular road maintenance and repair of associated damage minimizes the potential for such problems to spread. The SCI INRMP includes a management strategy that addresses island-wide erosion. Implementation of the SCI INRMP as well as the Erosion Control Plan (Navy 2013b, entire), which include best management practices to prevent, minimize, and restore impacts to sensitive resources, is expected to prevent erosion from adversely affecting the SCI species and their habitats.

Potential for erosion to affect species depends on whether the species and their habitats occur on soils or topography prone to erosion, and on

their proximity to activities that can cause or exacerbate erosion. The SSAs used a 30-m (100-ft) buffer around roads as an appropriate distance over which negative impacts to habitat could be perceptible and should be evaluated. Previously, we considered individuals that occur within 152 m (500 ft) of a paved or unpaved road vulnerable to habitat degradation (Forman and Alexander 1998, p. 217; 77 FR 29078, 29102, May 16, 2012). However, based on expert opinion and observations on SCI since 2012, increased erosion associated with roads does not extend as far from the road network as previously thought (O'Connor 2019, pers. comm.). Based on these observations, the buffer size was revised for our analysis.

SCI paintbrush—SCI paintbrush is found mostly on non-clay soils that are not prone to piping (formation of underground water channels), and no piping or soil erosion channels have been observed in SCI paintbrush locations (Vanderplank et al. 2019, p. 16). Only 2 percent of individuals detected in the 2011 and 2012 surveys were located in areas mapped as clay soils (Vanderplank et al. 2019, p. 16). Along the eastern escarpment, SCI paintbrush is found in steep canyons in proximity to Ridge Road, the primary road that traverses most of the island from northwest to southeast. Roadside occurrences of SCI paintbrush may experience runoff during storm events (Navy 2008a, pp. G.4, G.8). Of the SCI paintbrush current distribution, 144 individuals in 6 watersheds are located within 30 m (100 ft) of a road or the Artillery Vehicle Maneuver Road (AVMR) (USFWS 2020e, p. 41). Islandwide, this represents 7 percent of the total occupied watersheds and 0.2 percent of the total individuals.

SCI lotus-Less than 1 percent of the current population of SCI lotus occurs within training areas where there is an increased potential for erosion caused by military activities. The occurrence of SCI lotus in Wilson Cove is in proximity to Navy facilities where erosion is caused by construction of buildings and parking lots (USFWS 2008, p. 117). No individuals have been documented to be affected by erosion in this area (SERG 2015, p. 40). Within the current distribution, 434 individuals in 6 watersheds are located within 30 m (100 ft) of a road (USFWS 2020d, p. 39). Island-wide, this represents 2 percent of the total locations and 2 percent of the total individuals. Locations that could be affected by road impacts (including trampling, erosion, and increased invasive species) exist within 5 watersheds. Only one of these has 100 percent of their individuals located near

a road, and all of the rest have fewer than 20 percent of the individuals or locations in areas considered in this assessment to be at risk of road impacts (USFWS 2020d, p. 39).

SCI larkspur—Less than 10 percent of the current population of SCI larkspur lies within training areas, and none of these plants are located in AVMAs, which are the training areas where potential for erosion is of greatest concern. Of the distribution considered current, only 1 location comprising 70 individuals is located within 30 m (100 ft) of a road. Island-wide, this represents 1 percent of the total locations and 0.3 percent of the total individuals. This location that could see road impacts is just one of five in the watershed, comprising 11 percent of the total individuals in the watershed (USFWS 2020c, p. 56).

SCI bush-mallow—Approximately 13 percent of the current population of SCI bush-mallow lies within training areas, but none of these plants are located in AVMAs, which are the training areas with the greatest potential for erosion. No current locations of SCI bushmallow occur within 30 m (100 ft) of a road.

SC Bell's sparrow—While some habitat for SC Bell's sparrow may be affected by erosion, erosion is generally localized (i.e., not widespread and limited in size) and is unlikely to affect individuals of the sparrow.

The Navy monitors and evaluates soil erosion on SCI to assess priorities for remediation (SERG 2006, entire; SERG 2015, entire), and efforts are made through revegetation and outplanting to restore areas where erosion occurs (SERG 2016, p. 2). The INRMP requires that all projects with potential erosion impacts include soil conservation measures for best management practices, choosing sites that are capable of sustaining disturbance with minimum soil erosion, and stabilizing disturbed sites (Navy 2013a, pp. 3.33-3.37). In addition, the Erosion Control Plan includes specific guidelines for the development and application of best management practices to minimize soil erosion within these training areas, minimize offsite impacts, and prevent soil erosion from adversely affecting federally listed or proposed species or their habitats and other sensitive resources (Navy 2013b, entire).

Despite existing levels of soil erosion on the island, the distributions of all five species have increased since listing (42 FR 40682; August 11, 1977). Current erosion issues are localized, and erosion is generally decreasing on the island as the vegetation continues to recover. Only a small percentage of individuals

and localities of these species occur within training areas or within proximity to roads where activities can cause or exacerbate erosion. Although the erosional processes must be considered at an island-wide scale, impacts from erosion are not rangewide. Instead, impacts are localized (i.e., not widespread and limited in extent) and managed, so potential for loss of individuals due to erosion is limited or unlikely.

Fire and Fire Management

Fire is a natural component for regeneration and maintenance of many habitats; however, maritime desert scrub communities on SCI are not found to have been fire-dependent due to maritime-related humidity, limited natural ignition sources, and adaptations of specific indigenous plants. The history of fire on the island prior to 1979 is largely unknown, but fires were set intermittently during ranching to increase the cover of forbs and grasses (Navy 2009, p. 3-2; Navy 2013a, p. 3.47). After the island was purchased by the Navy in 1934, fire became a more common occurrence throughout much of the island. Since 1979, over 50 percent of the island has experienced at least one wildfire with smaller areas on the island having burned up to 10 times between 1979 and 2018 (Navy 2013a, p. 3-47; Navy, unpub. data).

The number and extent of fires (acres burned) varies annually, as does fire severity. Currently, most fires on the island are a result of military training and activities. Most large fires are ignited in the Impact Areas, with the majority of acreage burned concentrated in SHOBA (Navy 2013a, pp. 3-45). Fire severity data (2007 to present) indicate that most fires are classified as low severity, with vegetation considered lightly burned or scorched. However, 15.6 percent of the acreage burned has been of a severity class that has detrimental effects on shrubs, considered moderately severe to completely burned. At low severity

levels, fires have little effect on shrubs, which resprout and recover easily (Navy 2009, pp. 4–52). Typically, due to the patchy nature of fires, not all areas within a fire footprint are burned uniformly; that is, not all plants in a burn polygon are necessarily burned or burned at the same severity (SERG 2012, p. 39). Although fire ignition points are concentrated in the military training areas, fires that escape these areas could potentially spread to other areas of the island. However, due to vegetation and topography, fires have generally been confined to the same areas (Munson 2019, pers. comm.).

Future increased fire frequency from intensified military use could lead to localized changes in vegetation. The Navy significantly expanded the number of locations where live fire and demolition training can take place in 2008 (USFWS 2008, pp. 21-37). However, while the number of acres that burn annually varies greatly, the frequency and extent of fire has decreased since the Navy began actively managing fire and implementing the Wildland Fire Management Plan (Navy 2009, entire; USFWS 2020a, p. 56; USFWS 2020b, pp. 53-54; USFWS 2020c, pp. 64-65; USFWS 2020d, pp. 45-47; USFWS 2020e, p. 48). The biggest fire years between the time of listing and now, in 1985 and 1994, burned more than twice the acreage than the two biggest fire years in the last 15 years (2012 and 2017) and since implementation of the Wildland Fire Management Plan (Navy 2009, entire; USFWS 2020a, p. 56; USFWS 2020b, p. 53–54; USFWS 2020c, pp. 64–65; USFWS 2020d, pp. 45-46; USFWS 2020e, p. 48).

Severe fires can kill shrubs and woody vegetation and alter the vegetation community, while frequent fires may not allow individuals and habitat to recover between fire events and have the potential to exceed a plant's capacity to sustain populations by depleting seed banks and reducing reproductive output (Zedler *et al.* 1983, pp. 811–815). However, effects to

individual species depend on the species' fire tolerance and on the overlap of its distribution with areas where fires are likely to occur.

Fires can impact plants on San Clemente, but have been generally localized, infrequent, and of low severity, and have burned mostly in regions where these taxa are not documented (USFWS 2020b, pp. 52, 56; USFWS 2020c, pp. 61, 66; USFWS 2020d, pp. 44, 50; USFWS 2020e, pp. 46, 52). In addition, rhizomes and seed banks can help these plants survive and persist post-fire. Though severe fires may kill SCI lotus, some plants are likely to survive and resprout after low intensity fires (USFWS 2020d, pp. 20). Severe fires may also kill individual SCI paintbrush plants, but plants are likely to survive and may benefit from lowintensity fires (UWFSW 2020e, pp. 23-24). SCI larkspur does not appear to be significantly affected by fire, likely due to its dormant period coinciding with periods when fires are more likely (USFWS 2020c, pp. 30-31). SCI bushmallow may be tolerant of fire. Its continued presence in areas that have burned and documentation of resprouting and recovering after fires indicate it is at least somewhat tolerant of fires (USFWS 2020b, p. 25). All four plant species appear to have increased in distribution and population size under the current fire pattern and fire management.

While fires have the potential to burn most places on the island, land use, vegetation, and historical patterns indicate that fires are most likely to burn in the same areas they have historically. Table 5 indicates the number of locations of each of the plant species that have burned (USFWS 2020b, pp. 51-53; USFWS 2020c, pp. 61-65; USFWS 2020d, pp. 45-49; USFWS 2020e, pp. 47–51). The majority of habitat that support these four plant taxa has not burned and less than 10 percent of the occupied locations have burned more than once in the past 20 years (Table 5).

TABLE 5—NUMBER OF LOCATIONS AND INDIVIDUALS AFFECTED BY FIRE WITHIN THE LAST 20 YEARS

Species	Total number of locations	Number of locations burned	Number of locations burned two or more times in 20 years	Percent of locations burned two or more times in 20 years	Number of individuals	Watersheds
SCI lotus SCI paintbrush SCI larkspur SCI bush-mallow	249	26	12	4.8%	855	10
	601	133	47	7.8	8596	29
	74	5	0	0	458	2
	222	68	11	5.0	2076	4

Given the historical patterns, most fires have burned outside locations where the four SCI plants species occur. Where plant locations have burned, most of those locations have burned infrequently over the last 20 years, during which period the four SCI plant species have increased in distribution and abundance. If fires become more frequent outside of the current fire footprint or more severe in the future, the species could be adversely affected in areas that burn. However, the Navy is expected to continue implementing its SCI Wildland Fire Management Plan (Navy 2009), and we expect that fires will continue to occur in similar areas and affect a limited number of individuals and locations of the four SCI plant species. That said, we are not concerned that fire is a threat to the listed plants, since they have expanded their ranges significantly with the removal of nonnative herbivores.

SC Bell's sparrow—Fire can result in habitat loss and the direct mortality of adult SC Bell's sparrows and nestlings (Navy 2018, p. 20). While any fire severity can destroy nests and nestlings, low-severity fires are unlikely to eliminate habitat altogether, as shrubs used as nesting and foraging habitat are typically not impacted or are able to recover or resprout. Most fires on SCI have been classified as low severity, which may singe or stress shrubs but not kill or destroy them (USFWS 2020a, pp. 51-57). A burned area, unless experiencing a particularly severe fire, would still provide nesting substrate once the shrubs have recovered. Any fire can have a short-term negative impact on SC Bell's sparrows locally. Frequent, widespread, or high-severity fires could have a longer term negative impact depending on where and how they burn. A fire return-interval of 3 years or less has been shown to negatively impact woody shrubs on SCI (Keeley and Brennan 2015, p. 3). For instance, a fire that burns a substantial portion of the boxthorn habitat or sage brush habitat, areas with the highest densities of SC Bell's sparrow, could impact a substantial portion of the SC Bell's sparrow population. The northern boxthorn strata supports almost 35 percent of the population (USFWS 2020a, p. 38).

Based on current knowledge of habitat use, with the expansion of SC Bell's sparrows into a broader range of habitats, more of the subspecies' distribution is within areas we expect could be impacted by fire. However, the current fire patterns and severity indicate most fires typically start in the Impact Areas in SHOBA, away from the highest density areas for SC Bell's

sparrow. Fires are generally of low severity and burn limited areas due to the application of firebreaks and fire suppression. To date, no fires have broken out and burned the high-density boxthorn habitat (USFWS 2020a, p. 57). The Navy is expected to continue implementing its SCI Wildland Fire Management Plan (Navy 2009), and we expect that fires will continue to occur in similar areas and at similar frequency and intensity to that observed between 2010 and 2020, and affect a limited number of individuals and locations of SC Bell's sparrow.

Climate Change

Since listing (42 FR 40682; August 11, 1977), the potential impacts of ongoing, accelerated climate change have become a recognized threat to the flora and fauna of the United States (Intergovernmental Panel on Climate Change (IPCC) 2007, pp. 1-52; Point Reves Bird Observatory (PRBO) Conservation Science 2011, pp. 1–68). Climate change is likely to result in warmer and drier conditions with high overall declines in mean seasonal precipitation but with high variability from year to year (IPCC 2007, pp. 1–18; Cayan et al. 2012, p. ii; Kalansky et al. 2018, p. 10). SCI is located in a Mediterranean climatic regime with a significant maritime influence. Current models suggest that southern California will likely be adversely affected by global climate change through prolonged seasonal droughts and through rainfall coming at unusual periods and in different amounts (Pierce 2004, p. 1-33, Cayan et al. 2005, p. 3-7, Campo Environmental Protection Agency (CEPA) 2006, p. 33; Jennings et al. 2018, p. iii; Kalansky et al. 2018, p. 10); however, the Channel Islands are not well addressed in these models.

Climate change models indicate an increase in average temperature by 2 to 3 degrees Celsius (°C) (4 to 6 degrees Fahrenheit (°F)) (Representative Concentration Pathway (RCP) 4.5) to 4 to 5 °C (7 to 9 °F) (RCP 8.5) for the San Diego Area of southern California by the end of the century (Jennings et al. 2018, p. 9), with inland changes higher than the coast (Cayan et al. 2012, p. 7). By 2070, a 10 to 37 percent decrease in annual precipitation is predicted (PRBO 2011, p. 40; Jennings et al. 2018, p. iii), although other models predict little to no change in annual precipitation (Field et al. 1999, pp. 8-9; Cayan et al. 2008, p. S26). SCI typically receives less rainfall than neighboring mainland areas (Tierra Data Inc. 2005, p. 4). However, predictions of short-term and long-term climatic conditions for the Channel Islands remain uncertain, and

it is unknown at this time if the same climate predictions for coastal California (a warmer trend with localized drying, higher precipitation events, and/or more frequent El Niño or La Niña events) equally apply to the Channel Islands (Pierce 2004, p. 31).

Low-level temperature inversions are common along the California coast and Channel Islands, and these inversions form low cloud cover (fog), otherwise known as the marine layer, which has a strong influence on coastal ecosystems and SCI (Navy 2013a, pp. 3.13, 3.26). Although the island has a short rainy season, the presence of fog during the summer months helps to reduce drought stress for many plant species through shading and fog drip, and many species are restricted to this fog belt (Halvorson et al. 1988, p. 111; Fischer et al. 2009, p. 783). Thus, fog could help buffer species from effects of climatic change. However, coastal fog has been decreasing in southern California in recent decades, possibly due to urbanization (which would not affect SCI) or climate change (Williams et al. 2015, p. 1527; Johnstone and Dawson 2010, p. 4537; LaDochy and Witiw 2012, p. 1157). Coastal cloud cover and fog are poorly addressed in climate change models (Qu et al. 2014, pp. 2603–2605).

Warming projections in California, particularly the possibility that the interior will experience greater warming than the coast (Cayan et al. 2012, p. 7), suggest that the fate of coastal fog is uncertain (Field et al. 1999, pp. 21-22; Lebassi-Habtezion et al. 2011, pp. 8–11). One study found an increasing trend in the strength of low-level temperature inversions, which suggests that the marine layer is likely to persist and may even increase (Iacobellis *et al.* 2010, p. 129). Recent work examining projected changes in solar radiation and cloud albedo (portion of solar radiation reflected back to space by clouds) show projected increases in cloud albedo during the dry season (July–September) and decreases during the wet season (November and December, and March and April) (Clemesha 2020, entire). Such a scenario could moderate the effects of climate change on the Channel Islands and would be expected to reduce its potential threat to island plants, especially on the western shore's lower terraces, where the marine layer is common. Dry season low clouds and fog are particularly important to plant growth, survival, and population dynamics in arid systems through both a reduction in evapotranspiration demand and potentially water deposition (Corbin et al. 2005, p. 511; Johnstone and Dawson 2010, p. 4533; Oladi et al. 2017, p. 94).

Current trends based on meteorological information suggest climate change is already affecting southern California through sea level rise, warming, and extreme events like large storms associated with El Niño events (Sievanen *et al.* 2018, p. 7). Climate projections, suggest more severe droughts or extended dry periods on coastal California via lessened low stratus cloud regime and hydrologic effects of reduced fog delivery (Fischer et al. 2009, pp. 783–799; NOAA 2009; Sievanen et al. 2018, p. 7). While longterm effects of climate change are typically projected to have major effects in the latter half of this century (Cayan et al. 2012, p. 24; Clemesha 2020, entire; Kalansky *et al.* 2018, pp. 19–21), there is increasing uncertainty with longer timeframes. Although climate change is affecting coastal and inland habitat in the United States (Karl et al. 2009, pp. 13-152), the site-specific effects of climate change on SCI are uncertain. We, therefore, focused on a 20- to 30year window to evaluate changes in climate (precipitation and temperature) in the species status assessments for these four taxa. During this time period, we do not expect major effects of climate change. Models indicate an increase in average temperature by 1 to 2 degrees Celsius (°C) (2 to 3 degrees Fahrenheit (°F)) (RCP 4.5) to 2 to 3 °C (3 to 4 °F) (RCP 8.5) by 2040 for the San Diego Area of southern California (Jennings et al. 2018, p. 15), with inland changes higher than the coast (Cayan et al. 2012, p. 7). However, in the 20- to 30-year window, climate change may result in more frequent or severe fires, heavy periods of rainfall that could lead to major erosion events, or periods of drought (Kalansky et al. 2018, p. 10). As discussed in the species status assessments, predicting impacts due to climate change are further complicated by uncertainty regarding the timing of increased or decreased rainfall; wetter conditions in the winter and early spring can lead to more growth early in the season, which can provide more fuel for fire later. However, wetter summers and falls can prevent the fuel from drying out enough to burn (Lawson 2019, pers. comm.). Therefore, making predictions about future fire patterns as affected by climate change is difficult.

Less rainfall and warmer air temperatures could limit the range of plant species, and affect habitat and prey or forage for SC Bell's sparrow, although there is no direct research on the effects of climate change on any of the species. While SC Bell's sparrow's reproductive success is influenced by rainfall, and could be affected by longer

term changes in climate, the relationship between reproductive output and rainfall and the impacts of droughts of varying duration and severity on the population are unclear, and the mechanisms driving these relationships are unknown (USFWS 2020a, pp. 58-63). Changes in temperature or rainfall patterns have the potential to affect biotic interactions, such as decoupling the timing of plant phenology versus insect activity. The likely persistence of the marine layer would be expected to help moderate the effects of climate change on the Channel Islands and would be expected to reduce its potential effects to island plants, including nesting and cover substrates for SC Bell's sparrows.

While we recognize that climate change is an important issue with potential effects to listed species and their habitats, information is not available to make accurate predictions regarding its effects to the SCI species addressed in this proposed rule. However, given the timeframe presented in climate change studies, major impacts from climate change are unlikely to occur in the next 20 to 30 years, the period for which we are able to make reliable predictions based on the available climate change data.

Reduced Genetic Diversity

Genetic analysis suggests that SCI bush-mallow has very low genetic variation at both the species and population levels (Helenurm 1997, p. 50; Helenurm 1999, p. 39), and has been observed to have low seed production (Helenurm 1997, p. 50; Junak and Wilken 1998, p. 291; Helenurm 1999, p. 39). Low seed production, in combination with low genetic diversity, can contribute to observed low recruitment in populations (Huenneke 1991, pp. 37–40; Junak and Wilken 1998, p. 291; Helenurm 1999, pp. 39-40). A reduction in occurrence size through years of grazing may have substantially lowered genetic variation (Helenurm 2005, p. 1221), which could decrease genetic fitness and compromise the species' ability to adjust to novel or fluctuating environments, survive disease or other pathogens, survive stochastic events, or maintain high levels of reproductive performance (Huenneke 1991, p. 40). However, data on the genetic variation that existed historically are lacking.

In recent years, the detected numbers of SCI bush-mallow have increased in abundance, although it is unknown how much of this growth can be attributed to clonal growth versus sexual reproduction and new genets.

Successful seed collection in 2013

(SERG 2013, pp. 61–64) and the observation of cotyledons in the field provide anecdotal evidence that the species may be reproducing more often by sexual recombination. As the number of individuals (stems) increases, we would expect by probability alone more genetically distinct individuals over time because as the numbers of stems increase, the probability of crosspollination is increased (Rebman 2019, pers. comm.). However, we do not know whether and how often new genets are produced in the population.

Patches of SCI bush-mallow on SCI contain many clones of individuals but also contain distinct genetic individuals, and there is at least some increase in distribution through seedling recruitment (Munson 2019, pers. comm.). However, it is still likely that many patches, especially the small or more isolated ones, are comprised of only closely related individuals that share alleles, impeding the likelihood of successful sexual reproduction (Helenurm 1999, pp. 39-40). The apparent historical loss of genetic diversity resulting in current low genetic variation is a potential threat for which there is no immediate solution or amelioration. However, currently, low genetic diversity does not seem to preclude the ability of the species to sustain populations over time on the island; historical diversity is unknown, and it may have always been low for this species. This species has increased in numbers and distribution from that known at the time of listing (42 FR 40682; August 11, 1977) and has sustained populations through current levels of habitat disturbance, and we expect genetic variants within and among patches are increasing, however slowly.

Conservation Actions and Regulatory Mechanisms

Pursuant to the Sikes Act (16 U.S.C. 670 et seq.), as amended, the Navy manages land and water resources on the island under the San Clemente Island INRMP (Navy 2013a). The goal of the INRMP is to maintain long-term ecosystem health and minimize impacts to natural resources consistent with the operational requirements of the Navy's training and testing mission (Navy 2013a, p. 1–9). Specifically, the INRMP identifies key components that: (1) Facilitate sustainable military readiness and foreclose no options for future requirements of the Pacific Fleet; (2) Protect, maintain, and restore priority native species to reach self-sustaining levels through improved conditions of terrestrial, coastal, and nearshore ecosystems; (3) Promote ecosystem

sustainability against testing and training impacts; (4) Maintain the full suite of native species, emphasizing endemic species.

The SCI INRMP outlines appropriate management actions necessary to conserve and enhance land and water resources, including: Invasive species control island-wide including near listed and sensitive species; biosecurity protocols; public outreach to promote compliance; restoration of sites that support sensitive plants; habitat enhancement for sensitive and listed species. In addition, the Fire Management Plan (Navy 2009) outlines a strategy to reduce the impacts from fires, including fuel break installation to minimize fire spread; and fire suppression inside and outside of SHOBA to protect endangered, threatened, and other priority species (Navy 2013a, p. 3.45; Vanderplank et al. 2019, pp. 15, 18–19; Munson 2019, pers. comm.). The INRMP outlines management strategies for plant communities and sensitive species, including recommended avoidance and minimization measures that the Navy may consider during the Site Approval and Project Review Process (Navy 2013a, pp. 4-23, 4-28). The SCI INRMP also provides the mechanism for compliance with other federal laws and regulations such as the Federal Noxious Weed Act of Act of 1974 (7 U.S.C. 2801), the Comprehensive Environmental Response, Compensation, and Liability Act (42 U.S.C. 9601), the Resources Conservation and Recovery Act (42 U.S.C. 6901), and Soil Conservation Act (16 U.S.C. 3B). The INRMP and other conservation measures are expected to remain in effect and afford protection to these five species regardless of the listing status. Measures specific to species or threats that are the subject of this proposed rule are discussed below.

Migratory birds—The INRMP outlines steps to ensure compliance with Executive Order (E.O.) 13186 ("Responsibilities of Federal Agencies to Protect Migratory Birds"; see 66 FR 3853, January 17, 2001) and the 2014 memorandum of understanding (MOU) between the Department of Defense (DoD) and the Service to promote the conservation of migratory birds, which stipulates responsibilities for DoD. The MOU outlines a collaborative approach to promote the conservation of bird populations, and the INRMP is required to address migratory bird conservation regardless of status under the Act. As part of the program outlined under the INRMP, the Navy supports the SC Bell's sparrow population monitoring program. Population monitoring provides a robust population estimate

and facilitates planning to avoid and minimize impacts of Navy training and infrastructure projects.

Erosion—The Navy monitors and evaluates soil erosion on SCI and uses multi-year data to assess priorities for remediation (SERG 2006, entire; SERG 2015a, entire). The INRMP includes a management objective to "Conserve soil resources, especially erodible soils near the heads of canyons, knickpoints of gullies, and areas threatening the uninterrupted continuation of the military mission or special status species, to provide drainage stability, native vegetation cover, and soil water holding capacity and protect site productivity, native plant cover, receiving waters, and access for the military mission" (Navy 2013a, p. 3–35). Efforts are made to restore areas where erosion occurs, through revegetation efforts and the installation of erosion control materials (SERG 2016, p. 2). The Navy incorporates erosion control measures into all site feasibility studies and project design to minimize the potential to exacerbate existing erosion and avoid impacts to listed species. The INRMP requires that all projects include erosion control work (Navy 2013a, p. 3-33). These conservation actions include best management practices, choosing sites that are capable of sustaining disturbance with minimum soil erosion, and stabilizing disturbed sites (Navy 2013a, pp. 3.33-3.37).

Nonnative species—The Navy has monitored and controlled the expansion of highly invasive, nonnative plant species on an ongoing basis since the 1990s (O'Connor 2019, pers. comm.), and primary target species have included Brassica tournefortii (Saharan mustard), B. nigra (black mustard), Foeniculum vulgare (fennel), Asphodelus fistulosus (aspohodel), Stipa miliacea (smilo grass), Ehrharta calycina (African veldt grass), Plantago coronopus (buckhorn plantain), Tragopogon porrifolius (salsify), and Carpobrotus edulis (iceplant); additional priority species may also be controlled as they are located (e.g., SERG 2016, pp. 45-46). In general, the Navy treats over 100,000 individuals of these various species annually. Control of these invasive plants benefits the ecosystem on SCI by reducing their distribution and minimizing the potential that they will invade habitat occupied by listed and at-risk taxa. Because invasive species introductions are more likely to occur along roadsides and because roads function as corridors for the spread of invasive species propagules, much of the invasive species treatment on the island focuses on roadsides; however, other areas highly susceptible to

invasive species introductions (such as graded areas, soil stockpiles, and mowed areas) also are focal areas for control. High-priority invasive plants are treated at locations across the island. This control strategy has minimized the need to treat invasive plant species within areas occupied by federally listed plants.

While many conservation measures to limit the introduction and spread of nonnative plants are included in the INRMP (Navy 2013a, pp. 3.289-3.290), the recently completed Biosecurity Plan (Navy 2016, entire) will help more effectively control the arrival of potentially invasive propagules. The plan works to prevent and respond to new introductions of nonnative species and bio-invasion vectors. The Navy is currently working on an instruction that will contain feasible, enforceable measures from the plan. Through implementation of this plan and the ongoing island-wide nonnative plant control program, potential impacts from nonnative plants are expected to be minimized (O'Connor 2019, pers. comm.; Munson 2019, pers. comm.)

Nonnative predators—The current nonnative wildlife program focuses on island-wide nonnative predator management, which was initiated by the Navy in 1992 (USFWS 2008, p. 172). Complete eradication of feral cats, black rats, and house mice on SCI is currently infeasible. Nonnative wildlife management focuses on control of feral cats throughout the island and rodent control near San Clemente loggerhead shrike nest sites (Meiman *et al.* 2013, p. 2). This program affords some protection to the SC Bell's sparrow, primarily through cat removal. Rodent control is conducted using traps and bait stations around loggerhead shrike nest sites using Terad (active ingredient cholecalciferol). The Navy has removed numerous cats, on average 211 annually (2001–2016; Burlingame *et al.* 2018, p. 29), and rodenticide was calculated to have impacted 26,473 rodents in 2000 (Navy 2002, pp. 4-66). The results of cat and rat control efforts vary according to predator population cycles.

Fire—The Navy implements the SCI Wildland Fire Management Plan (Navy 2009, entire), which is focused on fire prevention, fuels management, and fire suppression. Implementation of the fire management plan provides planning guidelines to reduce the potential for ignitions during the drier times of the year, ensures that adequate fire suppression resources are present to protect resources, and provides flexibility for the timing of military training and to ensure that adequate fire suppression resources are present with

an increased level of training activities (Navy 2009, entire). These measures minimize the frequency and spread of fires that could result in impacts to habitat and to individuals of the five species.

SC Bell's sparrow—Current and ongoing conservation measures described above minimize impacts of threats to SC Bell's sparrow. Additionally, the SCI INRMP is currently being updated to include prioritization of conservation and management within four core SC Bell's sparrow habitat areas (approximately 2,604 ha; O'Connor 2019, pers. comm.). These areas were selected to assure representation (e.g., multiple plant communities) and redundancy (e.g., multiple areas). They include highdensity SC Bell's sparrow habitat, assumed source populations, refugia spread geographically, and areas of elevation and topographic importance to SC Bell's sparrow. The intent of priority conservation areas is to facilitate future planning in a manner that avoids impacts to important SC Bell's sparrow habitat, and to protect the population against stochastic catastrophic events (USFWS 2020a, p. 66).

Final delineation of areas and management strategies will be identified within an SC Bell's sparrow management plan, which is currently being prepared in coordination with the Service (USFWS 2020a, p. 66). Although the management plan is not finalized, we anticipate completion by fall/winter 2020/2021. With the identification of core habitat areas in the INRMP, and management of these areas consistent with the management plan, we anticipate that the Navy will: (1) Preclude significant development within these areas, to the extent feasible; (2) prioritize these four areas for protection under fire management plans; and (3) prioritize these four areas for invasive species control, as needed (USFWS 2020a, p. 66) to help manage for the SC Bell's sparrow. While we expect that incorporation of SC Bell's sparrow core habitat areas into the INRMP will improve coordination of conservation measures for the SC Bell's sparrow, the Navy's current and ongoing management described above minimizes the impacts of threats to SC Bell's

sparrow and its habitat under the existing training regime. Completion of a SC Bell's sparrow management plan will highlight important management areas to conserve and monitor to ensure the continued conservation of this taxon in the future.

Summary of conservation actions and regulatory mechanisms—The Sikes Act requires DoD installations to prepare and implement INRMPs that provide for the conservation and rehabilitation of natural resources, including non-listed species. Consequently, due to this requirement, the conservation actions outlined in the INRMP are expected to continue into the future, regardless of the listing status of the five species. While changes to military training are possible, it is expected that the training footprint would be similar to the baseline training footprint, and that conservation measures would continue to be implemented to meet the goals of the INRMP. Additionally, changes to training have and will be subject to environmental review under applicable laws and regulations, including the National Environmental Policy Act (NEPA) and the Navy's Site Approval and Review Process, which includes identifying avoidance and minimization measures for plant communities and sensitive species, including measures recommended in the SCI INRMP (Navy 2013a, pp. 4-23, 4-28). If these five species are delisted, they would continue to be considered sensitive species and any impacts would be evaluated through these processes (O'Connor 2019, pers. comm.).

Summary of Factors Influencing Viability

At the time of listing (42 FR 40682; August 11, 1977), the biggest threat to the SCI species was habitat destruction and modification due to feral grazers. Since the removal of the last feral herbivores, vegetation is recovering, and habitat conditions have improved substantially. Currently, all five species are now more widely distributed on the island with greater estimated numbers of individuals than were previously known.

Plants

For the plant species, we assessed threats to individuals and habitat

including land use, erosion, the spread of nonnatives, fire and fire management, and climate change. While full impacts of invasive species on the four plant species are unknown, the effects are likely minimal or localized, given the expansion of the species on the island despite the presence of invasive species. Climate change may influence the plant species by affecting germination or viability of adult plants if drought or increasing temperatures result in significant changes in vegetation communities on SCI. The magnitude of this rangewide threat and how it may affect the plant taxa is unknown at this time, but significant impacts from climate change are unlikely to occur in the next 20 to 30 years (USFWS 2020b, p. 57; USFWS 2020c, pp. 66-67; USFWS 2020d, p. 51; USFWS 2020e, p.

For all four plant species, we considered major threats to be impacts of military training and fire. For SCI paintbrush, SCI lotus, and SCI larkspur, we also considered erosion as a result of training or proximity to roads to be a major threat; SCI bush-mallow does not occur in areas near roads or in training areas where potential erosion is a concern. We ranked the levels of these threats in each watershed to evaluate the extent to which the species are exposed to and potentially affected by these threats (USFWS 2020b, pp. 59-60; USFWS 2020c, pp. 69-70; USFWS 2020d, pp. 54-55; USFWS 2020e, pp. 56-57). Level of threats were categorized as none, low, or moderate. A low level of threats is defined as threats that could potentially affect less than 50 percent of the locations, individuals, or area within the watershed. A moderate level of threat is defined as threats that could potentially affect 50 percent or more of the locations, individuals, or area within the watershed. Table 6, below, indicates the percentages and numbers of watersheds, and the estimated individuals in those watersheds that were categorized as having no identified or low threats, or moderate threats. The majority of watersheds where plant taxa occur are in areas with no or low exposure to threats affecting less than half of the locations, individuals, or area occupied.

TABLE 6—NUMBERS AND PERCENTAGES OF WATERSHEDS AND INDIVIDUALS ASSESSED TO HAVE VARYING LEVELS OF THREATS

[USFWS 2020b, pp. 59-60; USFWS 2020c, pp. 69-70; USFWS 2020d, pp. 54-55; USFWS 2020e, pp. 56-57]

Species	No or low threats % watersheds (n)	No or low threats % individuals (n)	Moderate threats % watersheds (n)	Moderate threats % individuals (n)
SCI lotus SCI paintbrush SCI larkspur SCI bush-mallow	78 (45)	90 (18,640)	22 (13)	10 (2,013)
	75 (65)	85 (35,702)	25 (22)	15 (6,402)
	100 (22)	100 (18,956)	0 (0)	0 (0)
	73 (11)	60 (3,345)	27 (4)	40 (2,266)

SC Bell's Sparrow

We assessed remaining threats to SC Bell's sparrow individuals and habitat, including predation, drought, climate change, military training, and fire. Ongoing predator control programs are implemented to control nonnative predator species on the island, and the population of SC Bell's sparrow has grown despite ongoing impacts. Drought could potentially affect SC Bell's sparrow, as reduced nesting success has been reported in drier years, especially if droughts become more frequent or severe. While the effects of drought on productivity of the island-wide population are not fully understood, and additional data are needed to clarify this relationship, the population has rebounded quickly from past droughts and is expected to retain its ability to do so in the future. Likewise, climate change may influence or affect vegetation and thus nesting and foraging habitat (USFWS 2020a, p. 63). The magnitude of this rangewide threat and how it may affect the SC Bell's sparrow is unknown at this time, but significant impacts from climate change are unlikely to occur in the next 20 to 30 years (USFWS 2020a, pp. 63-64).

Future military training impacts are expected to occur in the existing training footprint, and have the potential to impact a small percentage of the SC Bell's sparrow population, based on the estimated number of SC Bell's sparrows that inhabit the training footprint. Training within the current footprint that could have high-intensity impacts occurs on less than 20 percent

of the island, and those areas that are intensively used are currently either unoccupied or already support low densities of SC Bell's sparrows. The largest potential known threat to the SC Bell's sparrow is fire. The Navy actively implements fire prevention and containment measures as part of the fire management plan. Thus, although fire currently impacts SC Bell's sparrows and their habitat, current fire patterns do not appear to pose a threat to SC Bell's sparrow population viability.

Species Condition

Here, we discuss the current condition of each species, taking into account the risks to those populations that are currently occurring, as well as management actions that are currently occurring to address those risks.

Plants

In our evaluation of current conditions, for each plant species and watershed, we developed and assigned condition categories. To assess the resiliency of plant species, we assessed the overall condition of the population by evaluating occupancy, locations, and individuals within each watershed. We categorized our assessed resiliency scores by watershed based on number of individuals: "very high" means populations with 500 or more individuals; "high" means populations with 100-499 individuals; "moderate" means populations with 10-99 individuals; and "low" means populations with fewer than 10 individuals. We also examined

population trends, which indicate the ability of the species to withstand and recover from stochastic events.

Resiliency was considered higher within watersheds supporting a greater number of individuals over time; however, if all of the individuals within a watershed were in just one location, we assumed that they are less resilient than a watershed with the same number of individuals that are spread out across multiple locations, as plants will be more likely to sustain populations through stochastic events if one localized event is unable to affect all the plants in the entire watershed.

Because few comprehensive surveys have been conducted for plant species on SCI, data from 2011 and 2012, which represent the most recent comprehensive surveys, were supplemented with prior and subsequent data, following a rule set to exclude and buffer data that might result in double counting, and to exclude occurrence data more than 15 years old. Because of lack of pre- and post-fire surveys, numbers of individuals of SCI lotus and SCI paintbrush (the two species most likely to be negatively affected by severe fires) in watersheds that burned were adjusted to assume some mortality from two severe fires in the last 15 years (USFWS 2020d, pp. 56-57; USFWS 2020e, pp. 58-60). Adjusted numbers of locations and individuals were then used to categorize resiliency in each watershed as low, moderate, high, or very high (see Table 7, below).

TABLE 7—NUMBER OF WATERSHEDS WITH HIGH OR VERY HIGH RESILIENCE

Species	Number of watersheds with "very high" and "high" resilience (occupied watersheds)	Percent of individuals that occur in watersheds rated with "very high" and "high" resilience
SCI paintbrush SCI lotus SCI larkspur SCI bush-mallow	48 (87) 22 (58) 14 (22) 9 (15)	96 92 93 96

The majority of individuals of each of the plant species occur in watersheds with high or very high resilience, which suggests that the majority of watersheds are likely to be able to withstand stochastic events. While all four plant species are considered to consist of one population, their distributions across multiple watersheds with a variety of habitat types, elevations, and slopes also make it unlikely that the entire population of any of the species would be affected by a catastrophic event. Genetic variation in SCI bush-mallow is considered to be low for an island endemic, which, coupled with its clonal nature, could potentially make the species less able to adapt to changing environmental conditions. However, low genetic diversity does not seem to be precluding the species from sustaining itself on the island.

SC Bell's Sparrow

The current population (2018) is estimated at 2,676 territories (5,284 individuals) island-wide. Overall, the population of SC Bell's sparrows on SCI has increased since listing and, for at least the past 5 years, has withstood current stochastic effects. Given these trends and the relatively large population size, we consider this population to currently be highly resilient to stochastic factors. While we consider SC Bell's sparrow to consist of a single population, its distribution across the island and ability to use a range of elevations and habitats indicate the species' adaptability and that it is unlikely that the entire population of the species would be affected by a single catastrophic event.

Future Conditions

To assess current threats and future conditions, we evaluated the proportion of each population exposed to anthropogenic stressors under baseline

conditions, and considered different future scenarios for impacts of military training and fire: status quo (baseline impacts), and moderate or high increases in fire severity and training within the existing frequent fire and training footprint. We also considered these scenarios assuming moderate and low recruitment for the plant species, and high and low densities for SC Bell's sparrow. While specific effects of climate change are uncertain and were not modeled, increases in fire severity, which could result from either increased training or from effects of climate change, and low recruitment/ density serve as proxies for potential effects. We used a 20- to 30-year timeframe for modeling future conditions because beyond this timeframe, the impacts of climate change on SCI, specifically the persistence of the fog belt and the timing and patterns of fog and rainfall, are uncertain, making predictions unreliable.

Plants

As recovery of plant communities on SCI continues, the number of individuals within watersheds and number of occupied watersheds are expected to continue to increase. While existing data indicate that numbers and distribution of the plant species are greater than in the past, the rates at which groups of plants expand over time are unknown. Therefore, we modeled recruitment at moderate and low levels for SCI paintbrush and SCI lotus. Because SCI bush-mallow currently appears to be reproducing primarily clonally rather than through sexual reproduction and exhibits low seed production, we modeled low and no recruitment to account for this condition. Because of SCI larkspur's long dormancy periods, we do not know how many individuals are present at

any point in time and did not include recruitment in the modeling to avoid overestimating growth (i.e., apparent changes in abundance or distribution could be accounted for by individuals breaking dormancy rather than through recruitment of new individuals). As noted above under Species Condition, for purposes of modeling current and future conditions, the current baseline numbers of individuals of SCI lotus and SCI paintbrush (the two species most likely to be negatively affected by severe fires) were adjusted to assume some mortality from two severe fires in the last 15 years (USFWS 2020d, pp. 56-57; USFWS 2020e, pp. 58-60), so numbers presented here differ slightly from estimated current distribution and abundance.

To model fire severity, which could result from increased training or effects of climate change, we used the frequent fire footprint (burned 2 or more times) from the past 20 years to project where future fires are likely to occur. To model increases in fire severity, we assumed greater numbers of individuals would be affected by fire and removed from the population. Because SCI larkspur does not appear to be significantly affected by fire, likely due to its dormant period coinciding with periods when fires are more likely, we only included increased training in our modeling of future conditions for that plant.

To model effects of land use and training, we used the current footprint of training areas. Using the percent of individuals that occur either within a training area or near a road, we calculated the total number of individuals that could be affected by increased training in that watershed. We assumed an increasing number of locations and individuals would be affected by increased training intensity. The results are presented below in Table 8

Table 8—Number of Watersheds With High and Very High Resilience, Total Occupied Watersheds, and Number of Individuals Under Current and Future Scenarios

	Number of watersheds with high or very high resilience	Total number of occupied watersheds (with low and moderate recruitment)	Individuals (ranges represent low and moderate recruitment)
SCI paintbrush:			
Current	48	87	42,104
Status quo	48	87 (92–97)	43,489–51,773
Increased fire/training	42	84 (89–94)	40,435–48,137
Extreme fire/training	41	80 (85–90)	38,078-45,330
SCI lotus:			
Current	22	57	20,743
Status quo	23	57 (62–67)	21,595–25,708
Increased fire/training	21	57 (62–67)	20,627-24,556
Extreme fire/training	19	57 (62–67)	19,706–23,460

TABLE 8—NUMBER OF WATERSHEDS WITH HIGH AND VERY HIGH RESILIENCE, TOTAL OCCUPIED WATERSHEDS, AND NUMBER OF INDIVIDUALS UNDER CURRENT AND FUTURE SCENARIOS—Continued

	Number of watersheds with high or very high resilience	Total number of occupied watersheds (with low and moderate recruitment)	Individuals (ranges represent low and moderate recruitment)
SCI larkspur:			
Current	14	22	18,956
Status guo	14	22	18,956
Increased fire/training	13	22	18,749
Extreme fire/training	13	20	18,542
SCI bush-mallow:			
Current	9	15	5,611
Status quo	9	15	5,611-5,892
Increased fire/training	9	15	5,200-5,461
Extreme fire/training	9	15	4,131–4,337

SC Bell's Sparrow

We modeled the future condition of SC Bell's sparrow over a 20- to 30-year time frame given two different scenarios of future impacts from military training and fire, the two most significant current and future threats. Using both a low and high density estimate (calculated by manipulating the lowest and highest density estimates for each habitat stratum measured between 2013 and 2018 by one standard error), we

calculated the estimated number of territories for each stratum under two potential future scenarios: (1) A "status quo" scenario in which conditions remain similar to those observed between 2013 and 2018 (i.e., no changes in training intensity, or fire pattern or frequency), and (2) an "increased impacts" scenario in which increased impacts from training and fire reduce the suitability of habitat within existing training areas and frequent fire footprints to some extent. For the

second scenario, we report the number of SC Bell's sparrows that would be supported outside these areas where there may be increased impacts to the subspecies' habitat. This provided an estimate of the minimum number of territories that could be supported outside of projected fires and training area impacts within each stratum. We summed the territories in each stratum for an island-wide estimate, giving a range from low to high densities (see Table 9, below).

TABLE 9—NUMBER OF TERRITORIES AND NUMBER OF ADULTS OF SC BELL'S SPARROW UNDER CURRENT AND FUTURE SCENARIOS

SC Bell's sparrow	Current	"Status Quo": No further impacts (current habitat)	Increased impacts (minimum habitat)
Territories	1,494–3,859	1,449–4,650	1,113–3,413
	2,988–7,718	2,899–9,300	2,225–6,826

Limitations and Uncertainties

Our models project numbers of watersheds and individuals for plants and numbers of territories and adults for SC Bell's sparrow under a range of possible future conditions. However, there are several limitations and uncertainties associated with our projections (USFWS 2020a, pp. 77-78; USFWS 2020b, pp. 68–69; USFWS 2020c, pp. 77-78; USFWS 2020d, pp. 69-70; USFWS 2020e, pp. 72-73). These include differences in survey methodologies over time and lack of information regarding demographic and life-history characteristics of the species, which required us to make several assumptions in our estimates and projections. We presumed that where surveys were not conducted since 2004, individuals from the four plant

taxa continued to be present and that the four plant taxa are extant at those locations last reported in 2004. We also generally assumed that military training and fire would affect the same areas they have historically, and we made several assumptions about extent of future impacts within the same geographic footprint. We also concluded that the Navy will continue to manage and protect habitat where these five taxa occur on SCI. While there are a number of uncertainties and assumptions, our projections represent the best available scientific and commercial information and are useful predictions of the current and future viability of the species.

Summary of Future Conditions

While all five species might experience reductions in numbers of individuals or occupied watersheds or habitat within the existing fire and training footprint under the most extreme scenarios considered, all species are expected to remain resilient. Each species would continue to occupy a broad distribution on the island across a variety of habitats under status quo and increased threat scenarios, so representation and redundancy are not expected to decrease significantly.

We note that, by using the SSA framework to guide our analyses of the scientific information documented in the SSA reports, we have not only analyzed individual effects on the species, but we have also analyzed their potential cumulative effects. We incorporated the cumulative effects into our SSA analyses when we characterized the current and future condition of the species. To assess the current and future conditions of the

species, we undertook an iterative analysis that encompassed and incorporated the threats individually and then accumulated and evaluated the effects of all the factors that may be influencing the species, including threats and conservation efforts. Because the SSA framework considers not just the presence of the factors, but to what degree they collectively influence risk to the entire species, our SSA assessment integrated the cumulative effects of the factors and replaces a standalone cumulative effects analysis. We lack specific information on how various threats may interact, but potential cumulative effects include interactions of military training, fire, invasive species, and climate change. For example, effects of climate change could increase the frequency or severity of fire. Although we lack specific information on effects of climate change, we assumed in our modeling of future conditions that increased fire could result from either increased training or from climate change, or a combination. We also modeled a range of increased impacts of training and/or fire, as well as low and moderate recruitment or densities, and used conservative approaches to estimate resulting populations to account for the possibility of cumulative effects. We found in our evaluation of current and future conditions that all five species are likely to continue to maintain close to current levels of resiliency, redundancy, and representation, despite the potential for cumulative effects.

Determinations of Species Status

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species meets the definition of an "endangered species" or a "threatened species." The Act defines an endangered species as a species that is "in danger of extinction throughout all or a significant portion of its range," and a threatened species as a species that is "likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range." The Act requires that we determine whether a species meets the definition of an "endangered species" or a "threatened species" because of any of the following factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or

manmade factors affecting its continued existence.

Status Throughout All of Its Range

After evaluating threats to the species and assessing the cumulative effect of the threats under the section 4(a)(1) factors, we found that the primary threats to SC Bell's sparrow, SCI paintbrush, SCI lotus, SCI larkspur, and SCI bush-mallow identified at the time of and since listing have been eliminated or reduced. At the time of listing (42 FR 40682; August 11, 1977), habitat destruction and modification caused by nonnative herbivores (Factor A) was considered to be the primary cause of decline for all five species. Since removal of all nonnative herbivores was completed in 1992, plant communities on the island are recovering, and habitat conditions are improving for all species. The current sizes and distributions of each of the species are greater than were previously known. Currently and in the future, individuals and habitat of each of the five species may be affected by military training activities (Factors A and E), erosion (Factor A), invasive species (Factors A and E), and fire and fire management (Factors A and E). These remaining threats to the species, including fire, erosion, and invasive species, are managed by the Navy through implementation of the SCI INRMP, Fire Management Plan, Erosion Control Plan for SCI, and other associated management plans. Implementation of avoidance and minimization measures and programs outlined in these plans is expected to continue regardless of the listing status of the five species. In addition, the Navy will continue to consider these five species and incorporate avoidance and minimization measures for land use activities, including infrastructure projects and military training proposals as part of the Site Approval and Project Review process. Thus, existing conservation programs and regulatory mechanisms, such as the INRMP, are expected to continue to provide protections to these species, regardless of listing status. Because the Channel Islands are not well addressed in current climate models and there is uncertainty regarding how climate change may affect habitats and species on SCI, we were not able to assess its long-term effects, but because of moderating effects of maritime influence on SCI, we do not expect major impacts over the next 20 to 30 years. Our evaluation of current and future conditions indicates all five species are likely to continue to maintain close to

current levels of resiliency, redundancy, and representation.

In addition to threats in common to all five SCI species, small population size (Factor E) was formerly considered a threat to SC Bell's sparrow, with a low of 38 individuals reported in 1984. However, the species is now more widely distributed on the island, and population estimates have been consistently over 4,000 adults since 2013. Predation by black rats and feral cats (Factor C) was also considered a threat to SC Bell's sparrow at the time of listing. While predation on SC Bell's sparrow still occurs, the Navy implements predator control on SCI, and predation on SC Bell's sparrow does not appear to be limiting the population. The species is currently considered to be resilient and is expected to maintain close to current levels of resiliency, redundancy, and representation under a range of projected future conditions. Thus, after assessing the best available information, we determine that San Clemente Bell's sparrow is not in danger of extinction now or likely to become so in the foreseeable future throughout all of its range.

No additional threats beyond those common to all five SCI species have been identified for SCI paintbrush. With removal of nonnative herbivores, and conservation efforts implemented by the Navy, numbers and distribution of SCI paintbrush have increased. The SCI paintbrush population numbered approximately 1,000 individuals in 1984. The current island-wide population is estimated at 42,104 individuals across 87 watersheds. The majority of these individuals currently occur in watersheds with high or very high resiliency. Additionally, the species is expected to maintain close to current levels of resiliency, redundancy, and representation under a range of projected future conditions. Thus, after assessing the best available information, we determine that San Clemente Island paintbrush is not in danger of extinction now or likely to become so in the foreseeable future throughout all of its range.

No additional threats beyond those common to all five SCI species have been identified for SCI lotus. With removal of nonnative herbivores, and conservation efforts implemented by the Navy, numbers and distribution of SCI lotus have increased. While the historical range and distribution of SCI lotus is not known, its distribution has increased from the 6 locations noted in 1984 (USFWS 1984, pp. 17, 35). The current island-wide population is estimated at 21,251 individuals across 58 watersheds. The majority of these

individuals currently occur in watersheds with high or very high resiliency. Additionally, the species is expected to maintain close to current levels of resiliency, redundancy, and representation under a range of projected future conditions. Thus, after assessing the best available information, we determine that San Clemente Island lotus is not in danger of extinction now or likely to become so in the foreseeable future throughout all of its range.

No additional threats beyond those common to all five SCI species have been identified for SCI larkspur. While the historical range and distribution of SCI larkspur is not known, its distribution has increased from the 6 to 7 locations noted in 1984 (USFWS 1984, pp. 17, 35). The current island-wide population is estimated at 18,956 individuals within 22 watersheds. The majority of these individuals currently occur in watersheds with high or very high resiliency. Additionally, the species is expected to maintain close to current levels of resiliency, redundancy, and representation under a range of projected future conditions. Fire (Factors A and E) is thought to currently not significantly affect SCI larkspur, but changes in timing, frequency, or severity of fire could potentially negatively affect the species. However, the Navy's implementation of fire management is expected to continue to minimize the risk of fire to SCI larkspur. Thus, after assessing the best available information, we determine that San Clemente Island larkspur is not in danger of extinction now or likely to become so in the foreseeable future throughout all of its

In addition to threats common to all five SCI species, reduced genetic diversity (Factor E) has been identified as a potential threat for SCI bushmallow. However, currently, low genetic diversity does not seem to be precluding the species' ability to sustain itself on the island. With removal of nonnative herbivores, and conservation efforts implemented by the Navy, numbers and distribution of SCI bushmallow have increased. At the time of listing, SCI bush-mallow was only known from three locations (42 FR 40682; August 11, 1977). The current island-wide population is estimated at 5,611 individuals across 15 watersheds. The majority of these individuals currently occur in watersheds with high or very high resiliency. Additionally, the species is expected to maintain close to current levels of resiliency, redundancy, and representation under a range of projected future conditions. Thus, after assessing the best available information, we determine that San

Clemente Island bush-mallow is not in danger of extinction now or likely to become so in the foreseeable future throughout all of its range.

Status Throughout a Significant Portion of Its Range

Under the Act and our implementing regulations, a species may warrant listing if it is in danger of extinction or likely to become so in the foreseeable future throughout all or a significant portion of its range. Having determined that the SC Bell's sparrow, SCI paintbrush, SCI lotus, SCI larkspur, and SCI bush-mallow are not in danger of extinction or likely to become so in the foreseeable future throughout all of their ranges, we now consider whether any of these species may be in danger of extinction or likely to become so in the foreseeable future in a significant portion of its range—that is, whether there is any portion of the species' range for which it is true that both (1) the portion is significant, and (2) the species is in danger of extinction now or likely to become so in the foreseeable future in that portion. Depending on the case, it might be more efficient for us to address the "significance" question or the "status" question first. We can choose to address either question first. Regardless of which question we address first, if we reach a negative answer with respect to the first question that we address, we do not need to evaluate the other question for that portion of the species' range.

In undertaking this analysis for SC Bell's sparrow, SCI paintbrush, SCI lotus, SCI larkspur, and SCI bushmallow, we choose to address the status question first—we consider information pertaining to the geographic distribution of both the species and the threats that the species faces to identify any portions of the range where the species is endangered or threatened.

The SC Bell's sparrow, SCI paintbrush, SCI lotus, SCI larkspur, and SCI bush-mallow are found solely on San Clemente Island, an area of approximately 56 square mi (145 square km, 36,073 acres (ac), or 14,598 hectares (ha)). Each of these species is a narrow endemic that functions as a single, contiguous population. While we divided each of the species' ranges into analysis units in order to quantify threats and analyze resiliency, these units are not meant to represent "populations" in a biological sense; rather, these units were designed to facilitate assessing and reporting current and future resilience. Given the species' small ranges, and the Navy's management to eliminate or reduce threats through implementation of the SCI INRMP and other associated

management plans, there is no biologically meaningful way to break the limited ranges of these species into portions, and the threats that the species face affect the species throughout their entire ranges. This means that no portions of the species' ranges have a different status from their rangewide status. Therefore, no portion of the species' ranges can provide a basis for determining that the species are in danger of extinction now or likely to become so in the foreseeable future in a significant portion of their ranges, and we find that San Clemente Bell's sparrow, San Clemente Island paintbrush, San Clemente Island lotus, San Clemente Island larkspur, and San Clemente Island bush-mallow are not in danger of extinction now or likely to become so in the foreseeable future in any significant portion of their ranges. This is consistent with the courts' holdings in *Desert Survivors* v. Department of the Interior, No. 16-cv-01165-JCS, 2018 WL 4053447 (N.D. Cal. Aug. 24, 2018), and Center for Biological Diversity v. Jewell, 248 F. Supp. 3d, 946, 959 (D. Ariz. 2017).

Determination of Status

Our review of the best available scientific and commercial information indicates that the San Clemente Bell's sparrow, San Clemente Island paintbrush, San Clemente Island lotus, San Clemente Island larkspur, and San Clemente Island bush-mallow do not meet the definition of an endangered species or a threatened species in accordance with sections 3(6), 3(20), and 4(a)(1) of the Act. Therefore, we propose to delist (remove) the San Clemente Bell's sparrow, San Clemente Island paintbrush, San Clemente Island lotus, San Clemente Island larkspur, and San Clemente Island bush-mallow from the Lists of Endangered and Threatened Wildlife and Plants.

Effects of This Proposed Rule

This proposal, if made final, would revise 50 CFR 17.11(h) to remove San Clemente Bell's sparrow (Artemisiospiza belli clementeae), which is listed as San Clemente sage sparrow (Amphispiza belli clementeae), from the Federal List of Endangered and Threatened Wildlife, and would revise 50 CFR 17.12(h) to remove San Clemente Island bush-mallow (Malacothamnus clementinus), San Clemente Island paintbrush (Castilleja grisea), San Clemente Island lotus, (Acmispon dendroideus var. traskiae), and San Clemente Island larkspur (Delphinium variegatum ssp. kinkiense) from the Federal List of Endangered and Threatened Plants. The prohibitions and conservation measures provided by the Act, particularly through sections 7 and 9, would no longer apply to these species. Federal agencies would no longer be required to consult with the Service under section 7 of the Act in the event that activities they authorize, fund, or carry out may affect these species. There is no critical habitat designated for any of these species.

Post-Delisting Monitoring

Section 4(g)(1) of the Act requires us to monitor for not less than 5 years the status of all species that are delisted due to recovery. Post-delisting monitoring refers to activities undertaken to verify that a species delisted due to recovery remains secure from the risk of extinction after the protections of the Act no longer apply. The primary goal of post-delisting monitoring is to monitor the species to ensure that its status does not deteriorate, and if a decline is detected, to take measures to halt the decline so that proposing it as an endangered or threatened species is not again needed. If at any time during the monitoring period data indicate that protective status under the Act should be reinstated, we can initiate listing procedures, including, if appropriate, emergency listing. At the conclusion of the monitoring period, we will review all available information to determine if relisting, the continuation of monitoring, or the termination of monitoring is appropriate.

Section 4(g) of the Act explicitly requires that we cooperate with the States in development and implementation of post-delisting monitoring programs. However, we remain ultimately responsible for compliance with section 4(g) and, therefore, must remain actively engaged in all phases of monitoring. We also seek active participation of other entities that are expected to assume responsibilities for the species' conservation after delisting, in this case, the Navy, an integral partner and the sole owner and manager of San Clemente Island.

We are currently coordinating with the Navy to develop and implement effective post-delisting monitoring (PDM) for the SC Bell's sparrow, SCI lotus, SCI paintbrush, SCI larkspur, and SCI bush-mallow. The Draft Post-Delisting Monitoring Plan for Five San Clemente Island Species (USFWS 2020f, entire) is available at http://www.regulations.gov under Docket No. FWS-R8-ES-2020-0074. The PDM plan builds upon current monitoring techniques and research, as well as emerging technology and techniques. Monitoring will assess the species'

numbers, distribution, and threats status, as well as ongoing management and conservation efforts that have improved the status of the species since listing. The PDM plan identifies, to the extent practicable and in accordance with our current understanding of the species' life history, measurable thresholds and responses for detecting and reacting to significant changes in the species' populations, distribution, and viability. If declines are detected equaling or exceeding these thresholds, the Service, in combination with the Navy, will investigate causes of these declines, including considerations of habitat changes, anthropogenic impacts, stochastic events, or any other significant evidence. The result of the investigation will be to determine if any of the species warrant expanded monitoring, additional research, additional habitat protection, or resumption of Federal protection under the Act.

We currently appreciate any information on what should be included in post-delisting monitoring strategies for these species (see Information Requested, above). Given the Navy's past and current stewardship efforts, management for the species has been effective to date, and it is reasonable to expect that management will continue to be effective for the species and their habitats beyond a post-delisting monitoring period, and well into the future. In addition to post-delisting monitoring activities that would occur if this proposed rule becomes final, the Navy anticipates continued management of the species in accordance with the SCI INRMP and other management plans. Additional monitoring or research (beyond postdelisting monitoring requirements) may occur in the future for these and other rare endemics on SCI based on available resource levels. We will work closely with the Navy to ensure post-delisting monitoring is conducted if these species are delisted and to ensure future management strategies are implemented (as warranted) to benefit these species.

Required Determinations

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

- (1) Be logically organized;
- (2) Use the active voice to address readers directly;
- (3) Use clear language rather than jargon;

- (4) Be divided into short sections and sentences; and
- (5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in ADDRESSES. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

We have determined that we do not need to prepare an environmental assessment or environmental impact statement, as defined in the National Environmental Policy Act (42 U.S.C. 4321 et seq.), in connection with determining a species' listing status under the Endangered Species Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with Tribes in developing programs for healthy ecosystems, to acknowledge that Tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to Tribes. There are no Tribal lands associated with this proposed rule.

References Cited

A complete list of references cited in this rulemaking is available on the internet at http://www.regulations.gov and upon request from the Carlsbad Fish and Wildlife Office (see FOR FURTHER INFORMATION CONTACT).

Authors

The primary authors of this proposed rule are the staff members of the Fish and Wildlife Service's Species Assessment Team and the Carlsbad Fish and Wildlife Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title

50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

§17.11 [Amended]

■ 2. Amend § 17.11(h) by removing the entry for "Sparrow, San Clemente sage" under BIRDS from the List of Endangered and Threatened Wildlife.

§17.12 [Amended]

■ 3. Amend § 17.12(h) by removing the entries for "Acmispon dendroideus var. traskiae", "Castilleja grisea", "Delphinium variegatum ssp. kinkiense", and "Malacothamnus clementinus" under FLOWERING PLANTS from the List of Endangered and Threatened Plants.

Martha Williams,

Principal Deputy Director, Exercising the Delegated Authority of the Director, U.S. Fish and Wildlife Service.

[FR Doc. 2021-08581 Filed 5-4-21; 8:45 am]

BILLING CODE 4333-15-P

Notices

Federal Register

Vol. 86, No. 85

Wednesday, May 5, 2021

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection **Activities: Special Supplemental** Nutrition Program for Women, Infants, and Children (WIC) Infant and Toddler Feeding Practices Study-2 (WIC ITFPS-2) Year 9 Extension

AGENCY: Food and Nutrition Service

(FNS), USDA. **ACTION:** Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this proposed information collection. This collection is a revision of the currently approved collection for Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Infant and Toddler Feeding Practices 2 Study (ITFPS-2) [OMB Control Number 0584-0580]. The revision is to extend data collection on the original cohort of study participants by one more interview around their 9th birthday, which is four years after the end of their period of eligibility for WIC services. It also seeks to collect administrative data from WIC State agencies to examine the WIC participation patterns of participants who enrolled in the study but discontinued their participation during the first 5 years of the study (i.e., during the period of time when study children would be categorically eligible for WIC). DATES: Written comments must be

received on or before July 6, 2021.

ADDRESSES: Comments may be sent to: Amanda Reat, Office of Policy Support, Food and Nutrition Service, USDA, 1320 Braddock Place, Alexandria, VA 22314. Comments may also be submitted via fax to the attention of Amanda Reat at 703-305-2576 or via email to Amanda.Reat@usda.gov. Comments will also be accepted through

the Federal eRulemaking Portal. Go to http://www.regulations.gov and follow the online instructions for submitting comments electronically.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will be a matter of public record.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of this information collection should be directed to Amanda Reat at Amanda.Reat@usda.gov or Courtney Paolicelli at 571.302.6447.

SUPPLEMENTARY INFORMATION: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions that were used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Title: Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Infant and Toddler Feeding Practices Study-2 (ITFPS-2) Year 9 Extension.

Form Number: N/A. OMB Number: 0584-0580. Expiration Date: March 31, 2022. *Type of request:* Revision of a currently approved collection.

Abstract: The USDA Food and Nutrition Service's (FNS) WIC ITFPS-2 provides information on the feeding practices of children who received WIC benefits, from birth up to 6 years of age. The proposed data collection will extend the longitudinal data collection of the current cohort of study participants for one more interview at nine years of age, four years after the end of their eligibility for WIC services. This proposed extension is needed to understand the nutrition, health outcomes, and family feeding practices of school-aged children in the period after WIC program eligibility ends. The

results will assist in the development of appropriate and effective prevention strategies to improve the health of young children. With nearly 45 percent of US infants participating in WIC, it is hoped that prevention strategies implemented in WIC will have a substantial impact on the growth and health of U.S. infants and children.

The data will be used to estimate the type and prevalence of various feeding practices among children who received WIC program benefits, after their program eligibility ends. This study will also examine the circumstances and influences that shape caregivers' feeding decisions for their children, and will describe the impact of childhood WIC participation on subsequent dietary and health outcomes. In addition, the study will examine if those who left the longitudinal study are fundamentally different from those who remain in the

The study activities subject to this notice include: Inform 27 WIC State agencies and 80 local WIC sites of the data collection, and their role in the study; contact 27 WIC State agencies for administrative data on the participants who left the study before the child's fifth birthday; contact 3,020 caregivers before the 9-year interview to notify them of the study extension and for them to provide consent and contact information updates, and to send study reminders: administer an additional telephone interview to caregivers of children enrolled in the study when their child is 9 years old; administer a second dietary intake interview to a subsample of caregivers who complete the first interview; and obtain child's height and weight measurements around age nine, taken by their health care provider or at WIC sites, from caregivers.

The WIC State Agency and local WIC site staff will be invited to participate in a webinar that will highlight key study findings to date (from reports approved and published by FNS) and describe the data collection at age nine. The 27 State Agencies and 80 sites will participate in conference calls to discuss the followup activities. The 27 State Agencies will be asked to provide administrative data on the participants who left the study before the study child's fifth birthday.

Upon approval, the caregivers will be mailed a study announcement letter, consent form, and contact information

form. Periodically before the 9-year interview, caregivers will receive mailings, calls, emails, and text messages asking for their updated contact information. About a week prior to being contacted for the 9-year telephone interview, the caregiver for each child in the cohort will be mailed an advance letter that includes a tollfree number to call for questions or to complete the interview at any time during the six-week interview window. Children's H/W measures will come from provider records supplied by caregivers, or WIC site staff will weigh and measure study children around their ninth birthday. WIC site staff will also provide updated contact information on study participants who are still in contact with WIC, when requested. Healthcare providers will be contacted by the caregivers who do not wish to go to the WIC sites to measure the child.

From the last submission of the ICR to this revision, the number of the respondents to the telephone interview and height and weight measurement collection has decreased. The burden on the caregivers has increased slightly because of the increase in the interview length and the contacts to obtain updated contact information. The burden on the State agencies has increased substantially because of the request to provide administrative data on the participants who left the study before the study child's fifth birthday, which is new to this data collection.

Affected Public: (1) Individuals/ Households (2) State, Local, or Tribal government, and (3) Profit/Non-profit Business. Respondent groups identified include (1) caregivers of children formerly on WIC; (2) WIC State Agency staff from 27 states and territories and local site staff from 80 WIC sites (both government and business/non-profit), and (3) healthcare providers.

Estimated Number of Respondents: The total estimated number of respondents is 3,474. This includes 2,668 caregivers of children formerly receiving WIC who originally enrolled in the study; 27 WIC State Agency points-of-contact; 80 local WIC agencies (52 government and 28 business/non-profits) staff members; 347 healthcare providers; and 352 non-respondents.

Estimated Number of Responses per Respondent: The estimated number of responses per respondent across the entire collection is 10. Caregivers of former WIC children will be asked to respond to: 1 study letter; 1 informed consent; 1 contact information form; up to 3 reminders for the contact information form; 1 advance letter; 1 main telephone survey; 1 replicate dietary intake telephone survey; 1 child height/weight measurement; 3 interview reminders, on average; 3 height and weight measurement reminders on average; 1 thank-you message; 2 birthday messages/cards, for a total of 19 responses. WIC State Agency pointsof-contact will respond to 1 study extension announcement, 1 study webinar; 1 conference call; 1 written

summary of the study and agreed upon activities, and 1 administrative data request for a total of 5 responses. An estimated 14 out of the 27 State agencies will also respond to requests for contact information for an average of 9 responses. WIC local site points-ofcontact (both the state and local government and profit/non-profit businesses) will respond to 1 study announcement, 1 study webinar; 1 conference call; 1 written summary of the study and agreed upon activities; 15 requests (once monthly during the 15month data collection period) to WIC clinics requesting updates to contact information for hard to reach caregivers; and 4 child height/weight measurements, for a total of 23 responses. Healthcare providers will respond to one request from the caregiver to measure the child. We anticipate that there will be 352 nonrespondents and that these will all be caregivers of former WIC children.

Estimated Total Annual Responses: 34,759 total responses (total responses from respondents and non-respondents).

Estimated Time per Response: The estimated time per response varies from less than one minute to 54.65 hours, depending on the activity and respondent type. The average estimated time per response across the entire collection is 15.36 hours.

Estimated Total Annual Burden on Respondents: 5,340 hours. See Table 1 below for estimated total annual burden for each type of respondent.

Table 1: Estimated Burden by Respondent Type

				Buro	len Table									
Respondent Type	Respondent Description	Type of Study Activity	Sample size	Number of Respondents	Frequency of Response (annual)	Total Annual Responses	Average Hours per Response	Sub-Total Annual Burden	Number of non - respondents	Frequency of Response (annual)	Total Annual Responses	Average Hours per response	Sub-Total Annual Burden	Total Burden Hours
		Age 9 Study Consent Form (a)	3,020	2,668	1	2,668	0.08	222.78	352	1	352	0.08	29.39	252.1
		Study extension letter (a)	3,020	2,668	1	2,668	0.05	133.67	352	1	352	0.05	17.64	151.3
		Contact Information Form - Round 1 (b)	2,668	1,067	1	1,067	0.10	106.93	1,601	1	1,601	0.10	160.40	267.33
		Contact Information Form Reminder - Round 2 (b)	2,668	1,067	1	1,067	0.10	106.93	1,601	1	1,601	0.10	160.40	267.33
		Contact Information Form Reminder - Round 3 (b)	1,601	641	1	641	0.10	64.23	960	1	960	0.10	96.17	160.4
ş		Contact Information Form Reminder - Round 4 (b)	960	384	1	384	0.10	38.47	576	1	576	0.10	57.70	96.1
ndividuais and Households	Le .	9 Year Interview advance letter (c)	2,668	2,268	1	2,268	0.05	113.62	400	1	400	0.05	20.05	133.6
S.	egivers of WIC children	9 Year Interview telephone survey (d)	3,020	1,068	1	1,068	1.00	1,068.00	1,952	1	1,952	0.01	19.52	1,087.5
Ϊ	Caregivers of ner WIC child	9 Year 2nd AMPM telephone survey (e)	160	107	1	107	0.50	53.67	53	1	53	0.01	0.53	54.20
ĕ	, se .	9 Year H/W measurement card (f)	2,668	694	1	694	1.00	694.20	1,974	1	1,974	0.01	19.74	713.9
E a	Care former!	Reminders 9-Year interview (g)	1,068	427	1	427	0.07	28.54	641	1	641	0.07	44.86	73.39
-5	Ď	Reminders 9-Year interview (g)	641	256	1.	256	0.07	17.13	385	1.	385	0.07	26.92	44.0
2		Reminders 9-Year interview (g)	385	154	1	154	0.07	10.29	231	1	231	0.07	16.17	26.40
	1	Height and weight reminders (h)	694	278	1	278	0.01	2.30	415	1	416	0.01	4.16	6.47
		Height and weight reminders (h)	416	166	1	166	0.01	1.38	250	1	250	0.01	2.50	3.8
		Height and weight reminders (h)	250	100	1	100	0.01	0.83	150	1	150	0.01	1.50	2.33
		9-Year thank you (i)	1,068	1,068	1	1,068	0.01	10.68	0			0.00	0.00	10.58
		Birthday card respondent year 9 (j)	2,668	2,134	1	2,134	0.01	17.71	534		534	0.01	4.43	22.14
		Birthday card child age 9 (k)	2,668	2,134		2,134	0.01	17.71	534	1	534	0.01	4.43	22.14
ndividuals and Households Subtotal (a) (c) 3,020 2,668 7 19,350 0.14 2,709.06 352 37 12,961 0.05 686.51						3,395.58								

	L	Study extension announcement	27	27	1	27	0.08	2.25	0	0	0	0.00	0.00	2,25
	trac	Study extension webinar (I)	27	27	1	27	1.00	27,00	0			0.00	0.00	27.00
	100	Conference calls on extension (m)	27	27	1	27	1.00	27.00	0	0	0		0.00	27.00
	State WIC staff point of contact	Study extension summary and agreement (n)	27	27	i	27	0.27	7.21	0	o	0	0.00	0.00	7.21
ment	C staff ₁	Request for contact information (p)	14	14	9	126	0.08	10.52	0	D	0	0.00	0.00	10.52
State & Local Government	ate Wile	Administrative data on Lost to Followup Participants (o)	27	27	1	27	54.65	1,475.55	0	0	0	0.00	0.00	1,475.55
10	ಗ	Subtotal (r)	27	27	10	261	6	1,549.54	0	0	0	0	0.00	1,549.54
3		Study extension announcement	52	52	1	52	80.0		0	***************************************			0.00	4.34
l e		Study extension webinar	52	52	1	52	1.00	52.00	0			0.00	0.00	52.00
35	tac	Conference call on extension	52	52	1	52	1.00	52.00	0	0	0	0.00	0.00	52.00
	WIC site staff point of contact	Study extension summary and agreement	52	52	1	52	0.27	13.89	0	D	0	0.00		13.89
	Win	Request for contact information (p)	52	52	15	780	80.0	65.13	0				0.00	65.13
	a.	HT/WT measurement (q)	52	52	4	208	0.17	34.74	0	0	0	0.00	0.00	34.74
		Subtotal (r)	52	52	23	1,196	0.19	222.10	0	0	0	0.00	0.00	222.10
State/Local Go	overnment Su	btotal	79	79	18	1,457	1.22	1,771.64	0	0	0	0.00	0.00	1,771.64
State/Local Go	overnment Su	btotal	79	79	18	1,457	1.22	1,771.64	0	0	0	0.00	0.00	1,771.64
		Study extension announcement	28	28	1	28	0.08	2.34	0	0	0	0.00	0.00	2.34
		Study extension webinar	28	28	1	28	1.00	28.00	0	0	0	0.00	0.00	28.00
9	WIC site staff point of contact	Conference call on extension	28	28	1	28	1.00	28.00	0	0	0	0.00	0.00	28.00
Profit/Non-Profit Business	WIC site staff	Study extension summary and agreement	28	28	1	28	0.08	2.34	0	0	0	0.00	0.00	2.34
Ħ	ă	Request for contact information (p)	28	28	15	420	0.08	35.07	0	0	0	0.00	0.00	35.07
9		HT/WT measurement (q)	28	28	4	112	0.17	18.70	0	0	0	0.00	0.00	18.70
Non		Subtotal (r)	28	28	23	644	0.18	114.45	0	0	0	0.00	0.00	114.45
Profit	Health care provider	H/W measurement (s)	347	347	1	347	0.17	57.95	0	0	0	0.00	0.00	57.95
Profit/Non-Pr	ofit Business S	Subtotal	375	375	3	991	0.17	172.40	0	0	0	0.00	0.00	172,40
GRAND TOTAL	L		3,474	3,122	7	21,798	0.213	4,653	352	37	12,961	0.053	686,51	5,339.62

Cynthia Long,

Acting Administrator, Food and Nutrition Service.

[FR Doc. 2021-09488 Filed 5-4-21; 8:45 am] BILLING CODE 3410-30-P

DEPARTMENT OF AGRICULTURE

Forest Service

Wenatchee-Okanogan Resource Advisory Committee; Meetings

AGENCY: Forest Service, USDA. **ACTION:** Notice of meetings.

SUMMARY: The Wenatchee-Okanogan Resource Advisory Committee (RAC) will hold a series of virtual meetings by phone and/or video conference. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act as well as make recommendations on recreation fee proposals for sites on the Okanogan-Wenatchee National Forest within

Okanogan, Chelan, Kittitas, and Yakima Counties, consistent with the Federal Lands Recreation Enhancement Act. RAC information and virtual meeting information can be found at the following website: https:// www.fs.usda.gov/main/okawen/ workingtogether/advisorycommittees.

DATES: The meetings will be held on: • June 1, 2021, 9:00 a.m.-4:00 p.m.,

- Pacific Daylight Time; • June 4, 2021, 9:00 a.m.-4:00 p.m.,
- Pacific Daylight Time; and
- June 16, 2021, 9:00 a.m.-4:00 p.m., Pacific Daylight Time.

All RAC meetings are subject to cancellation. For status of meetings prior to attendance, please contact the person listed under FOR FURTHER INFORMATION CONTACT.

ADDRESSES: The meetings will be held virtually via telephone and/or video. Written comments may be submitted as described under SUPPLEMENTARY **INFORMATION**. 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.

FOR FURTHER INFORMATION CONTACT: RAC Coordinator Robin DeMario by phone at 509-664-9292 or via email at robin.demario@usda.gov.

Individuals who use telecommunication devices for the hearing-impaired (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 between 8:00 a.m. and 8:00 p.m., Eastern Daylight Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to:

- 1. Hear from Title II project proponents and discuss project proposals;
- 2. Make funding recommendations on Tittle II projects:
 - 3. Approve meeting minutes; and
 - Schedule the next meeting.

These meetings are open to the public. The agendas will include time for individuals to make oral statements of three minutes or less. Individuals wishing to make an oral statement at any of the meetings should request in writing by May 12, 2021, to be scheduled on the agenda for that particular meeting. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time for oral comments must be sent to RAC Coordinator Robin DeMario, 215 Melody Lane, Wenatchee, Washington,

98801; or by email to *robin.demario@* usda.gov.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices, or other reasonable accommodation. For access to the facility or proceedings, please contact the person listed in the section titled FOR FURTHER INFORMATION CONTACT. All reasonable accommodation requests are managed on a case-by-case basis.

Cikena Reid,

 $USDA\ Committee\ Management\ Officer.$ [FR Doc. 2021–09455 Filed 5–4–21; 8:45 am]

BILLING CODE 3411-15-P

DEPARTMENT OF AGRICULTURE

Forest Service

Lynn Canal Icy-Strait Resource Advisory Committee; Meeting

AGENCY: Forest Service, USDA. **ACTION:** Notice of meeting.

SUMMARY: The Lynn Canal-Icy Strait (LCIS) Resource Advisory Committee (RAC) will hold a virtual meeting by phone and/or video conference. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act. The committee also makes recommendations on recreation fee proposals for sites on the Tongass National Forest within boroughs associated with the LCIS RAC, consistent with the Federal Lands Recreation Enhancement Act. General RAC information can be found at the following website: http:// www.fs.usda.gov/main/pts/ specialprojects/racweb.

DATES: The meeting will be held on Wednesday, June 16, 2021 from 1:00 p.m.—4:00 p.m. Alaska Daylight Time. All RAC meetings are subject to cancellation. For status of the meeting prior to attendance, please contact Robin Hasselquist by phone at 907–789–6212 or email at robin.hasselquist@usda.gov.

ADDRESSES: The meeting will be held virtually via telephone and/or videoconference. The phone call-in number is 1–202–650–0123, Phone

Conference ID: 771 850 094#. To have the video conference link emailed to you, please contact Robin Hasselquist by phone at 907–789–6212 or email at *robin.hasselquist@usda.gov* by June 4, 2021.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION**. 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.

FOR FURTHER INFORMATION CONTACT: Robin Hasselquist, RAC Coordinator, by phone at 907–789–6212 or email at robin.hasselquist@usda.gov.

Individuals who use telecommunication devices for the hearing-impaired (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Daylight Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to:

- 1. Review/Approve meeting minutes;
- 2. Review current budget;
- 3. Hear from Title II project proponents and discuss project proposals;
- 4. Make funding reccomendations on Tittle II projects; and
 - 5. Schedule the next meeting.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing, by Friday, June 4, 2021, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time for oral comments must be sent to Robin Hasselquist, 8510 Mendenhall Loop Road, Juneau, Alaska 99801, or by email to robin.hasselquist@usda.gov.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices, or other reasonable accommodation. For access to the proceedings, please contact Robin Hasselquist. All reasonable accommodation requests are managed on a case-by-case basis.

Cikena Reid,

USDA Committee Management Officer. [FR Doc. 2021–09457 Filed 5–4–21; 8:45 am] BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Daniel Boone Resource Advisory Committee; Meeting

AGENCY: Forest Service, USDA. **ACTION:** Notice of meeting.

SUMMARY: The Daniel Boone Resource Advisory Committee (RAC) will hold a virtual meeting by phone and/or video conference. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act. RAC information and virtual meeting information can be found at the following website: https:// www.fs.usda.gov/main/dbnf/ workingtogether/advisorycommittees.

DATES: The meeting will be held on June 9, 2021 at 6:00 p.m., Eastern Daylight Time.

All RAC meetings are subject to cancellation. For status of the meeting prior to attendance, please contact the person listed under FOR FURTHER INFORMATION CONTACT.

ADDRESSES: The meeting will be held virtually via telephone and/or video conference.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION**. 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.

FOR FURTHER INFORMATION CONTACT: Tim Reed, Designated Federal Officer (DFO), by phone at 606–515–7942 or via email at *timothy.reed@usda.gov.*

Individuals who use telecommunication devices for the hearing-impaired (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Daylight Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to:

- 1. Elect a chairperson;
- 2. Approve operating guidelines;
- 3. Review new Title II project proposals;
 - 4. Receive public input; and
- 5. Recommend Title II projects for funding.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by May 28, 2021, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time for oral comments must be sent to Tim Reed, Designated Federal Officer, Stearns Ranger District, 3320 Highway 27 North, Whitley City, Kentucky, 42653; by email to timothy.reed@usda.gov.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices, or other reasonable accommodation. For access to the facility or proceedings, please contact the person listed in the section titled FOR FURTHER INFORMATION

CONTACT. All reasonable accommodation requests are managed on a case-by-case basis.

Dated: April 29, 2021.

Cikena Reid,

USDA Committee Management Officer. [FR Doc. 2021–09456 Filed 5–4–21; 8:45 am] BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Newspapers Used for Publication of Legal Notices by the Rocky Mountain Region: Colorado, Kansas, Nebraska, and Parts of South Dakota and Wyoming

AGENCY: Forest Service, USDA.

ACTION: Notice.

SUMMARY: This notice lists the newspapers that will be used by the ranger districts, districts, forests, and regional office of the Rocky Mountain Region to publish legal notices. The intended effect of this action is to inform interested members of the public which newspapers the Forest Service will use to publish notices of proposed actions and notices of decision. This will provide the public with constructive notice of Forest Service proposals and decisions, provide information on the procedures to comment, object or appeal, and establish the date that the Forest Service will use to determine if comments or appeals/objections were timely.

DATES: Publication of legal notices in the listed newspapers will begin on the

date of this publication and continue until further notice.

Addresses: Lucy Aragon, Regional Administrative Review Coordinator (Acting), Rocky Mountain Region, 1617 Cole Blvd., Bldg. 17, Lakewood, CO 80401.

FOR FURTHER INFORMATION CONTACT:

Lucy Aragon, Regional Administrative Review Coordinator (Acting), by telephone at (303) 275–5188 or by email at *lucy.aragon@usda.gov*.

SUPPLEMENTARY INFORMATION: The administrative procedures at 36 CFR parts 214, 218, and 219 require the Forest Service to publish notices in a newspaper of general circulation. The content of the notices is specified in 36 CFR parts 214, 218, and 219. In general, the notices will identify: The decision or project, by title or subject matter; the name and title of the official making the decision; how to obtain additional information; and where and how to file comments or appeals/objections. The date the notice is published will be used to establish the official date for the beginning of the comment or appeal/ objection period. The newspapers to be used are as follows:

Regional Forester, Rocky Mountain Region

Regional Forester decisions affecting National Forests in Colorado, Kansas, Nebraska and those portions of South Dakota and Wyoming within the Rocky Mountain Region: *The Denver* Post

Arapaho and Roosevelt National Forests and Pawnee National Grassland

Forest Supervisor decisions: *Coloradoan* Canyon Lakes District Ranger decisions: *Coloradoan*

Pawnee District Ranger decisions: Greeley Tribune

Boulder District Ranger decisions: Daily Camera

Clear Creek District Ranger decisions: Clear Creek Courant

Sulphur District Ranger decisions: Middle Park Times

Bighorn National Forest

Forest Supervisor and District Ranger decisions: Casper Star-Tribune

Black Hills National Forest

Forest Supervisor and District Ranger decisions: *The Rapid City Journal*

Grand Mesa, Uncompangre, and Gunnison National Forests

Forest Supervisor decisions: Grand Junction Daily Sentinel Grand Valley District Ranger decisions: Grand Junction Daily Sentinel Paonia District Ranger decisions: *Delta County Independent*

Gunnison District Ranger decisions: Gunnison Country Times

Norwood District Ranger decisions: Telluride Daily Planet

Ouray District Ranger decisions: Montrose Daily Press. A "courtesy" copy will also be published in the Ouray County Plaindealer

Medicine Bow-Routt National Forests and Thunder Basin National Grassland

Forest Supervisor decisions: *Laramie*Daily Boomerang

Laramie District Ranger decisions:

Laramie Daily Boomerang

Douglas District Ranger decisions: Casper Star-Tribune

Brush Creek-Hayden District Ranger decisions: *Rawlins Daily Times*

District Ranger decisions for Hahns Peak-Bears Ears and Yampa: Steamboat Pilot

Parks District Ranger decisions: *Jackson County Star*

Nebraska National Forest, Nebraska and South Dakota

Forest Supervisor decisions: *The Rapid City Journal*

Bessey District/Charles E. Bessey Tree Nursery District Ranger decisions: The North Platte Telegraph

Pine Ridge District Ranger decisions: The Rapid City Journal

District Ranger decisions for Samuel R. McKelvie National Forest: *The North Platte Telegraph*

District Ranger decisions for Fall River and Wall Districts, Buffalo Gap National Grassland: *The Rapid City Journal*

District Ranger decisions for Fort Pierre National Grassland: *The Capital Journal*

Pike and San Isabel National Forests and Cimarron and Comanche National Grasslands

Forest Supervisor decisions: *Pueblo Chieftain*

San Carlos District Ranger decisions: Pueblo Chieftain

Comanche District-Carrizo Unit District Ranger decisions: *Plainsman Herald*

Comanche District-Timpas Unit District Ranger decisions: *Tribune Democrat* Cimarron District Ranger decisions: *Tri-State News*

South Platte District Ranger decisions: Douglas County News Press

Leadville District Ranger decisions: Herald Democrat

Salida District Ranger decisions: *The Mountain Mail*

South Park District Ranger decisions: Fairplay Flume

Pikes Peak District Ranger decisions: The Gazette

Rio Grande National Forest

Forest Supervisor and District Ranger decisions: *Valley Courier*

San Juan National Forest

Forest Supervisor decisions: *Durango Herald*

Columbine District Ranger decisions: Durango Herald

Pagosa District Ranger decisions: *Pagosa Sun*

Dolores District Ranger decisions: Cortez Journal

Shoshone National Forest

Forest Supervisor decisions: *Cody Enterprise*

Clarks Fork District Ranger decisions: Powell Tribune

Wapiti and Greybull Districts Ranger decisions: *Cody Enterprise*

Wind River District Ranger decisions: *The Dubois Frontier*

Washakie District Ranger decisions: Lander Journal

White River National Forest

Forest Supervisor decisions: *The Glenwood Springs Post Independent*Aspen-Sopris District Ranger decisions: *Aspen Times*

Blanco District Ranger decisions: *Rio Blanco Herald Times*

Dillon District Ranger decisions: Summit Daily

Eagle-Holy Cross District Ranger decisions: *Vail Daily*

Rifle District Ranger decisions: *Citizen Telegram*

Dated: April 29, 2021.

Tina J. Terrell,

 $Acting \ Deputy \ Chief, \ National \ Forest \ System.$ [FR Doc. 2021–09453 Filed 5–4–21; 8:45 am]

BILLING CODE 3411-15-P

DEPARTMENT OF AGRICULTURE

Forest Service

Newspapers Used for Publication of Legal Notices by the Intermountain Region: Utah, Idaho, Nevada, and Wyoming

AGENCY: Forest Service, USDA.

ACTION: Notice.

SUMMARY: This notice lists the newspapers that will be used by the ranger districts, forests and regional office of the Intermountain Region to publish legal notices. The intended effect of this action is to inform interested members of the public which newspapers the Forest Service will use to publish notices of proposed actions and notices of decision. This will provide the public with constructive

notice of Forest Service proposals and decisions, provide information on the procedures to comment, object or appeal, and establish the date that the Forest Service will use to determine if comments or appeals/objection were timely.

DATES: Publication of legal notices in the listed newspapers will begin on or after October 2020. The list of newspapers will remain in effect until September 2021 when another notice will be published in the **Federal Register**.

Addresses: Pete Gomben, Regional Administrative Review and Litigation Coordinator, Intermountain Region, 324 25th Street, Ogden, UT 84401.

FOR FURTHER INFORMATION CONTACT: Pete Gomben, Regional Administrative Review and Litigation Coordinator, by telephone at (801) 625–5069 or by email at peter.gomben@usda.gov.

SUPPLEMENTARY INFORMATION: The administrative procedures at 36 CFR 214, 219, and 218 require the Forest Service to publish notices in a newspaper of general circulation. The content of the notices is specified in 36 CFR 214, 219 and 218.

In general, the notices will identify: The decision or project, by title or subject matter; the name and title of the official making the decision; how to obtain additional information; and where and how to file comments or appeals/objection. The date the notice is published will be used to establish the official date for the beginning of the comment or appeal/objection period. The newspapers to be used are as follows:

Regional Forester, Intermountain Region

Regional Forester decisions affecting National Forests in Idaho: *Idaho* Statesman

Regional Forester decisions affecting National Forests in Nevada: *Reno Gazette-Journal*

Regional Forester decisions affecting National Forests in Wyoming: Casper Star-Tribune

Regional Forester decisions affecting National Forests in Utah: Salt Lake Tribune

Regional Forester decisions that affect all National Forests in the Intermountain Region: Salt Lake Tribune

Ashley National Forest

Ashley Forest Supervisor decisions: Vernal Express

District Ranger decisions for Duchesne, Roosevelt: *Uintah Basin Standard* Flaming Gorge District Ranger for decisions affecting Wyoming: *Rocket Miner*

Flaming Gorge and Vernal District Ranger for decisions affecting Utah: Vernal Express

Boise National Forest

Boise Forest Supervisor decisions: *Idaho Statesman*

Cascade District Ranger decisions: *The Star-News*

Emmett District Ranger decisions: Messenger-Index

District Ranger decisions for Idaho City and Mountain Home: *Idaho* Statesman

Lowman District Ranger decisions: *Idaho World*

Bridger-Teton National Forest

Bridger-Teton Forest Supervisor and District Ranger decisions: *Casper Star-Tribune*

Caribou-Targhee National Forest

Caribou-Targhee Forest Supervisor decisions for the Caribou portion: *Idaho State Journal*

Caribou-Targhee Forest Supervisor decisions for the Targhee portion: Post Register

District Ranger decisions for Ashton, Dubois, Island Park, Palisades and Teton Basin: *Post Register*

District Ranger decisions for Montpelier, Soda Springs and Westside: *Idaho* State Journal

Dixie National Forest

Dixie Forest Supervisor decisions: *The Spectrum*

District Ranger decisions for Cedar City and Pine Valley: *The Spectrum* District Ranger decisions for Escalante

Fremont (formerly Teasdale) District Ranger decisions: *The Richfield Reaper*

Fishlake National Forest

and Powell: The Insider

Fishlake Forest Supervisor and District Ranger decisions: *The Richfield Reaper*

Humboldt-Toiyabe National Forest

Humboldt-Toiyabe Forest Supervisor decisions that encompass all or portions of both the Humboldt and Toiyabe National Forests: *Reno Gazette-Journal*

Humboldt-Toiyabe Forest Supervisor decisions for the Humboldt portion: *Elko Daily Free Press*

Humboldt-Toiyabe Forest Supervisor decisions for the Toiyabe portion: Reno Gazette-Journal

Austin-Tonopah District Ranger decisions: Reno Gazette-Journal

Bridgeport District Ranger decisions: Reno Gazette-Journal

Carson District Ranger decisions: *Reno Gazette-Journal*

Ely District Ranger decisions: *The Ely Times*

Mountain City, Ruby Mountains and Jarbidge District Ranger decisions: Elko Daily Free Press

Santa Rosa District Ranger decisions: Humboldt Sun

Spring Mountains National Recreation Area District Ranger decisions: *Las Vegas Review Journal*

Manti-La Sal National Forest

Manti-La Sal Forest Supervisor decisions: ETV News Sun Advocate (Emery Telcom)

Ferron District Ranger decisions: ETV News Progress (Emery Telcom) Moab District Ranger decisions: The Times-Independent

Monticello District Ranger decisions: San Juan Record

Price District Ranger decisions: ETV News Sun Advocate (Emery Telcom) Sanpete District Ranger decisions: Sanpete Messenger

Payette National Forest

Payette Forest Supervisor decisions: *Idaho Statesman*

Council District Ranger decisions: Adams County Record

District Ranger decisions for Krassel,
McCall and New Meadows: Star News
Weiser District Ranger decisions: Signal
American

Salmon-Challis National Forest

Salmon-Challis Forest Supervisor decisions for the Salmon portion: *The Recorder-Herald*

Salmon-Challis Forest Supervisor decisions for the Challis portion: *The* Challis Messenger

District Ranger decisions for Lost River, Middle Fork and Challis-Yankee Fork: The Challis Messenger

District Ranger decisions for Leadore, North Fork and Salmon-Cobalt: *The Recorder-Herald*

Sawtooth National Forest

Sawtooth Forest Supervisor decisions: The Times News

District Ranger decisions for Fairfield and Minidoka: *The Times News* Ketchum District Ranger decisions:

Idaho Mountain Express Sawtooth National Recreation Area: The Challis Messenger

Uinta-Wasatch-Cache National Forest

Forest Supervisor decisions for the Uinta portion, including the Vernon Unit: *Provo Daily Herald* Forest Supervisor decisions for the

Forest Supervisor decisions for the Wasatch-Cache portion: Salt Lake Tribune

Forest Supervisor decisions for the entire Uinta-Wasatch-Cache: Salt Lake Tribune

District Ranger decisions for the Heber-Kamas, Pleasant Grove and Spanish Fork Ranger Districts: *Provo Daily*

District Ranger decisions for Evanston and Mountain View: *Uinta County Herald*

District Ranger decisions for Salt Lake: Salt Lake Tribune

District Ranger decisions for Logan: Logan Herald Journal

District Ranger decisions for Ogden: Standard Examiner

Dated: April 29, 2021.

Tina J. Terrell,

 $Acting\ Deputy\ Chief,\ National\ Forest\ System.$ [FR Doc. 2021–09454 Filed 5–4–21; 8:45 am]

BILLING CODE 3411-15-P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the California Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the California Advisory Committee (Committee) will hold a meeting via web teleconference on Friday, May 21, 2021, from 1:00 p.m.–2:30 p.m. Pacific Time for the purpose of discussing potential civil rights focus to study.

DATES: The meeting will be held on:

Friday, May 21, 2021, from 1:00 p.m.–
 2:30 p.m. Pacific Time

Public WebEx Registration Link: https:// tinyurl.com/b8f84yjt

FOR FURTHER INFORMATION CONTACT:

Brooke Peery, Designated Federal Officer (DFO), at *bpeery@usccr.gov* or by phone at (202) 701–1376.

SUPPLEMENTARY INFORMATION: Members of the public may listen to the discussion. This meeting is available to the public through the public WebEx registration link listed above. An open comment period will be provided to allow members of the public to make a statement as time allows. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. 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 landline connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are also entitled to submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be emailed to Brooke Peery at bpeery@usccr.gov. Persons who desire additional information may contact the Regional Programs Unit Office/Advisory Committee
Management Unit at (202) 701–1376.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available at: https://www.facadatabase.gov/FACA/FACAPublicViewCommittee
Details?id=a10t0000001gzkUAAQ.

Please click on the "Meeting Details" and "Documents" links. Persons interested in the work of this Committee are also directed to the Commission's website, http://www.usccr.gov, or may contact the Regional Programs Unit office at the above email address.

Agenda

I. Welcome & Roll Call
II. Overview of Project Process
III. Committee Discussion
IV. Public Comment
V. Adjournment

Dated: April 29, 2021.

David Mussatt,

Supervisory Chief, Regional Programs Unit. [FR Doc. 2021–09392 Filed 5–4–21; 8:45 am] BILLING CODE P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

In the Matter of: Abel Hernandez, Jr., 120 Saint John Drive, Pharr, Texas 78577; Order Denying Export Privileges

On August 29, 2019, in the U.S. District Court for the Southern District of Texas, Abel Hernandez, Jr. ("Hernandez") was convicted of violating 18 U.S.C. 554(a). Specifically, Hernandez was convicted of fraudulently and knowingly exporting

and sending or attempting to export and send from the United States to Mexico, 2,080 rounds of 7.62X39mm caliber ammunition, in violation of 18 U.S.C. 554. Hernandez was sentenced to 27 months in prison, supervised release for three years, and a \$100 assessment.

Pursuant to Section 1760(e) of the Export Control Reform Act ("ECRA"),¹ the export privileges of any person who has been convicted of certain offenses, including, but not limited to, 18 U.S.C. 554(a), may be denied for a period of up to ten (10) years from the date of his/her conviction. 50 U.S.C. 4819(e) (Prior Convictions). In addition, any Bureau of Industry and Security (BIS) licenses or other authorizations issued under ECRA, in which the person had an interest at the time of the conviction, may be revoked. *Id.*

BIS received notice of Hernandez's conviction for violating 18 U.S.C. 554(a), and has provided notice and opportunity for Hernandez to make a written submission to BIS, as provided in Section 766.25 of the Export Administration Regulations ("EAR" or the "Regulations"). 15 CFR 766.25.2 BIS has not received a written submission from Hernandez.

Based upon my review of the record and consultations with BIS's Office of Exporter Services, including its Director, and the facts available to BIS, I have decided to deny Hernandez's export privileges under the Regulations for a period of 10 years from the date of Hernandez's conviction. The Office of Exporter Services has also decided to revoke any BIS-issued licenses in which Hernandez had an interest at the time of his conviction.³

Accordingly, it is hereby ordered: First, from the date of this Order until August 29, 2029, Abel Hernandez, Jr., with a last known address of 120 Saint John Drive, Pharr, Texas 78577, and when acting for or on his behalf, his successors, assigns, employees, agents or representatives ("the Denied Person"), may not directly or indirectly participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as "item") exported or to be exported from the United States that is subject to the

Regulations, including, but not limited to:

A. Applying for, obtaining, or using any license, license exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or engaging in any other activity subject to the Regulations; or

C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or from any other activity subject to the Regulations.

Second, no person may, directly or indirectly, do any of the following:

A. Export or reexport to or on behalf of the Denied Person any item subject to the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by the Denied Person of the ownership, possession, or control of any item subject to the Regulations that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby the Denied Person acquires or attempts to acquire such ownership, possession or control;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from the Denied Person of any item subject to the Regulations that has been exported from the United States;

D. Obtain from the Denied Person in the United States any item subject to the Regulations with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or

E. Engage in any transaction to service any item subject to the Regulations that has been or will be exported from the United States and which is owned, possessed or controlled by the Denied Person, or service any item, of whatever origin, that is owned, possessed or controlled by the Denied Person if such service involves the use of any item subject to the Regulations that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

Third, pursuant to Section 1760(e) of the Export Control Reform Act (50 U.S.C. 4819(e)) and Sections 766.23 and 766.25 of the Regulations, any other person, firm, corporation, or business organization related to Hernandez by ownership, control, position of responsibility, affiliation, or other connection in the conduct of trade or business may also be made subject to the provisions of this Order in order to prevent evasion of this Order.

Fourth, in accordance with Part 756 of the Regulations, Hernandez may file an appeal of this Order with the Under Secretary of Commerce for Industry and Security. The appeal must be filed within 45 days from the date of this Order and must comply with the provisions of Part 756 of the Regulations.

Fifth, a copy of this Order shall be delivered to Hernandez and shall be published in the **Federal Register**.

Sixth, this Order is effective immediately and shall remain in effect until August 29, 2029.

John Sonderman,

Director, Office of Export Enforcement. [FR Doc. 2021–09494 Filed 5–4–21; 8:45 am] BILLING CODE 3510–DT–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

In the Matter of: Sergio Daniel Serrano-Lopez; Inmate Number: 51056–479; Big Spring (Flightline), Correctional Institution, 2001 Rickabaugh Drive, Big Spring, TX 79720; Order Denying Export Privileges

On August 30, 2019, in the U.S. District Court for the Southern District of Texas, Sergio Daniel Serrano-Lopez ("Serrano-Lopez"), was convicted of violating 18 U.S.C. 554(a). Specifically, Serrano-Lopez was convicted of fraudulently and knowingly exporting and sending, or attempting to export and send from the United States to Mexico, 4.500 rounds of 7.62x39mm caliber ammunition; 500 rounds of .38 Super caliber ammunition; one Glock .40 caliber magazine; three .38 Super caliber magazines; three MGB .380 caliber magazines; three 9mm Luger caliber magazines; one Ruger .223 caliber magazine; and three Ruger 7.62x39mm caliber magazines, in violation of 18 U.S.C. 554. Serrano-Lopez was sentenced to 40 months in prison and a \$100 assessment.

Pursuant to Section 1760(e) of the Export Control Reform Act ("ECRA"),¹

¹ ECRA was enacted as part of the John S. McCain National Defense Authorization Act for Fiscal Year 2019, and as amended is codified at 50 U.S.C. 4801–4852. Hernandez's conviction post-dates ECRA's enactment on August 13, 2018.

² The Regulations are currently codified in the Code of Federal Regulations at 15 CFR Parts 730–774 (2020).

³ The Director, Office of Export Enforcement, is now the authorizing official for issuance of denial orders, pursuant to recent amendments to the Regulations (85 FR 73411, November 18, 2020).

¹ ECRA was enacted as part of the John S. McCain National Defense Authorization Act for Fiscal Year 2019, and as amended is codified at 50 U.S.C. 4801–4852. Serrano-Lopez's conviction post-dates ECRA's enactment on August 13, 2018.

the export privileges of any person who has been convicted of certain offenses, including, but not limited to, 18 U.S.C. 554(a), may be denied for a period of up to ten (10) years from the date of his/her conviction. 50 U.S.C. 4819(e) (Prior Convictions). In addition, any Bureau of Industry and Security (BIS) licenses or other authorizations issued under ECRA, in which the person had an interest at the time of the conviction, may be revoked. *Id.*

BIS received notice of Serrano-Lopez's conviction for violating 18 U.S.C. 554(a), and has provided notice and opportunity for Serrano-Lopez to make a written submission to BIS, as provided in Section 766.25 of the Export Administration Regulations ("EAR" or the "Regulations"). 15 CFR 766.25.2 BIS has not received a written submission from Serrano-Lopez.

Based upon my review of the record and consultations with BIS's Office of Exporter Services, including its Director, and the facts available to BIS, I have decided to deny Serrano-Lopez's export privileges under the Regulations for a period of 10 years from the date of Serrano-Lopez's conviction. The Office of Exporter Services has also decided to revoke any BIS-issued licenses in which Serrano-Lopez had an interest at the time of his conviction.³

Accordingly, it is hereby ordered: First, from the date of this Order until August 30, 2029, Sergio Daniel Serrano-Lopez, with a last known address of Inmate Number: 51056-479, Big Spring (Flightline), Correctional Institution, 2001 Rickabaugh Drive, Big Spring, TX 79720, and when acting for or on his behalf, his successors, assigns, employees, agents or representatives ("the Denied Person"), may not directly or indirectly participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as "item") exported or to be exported from the United States that is subject to the Regulations, including, but not limited

A. Applying for, obtaining, or using any license, license exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction

involving any item exported or to be exported from the United States that is subject to the Regulations, or engaging in any other activity subject to the Regulations; or

Č. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or from any other activity subject to the Regulations.

Second, no person may, directly or indirectly, do any of the following:

A. Export or reexport to or on behalf of the Denied Person any item subject to the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by the Denied Person of the ownership, possession, or control of any item subject to the Regulations that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby the Denied Person acquires or attempts to acquire such ownership, possession or control;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from the Denied Person of any item subject to the Regulations that has been exported from the United States:

D. Obtain from the Denied Person in the United States any item subject to the Regulations with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or

E. Engage in any transaction to service any item subject to the Regulations that has been or will be exported from the United States and which is owned, possessed or controlled by the Denied Person, or service any item, of whatever origin, that is owned, possessed or controlled by the Denied Person if such service involves the use of any item subject to the Regulations that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

Third, pursuant to Section 1760(e) of the Export Control Reform Act (50 U.S.C. 4819(e)) and Sections 766.23 and 766.25 of the Regulations, any other person, firm, corporation, or business organization related to Serrano-Lopez by ownership, control, position of responsibility, affiliation, or other connection in the conduct of trade or business may also be made subject to the provisions of this Order in order to prevent evasion of this Order.

Fourth, in accordance with Part 756 of the Regulations, Serrano-Lopez may file an appeal of this Order with the Under Secretary of Commerce for Industry and Security. The appeal must be filed within 45 days from the date of this Order and must comply with the provisions of Part 756 of the Regulations.

Fifth, a copy of this Order shall be delivered to Serrano-Lopez and shall be published in the Federal Register.

Sixth, this Order is effective immediately and shall remain in effect until August 30, 2029.

John Sonderman,

Director, Office of Export Enforcement. [FR Doc. 2021–09497 Filed 5–4–21; 8:45 am] BILLING CODE 3510–DT–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

In the Matter of: Mehmet Hakan Atilla, Millet Cad. No: 26 D:15, Fatih Istanbul, Turkey and Molla Seref Mah Hikayeci Sok AZ, Fatih Istanbul, Turkey

Order Denying Export Privileges

On May 16, 2018, in the U.S. District Court for the Southern District of New York, Mehmet Hakan Atilla ("Atilla") was convicted of violating the International Emergency Economic Powers Act ("IEEPA"), 50 U.S.C § 1701, et seq.,by knowingly and willfully conspiring with others known and unknown to provide financial services to Iran and to the Government of Iran, without obtaining the required approval from the Office of Foreign Assets Control. Atilla was sentenced to 32 months in prison and a special assessment of \$500.

The Export Administration Regulations ("EAR" or "Regulations") are administered and enforced by the U.S. Department of Commerce's Bureau of Industry and Security ("BIS").1

² The Regulations are currently codified in the Code of Federal Regulations at 15 CFR Parts 730–774 (2020).

³ The Director, Office of Export Enforcement, is now the authorizing official for issuance of denial orders, pursuant to recent amendments to the Regulations (85 FR 73411, November 18, 2020).

¹ The Regulations are currently codified in the Code of Federal Regulations at 15 CFR parts 730-774 (2020). The Regulations originally issued under the Export Administration Act of 1979, as amended, 50 U.S.C. 4601–4623 (Supp. III 2015) ("EAA"), which lapsed on August 21, 2001. The President, through Executive Order 13,222 of August 17, 2001 (3 CFR, 2001 Comp. 783 (2002)), which was extended by successive Presidential Notices. continued the Regulations in full force and effect under IEEPA. On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which includes the Export Control Reform Act of 2018, 50 U.S.C. 4801-4852 ("ECRA"). While Section 1766 of ECRA repeals the provisions of the EAA (except for three sections which are inapplicable here), Section 1768 of ECRA provides, in pertinent part, that all rules and regulations that were made or issued under the EAA, including as continued in effect pursuant to IEEPA, and were in effect as of ECRA's date of enactment (August 13, 2018), shall continue in effect according to their terms until modified, superseded, set aside, or

Section 766.25 of the Regulations provides, in pertinent part, that the "Director of [BIS's] Office of Export Enforcement, in consultation with the Director of [BIS's] Office of Exporter Services, may deny the export privileges of any person who has been convicted of a violation of any of the statues set forth at 50 U.S.C. 4819 (e)(1)(B),"2 including IEEPA. 15 CFR 766.25(a).3 The denial of export privileges under this provision may be for a period of up to 10 years from the date of the conviction. 15 CFR 766.25(d). In addition, pursuant to Section 750.8 of the Regulations, BIS's Office of Exporter Services may revoke any BIS-issued licenses in which the person has an interest at the time of his/her conviction.4

BIS received notice of Atilla's conviction for violating IEEPA, and pursuant to Section 766.25 of the Regulations, has provided notice and an opportunity for Atilla to make a written submission to BIS. BIS has received and considered a written submission from Atilla

Based upon my review of the record, including Atilla's written response, and consultations with BIS's Office of Exporter Services, including its Director, and the facts available to BIS, I have decided to deny Atilla's export privileges under the Regulations for a period of 10 years from the date of Atilla's conviction. The Office of Exporter Services has also decided to revoke any BIS-issued license in which Atilla had an interest at the time of his conviction.

Accordingly, it is hereby ordered: First, from the date of this Order until May 16, 2028, Mehmet Hakan Atilla, with last known addresses of Millet Cad. No: 26 D:15, Fatih Istanbul, Turkey and Molla Seref Mah Hikayeci Sok AZ, Fatih Istanbul, Turkey, and when acting for or on his behalf, his successors, assigns, employees, agents or representatives ("the Denied Person"), may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as "item") exported or to be exported from the United States that is subject to the Regulations, including, but not limited to:

A. Applying for, obtaining, or using any license, license exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or engaging in any other activity subject to the Regulations; or

C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or from any other activity subject to the Regulations.

Second, no person may, directly or indirectly, do any of the following:

A. Export or reexport to or on behalf of the Denied Person any item subject to the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by the Denied Person of the ownership, possession, or control of any item subject to the Regulations that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby the Denied Person acquires or attempts to acquire such ownership, possession or control;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from the Denied Person of any item subject to the Regulations that has been exported from the United States:

D. Obtain from the Denied Person in the United States any item subject to the Regulations with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or

E. Engage in any transaction to service any item subject to the Regulations that has been or will be exported from the United States and which is owned, possessed or controlled by the Denied Person, or service any item, of whatever origin, that is owned, possessed or controlled by the Denied Person if such service involves the use of any item subject to the Regulations that has been

or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

Third, after notice and opportunity for comment as provided in Section 766.23 of the Regulations, any other person, firm, corporation, or business organization related to Atilla by ownership, control, position of responsibility, affiliation, or other connection in the conduct of trade or business may also be made subject to the provisions of this Order in order to prevent evasion of this Order.

Fourth, in accordance with Part 756 of the Regulations, Atilla may file an appeal of this Order with the Under Secretary of Commerce for Industry and Security. The appeal must be filed within 45 days from the date of this Order and must comply with the provisions of Part 756 of the Regulations.

Fifth, a copy of this Order shall be delivered to Atilla and shall be published in the Federal Register.

Sixth, this Order is effective immediately and shall remain in effect until May 16, 2028.

John Sonderman,

Director, Office of Export Enforement.
[FR Doc. 2021–09500 Filed 5–4–21; 8:45 am]
BILLING CODE 3510–DT–P

DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Services Surveys: BE–125, Quarterly Survey of Transactions in Selected Services and Intellectual Property With Foreign Persons

AGENCY: Bureau of Economic Analysis, Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

revoked through action undertaken pursuant to the authority provided under ECRA.

² The Director, Office of Export Enforcement, is now authorizing official for issuance denial orders, pursuant to recent amendments to the Regulations (85 FR 73411, November 18, 2020).

³ As codified at the time of the underlying conviction at issue, Section 11(h)(1) of the EAA, as amended, provided that: "No person convicted of a violation of this chapter (or any regulation, license, or older issued under this chapter), any regulation, license, or order issed under the International Emergnecy Economic Powers Act [50 U.S.C. 1701, et seq.], section 793, 794 or 798 of title 18, section 783(b) of this title, or section 2778 of title 22 shall be eligible, at the discretion of the Secretary, to apply for or use any export license under this chapter for a period of up to 10 years from the date of conviction. The Secretary may revoke any export license under this chapter in which such person has an interest at the time of conviction." 50 U.S.C. 4610(h)(1).

⁴ See notes 1 and 3, supra.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before July 6, 2021.

ADDRESSES: Interested persons are invited to submit written comments to Christopher Stein, Chief, Services Surveys Branch, Bureau of Economic Analysis, at *christopher.stein@bea.gov* or *PRAcomments@doc.gov*. Please reference OMB Control Number 0608–0067 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Christopher Stein, Chief, Services Surveys Branch, Bureau of Economic Analysis, (301) 278–9189, and christopher.stein@bea.gov.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Quarterly Survey of Transactions in Selected Services and Intellectual Property with Foreign Persons (Form BE-125) is a survey that collects data from U.S. persons who engage in covered transactions in selected services or intellectual property with foreign persons. A U.S. person means any individual, branch, partnership, associated group, association, estate, trust, corporation, or other organization (whether or not organized under the laws of any State), resident in the United States or subject to the jurisdiction of the United States. A U.S. person must report if they had combined sales of covered services or intellectual property to foreign persons that exceeded \$6 million for the previous fiscal year, or are expected to exceed that amount during the current fiscal year, or if they had combined purchases of covered services or intellectual property from foreign persons that exceeded \$4 million for the previous fiscal year, or are expected to exceed that amount during the current fiscal year.

The data are needed to monitor U.S. trade in services, to analyze the impact of these cross-border services on the U.S. and foreign economies, to compile and improve the U.S. economic accounts, to support U.S. commercial policy on trade in services, to conduct trade promotion, and to improve the ability of U.S. businesses to identify and evaluate market opportunities. The data are used in estimating the trade in services component of the U.S. international transactions accounts

(ITAs) and national income and product accounts (NIPAs).

The Bureau of Economic Analysis (BEA) is proposing minor modifications to the existing transaction categories covered by the BE–125 survey and a change to the survey due date, beginning with reporting for first quarter 2022. The proposed modifications to the BE–125 survey would allow BEA to align its statistics more closely with international economic accounting guidelines and to increase the quality and usefulness of BEA's statistics on trade in services.

BEA proposes to eliminate the three transaction categories of other intellectual property. Rights to use other intellectual property (code 8.1), rights to reproduce and/or distribute other intellectual property (code 8.2), and outright sales or purchases of proprietary rights related to other intellectual property (code 8.3) would no longer be collected. BEA typically reclassifies transactions reported to BEA in these categories to research and development (R&D) services (transaction code 29.1, the provision of customized and non-customized R&D services; and, transaction code 29.2, other R&D services, including testing) and to other selected services (transaction code 42). With the elimination of the other intellectual property categories, respondents will be instructed to report transactions in these alternate categories.

BEA also proposes to change the due date of the survey to 30 days after the close of each quarter from 45 days for the three quarters that are not the final fiscal quarter of the year. For the final fiscal quarter of the year, reports would be due 45 days after the close of the quarter instead of 90 days. Shortening the reporting timeline will allow BEA to produce more accurate and complete trade in services statistics in preliminary estimates of the ITAs, which is critical information for policymakers' timely decisions on international trade policy. The earlier due date will allow BEA to use more reported data for preliminary statistics, improving the accuracy of both the aggregates and the country and servicetype details, and reducing revisions in subsequent statistical releases. In addition, the proposed reporting deadlines are also consistent with the reporting deadlines of BEA's quarterly direct investment surveys.

BEA estimates there will be no change in the average number of burden hours per response, which is currently estimated to be 21 hours. While survey respondents will have to file earlier, the burden for the survey is unchanged because the same information will be required on the survey as in the past. The language in the instructions and definitions will be reviewed and adjusted as necessary to clarify survey requirements.

II. Method of Collection

BEA contacts potential respondents by mail at the end of each quarter. Respondents would be required to file the completed BE-125 forms within 30 days after the end of each fiscal quarter that is not the final fiscal quarter of the year and within 45 days after the close of the final fiscal quarter of the year. Reports would be required from each U.S. person that had combined sales of covered services or intellectual property to foreign persons that exceeded \$6 million for the previous fiscal year, or are expected to exceed that amount during the current fiscal year, or that had combined purchases of covered services or intellectual property from foreign persons that exceeded \$4 million for the previous fiscal year, or that are expected to exceed that amount during the current fiscal year. Entities required to report will be contacted individually by BEA. Entities not contacted by BEA have no reporting responsibilities.

BEA offers its electronic filing option, the eFile system, for use in reporting on Form BE–125. For more information about eFile, go to www.bea.gov/efile. In addition, BEA posts all its survey forms and reporting instructions on its website, www.bea.gov/ssb. These may be downloaded, completed, printed, and submitted via fax or mail.

III. Data

OMB Control Number: 0608–0067. Form Number(s): BE–125.

Type of Review: Regular submission. Affected Public: Business or other forprofit organizations.

Estimated Number of Respondents: 8,800 annually (2,200 filed each quarter; 1,700 reporting mandatory data, and 500 that would file exemption claims or voluntary responses).

Estimated Time per Response: 21 hours is the average for those reporting data and one hour is the average for those filing an exemption claim. Hours may vary considerably among respondents because of differences in company size and complexity.

Estimated Total Annual Burden Hours: 144,800.

Estimated Total Annual Cost to Public: \$0.

Respondent's Obligation: Mandatory. Legal Authority: International Investment and Trade in Services Survey Act (Pub. L. 94–472, 22 U.S.C. 3101–3108, as amended).

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (b) the accuracy of the Agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–09423 Filed 5–4–21; 8:45 am] **BILLING CODE 3510–06–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 Department of Commerce (Commerce) has received requests to conduct administrative reviews of various antidumping duty (AD) and countervailing duty (CVD) orders and findings with March anniversary dates. In accordance with Commerce's regulations, we are initiating those administrative reviews.

DATES: Applicable May 5, 2021. **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 and findings with March 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

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), 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 antidumping duty 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 this 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 this AD proceeding (e.g., investigation, administrative review, new shipper review, or changed circumstances review). For any company subject to this 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 this 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.

¹ See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures, 76 FR 39263 (July 6, 2011).

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 antidumping duty 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://enforcement.trade.gov/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 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 proceeding 3 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:// enforcement.trade.gov/nme/nme-seprate.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 NMEowned 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 respondent selection. 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 March 31, 2022.

	Period to be reviewed
AD Proceedings	
BRAZIL: Certain Uncoated Paper, A-351-842	3/1/20-2/28/21
Suzano Papel e Celulose S.A.	
Suzano S.A.	
PORTUGAL: Certain Uncoated Paper, A-471-807	3/1/20–2/28/21
The Navigator Company, S.A.	

² See Trade Preferences Extension Act of 2015, Public Law 114–27, 129 Stat. 362 (2015).

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.

⁴Only 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.

	Period to be reviewed
HAILAND: Circular Welded Carbon Steel Pipes and Tubes, A-549-502	3/1/20–2/28/2
Apex International Logistics.	
Aquatec Maxcon Asia. Asian Unity Part Co., Ltd.	
Better Steel Pipe Company Limited.	
Bis Pipe Fitting Industry Co., Ltd.	
Blue Pipe Steel Center Co. Ltd.	
Chuhatsu (Thailand) Co., Ltd.	
CSE Technologies Co., Ltd.	
Expeditors International (Bangkok). Expeditors Ltd.	
FS International (Thailand) Co., Ltd.	
K Line Logistics.	
Kerry-Apex (Thailand) Co., Ltd.	
Oil Steel Tube (Thailand) Co., Ltd.	
Otto Ender Steel Structure Co., Ltd.	
Pacific Pipe and Pump. Pacific Pipe Public Co., Ltd.	
Panalpina World Transport Ltd.	
Polypipe Engineering Co., Ltd.	
Saĥa Thai Steel Pipe Public Co., Ltd.	
Schlumberger Overseas S.A.	
Siam Fittings Co., Ltd.	
Siam Steel Pipe Co., Ltd. Sino Connections Logistics (Thailand) Co., Ltd.	
Thai Malleable Iron and Steel.	
That Mill Group.	
Thai Oil Pipe Co., Ltd.	
Thai Premium Pipe Co. Ltd.	
Vatana Phaisal Engineering Company.	
Visavakit Patana Corp., Ltd. 'HE PEOPLE'S REPUBLIC OF CHINA: Certain Amorphous Silica Fabric, A-570-038	3/1/20–2/28/2
Access China Industrial Textile (Pinghu) Inc. (ACIT).	3/1/20-2/20/2
Access China Industrial Textile (Shanghai) Inc. (ACIT).	
Acmetex Co., Ltd.	
Beijing Great Pack Materials Co., Ltd.	
Beijing Landingji Engineering Tech. Co., Ltd.	
Beijing Tianxing Ceramic Fiber Composite Materials Corp.	
Changshu Yaoxing Fiberglass Insulation Products Co., Ltd. Changzhou Kingze Composite Materials Co., Ltd.	
Changzhou Utek Composite Co.	
Chengdu Chang Yuan Shun Co., Ltd.	
Chengdu Youbang Hengtai New Material Co., Ltd.	
China Beihai Fiberglass Co., Ltd.	
China National Building Materials International Corporation.	
China Yangzhou Guo Tai Fiberglass Co., Ltd. Chongqing Polycomp International Corp. (CPIC).	
Chongqing Tenways Material Corporation.	
Chongqing Yangkai Import & Export Trade Co., Ltd.	
Cixi Sunrise Sealing Material Co., Ltd.	
Fujian Minshan Fire-Fighting Co., Ltd.	
Ganzhou Guangjian Fiberglass Co., Ltd.	
Grant Fiberglass Co., Ltd.	
Haining Jiete Fiberglass Fabric Co., Ltd. Haining Jorhom Imp. & Ex. Co., Ltd.	
Hebei Yuniu Fiberglass Manufacturing Co., Ltd.	
Hebei Yuyin Trade Co., Ltd.	
Hengshui Aohong International Trading Co., Ltd.	
Hitex Insulation (Ningbo) Co., Ltd.	
Huatek New Material Inc.	
Jiangsu Jiuding New Material Co., Ltd.	
Jiangxi Aidmer Seal & Packing Co., Ltd. Jiujiang Huaxing Glass Fiber Co., Ltd.	
Langfang Wanda Industrial Co., Ltd.	
Lanxi Joen Fiberglass Co., Ltd.	
Mowco Industry Limited.	
Nantong Jinpeng Fiberglass Products Co., Ltd.	
Nanjing Debeili New Materials Co., Ltd.	
Nanjing Tianyuan Fiberglass Material Co., Ltd.	
New Fire Co., Ltd.	
New Fire, Ltd. Newtex Asia Pacific Pte Ltd.	
Newtex Asia Pacific Pte Ltd. Ningbo EAS Material Co., Ltd.	
Ningbo EAS Material Co., Etc. Ningbo Firewheel Thermal Insulation & Sealing Co., Ltd.	1

	Davied to be reviewed
	Period to be reviewed
Ningbo Fitow High Strength Composites Co., Ltd. Ningbo Universal Star Industry & Trade Limited.	
Ningguo BST Thermal Protection Products Co., Ltd.	
Nische New Material (Nantong) Co., Ltd.	
Pizhou Hua Yixiang Import and Export.	
Pizhou Hua Yixiang Import and Export Trading Co., Ltd.	
Qingdao Feelongda Industry & Trade Co., Ltd. Qingdao Junfeng Industry Company Limited.	
Qingdao Meikang Fireproof Materials Co., Ltd.	
Qingdao Shishuo Industry Co., Ltd.	
Rugao City Ouhua Composite Material Co., Ltd.	
Rugao Nebula Fiberglass Co., Ltd. Shandong Rondy Composite Materials, Co., Ltd.	
Shanghai Bonthe Insulative Material Co., Ltd.	
Shanghai Horse Construction Co., Ltd.	
Shanghai Industrial Products Imp. & Exp. Co., Ltd.	
Shanghai Liankun Electronics Material Co., Ltd. Shanghai New Union Textra Import.	
Shanghai Porcher Industries Co., Ltd.	
Shanghai Suita Environmental Protection Technology Co., Ltd.	
Shanghai Weldflame Co., Ltd.	
Shangqiu Huanyu Fiberglass Co., Ltd. Shaoxing Sunway Tools & Hardware Import & Export Co., Ltd.	
Shaoxing Sunway Tools & Hardware Import & Export Co., Ltd. Shengzhou Top-Tech New Material Co., Ltd.	
Shrzhen Core-Tex Composite Materials Co., Ltd.	
Shenzhen Songxin Silicone Products Co., Ltd.	
Suntex Composite Industrial Co., Ltd.	
Suretex Composite Co., Ltd. Taian Fibtex Trade Co., Ltd.	
Taian Juli Composite Materials Co., Ltd.	
Taixing Chuanda Plastic Co., Ltd.	
Taixing Kaixin Composite Materials Co., Ltd.	
Taixing Ruifeng Rubber Products Co., Ltd.	
Taixing Vichen Composite Material Co., Limited. TaiZhou Xinxing Fiberglass Products Co., Ltd.	
Tenglong Sealing Products Manufactory Yuyao.	
Texaspro (China) Company.	
Tianjin Bin Jin Fiberglass Products Co., Ltd.	
Tongxiang Suretex Composite Co., Ltd. Wallean Industries Co., Ltd.	
Wuhan Dinfn Industries Co., Ltd.	
Wuxi First Special-Type Fiberglass Co., Ltd.	
Wuxi Xingxiao Hi-tech Material Co., Ltd.	
Yuyao Feida Insulation Sealing Factory.	
Yuyao Tianyi Special Carbon Fiber Co., Ltd. Zibo Irvine Trading Co., Ltd.	
Zibo Yao Xing Fire-Resistant and Heat Preservation Material Co., Ltd.	
Zibo Yuntai Furnace Technology Co., Ltd.	
THE PEOPLE'S REPUBLIC OF CHINA: Glycine, A-570-836	3/1/20–2/28/21
Baoding Mantong Fine Chemistry Co., Ltd. THE PEOPLE'S REPUBLIC OF CHINA: Truck and Bus Tires, A–570–040	2/1/20–1/31/21
Giti Tire (Fujian) Company Ltd.	2/1/20-1/31/21
Giti Tire (Anhui) Company Ltd.	
CVD Proceedings Period to be Reviewed	
CANADA: Certain Softwood Lumber Products from Canada, C–122–858 6	1/1/20-12/31/20
Cedarcoast Lumber Products.	,20 .2,31/20
54 Reman.	
INDIA: Fine Denier Polyester Staple Fiber, C–533–876	1/1/20–12/31/20
Reliance Industries Limited. THE PEOPLE'S REPUBLIC OF CHINA: Certain Amorphous Silica Fabric, C–570–039	1/1/20–12/31/20
Access China Industrial Textile (Pinghu) Inc. (ACIT).	1/1/20 12/01/20
Access China Industrial Textile (Shanghai) Inc. (ACIT).	
Acmetex Co., Ltd.	
Beijing Great Pack Materials Co., Ltd. Beijing Landingji Engineering Tech. Co., Ltd.	
Beijing Landingji Engineering Tech. Co., Ltd. Beijing Tianxing Ceramic Fiber Composite Materials Corp.	
Changshu Yaoxing Fiberglass Insulation Products Co., Ltd.	
Changzhou Kingze Composite Materials Co., Ltd.	
Changzhou Utek Composite Co.	
Chengdu Chang Yuan Shun Co., Ltd. Chengdu Youbang Hengtai New Material Co., Ltd.	
China Beihai Fiberglass Co., Ltd.	
China National Building Materials International Corporation.	
-	

Period to be reviewed

China Yangzhou Guo Tai Fiberglass Co., Ltd. Chongging Polycomp International Corp. (CPIC). Chongqing Tenways Material Corporation. Chongqing Yangkai Import & Export Trade Co., Ltd. Cixi Sunrise Sealing Material Co., Ltd. Fujian Minshan Fire-Fighting Co., Ltd. Ganzhou Guangjian Fiberglass Co., Ltd. Grant Fiberglass Co., Ltd. Haining Jiete Fiberglass Fabric Co., Ltd. Haining Jorhom Imp. & Ex. Co., Ltd. Hebei Yuniu Fiberglass Manufacturing Co., Ltd. Hebei Yuyin Trade Co., Ltd. Hengshui Aohong International Trading Co., Ltd. Hitex Insulation (Ningbo) Co., Ltd. Huatek New Material Inc. Jiangsu Jiuding New Material Co., Ltd. Jiangxi Aidmer Seal & Packing Co., Ltd. Jiujiang Huaxing Glass Fiber Co., Ltd. Langfang Wanda Industrial Co., Ltd. Lanxi Joen Fiberglass Co., Ltd. Mowco Industry Limited. Nantong Jinpeng Fiberglass Products Co., Ltd. Nanjing Debeili New Materials Co., Ltd. Nanjing Tianyuan Fiberglass Material Co., Ltd. New Fire Co., Ltd. New Fire, Ltd. Newtex Asia Pacific Pte Ltd. Ningbo EAS Material Co., Ltd. Ningbo Firewheel Thermal Insulation & Sealing Co., Ltd. Ningbo Fitow High Strength Composites Co., Ltd. Ningbo Universal Star Industry & Trade Limited. Ningguo BST Thermal Protection Products Co., Ltd. Nische New Material (Nantong) Co., Ltd. Pizhou Hua Yixiang Import and Export. Pizhou Hua Yixiang Import and Export Trading Co., Ltd. Qingdao Feelongda Industry & Trade Co., Ltd. Qingdao Junfeng Industry Company Limited. Qingdao Meikang Fireproof Materials Co., Ltd. Qingdao Shishuo Industry Co., Ltd. Rugao City Ouhua Composite Material Co., Ltd. Rugao Nebula Fiberglass Co., Ltd. Shandong Rondy Composite Materials, Co., Ltd. Shanghai Bonthe Insulative Material Co., Ltd. Shanghai Horse Construction Co., Ltd. Shanghai Industrial Products Imp. & Exp. Co., Ltd. Shanghai Liankun Electronics Material Co., Ltd. Shanghai New Union Textra Import. Shanghai Porcher Industries Co., Ltd. Shanghai Suita Environmental Protection Technology Co., Ltd. Shanghai Weldflame Co., Ltd. Shangqiu Huanyu Fiberglass Co., Ltd. Shaoxing Sunway Tools & Hardware Import & Export Co., Ltd. Shengzhou Top-Tech New Material Co., Ltd. Shnzhen Core-Tex Composite Materials Co., Ltd. Shenzhen Songxin Silicone Products Co., Ltd. Suntex Composite Industrial Co., Ltd. Suretex Composite Co., Ltd. Taian Fibtex Trade Co., Ltd. Taian Juli Composite Materials Co., Ltd. Taixing Chuanda Plastic Co., Ltd. Taixing Kaixin Composite Materials Co., Ltd. Taixing Ruifeng Rubber Products Co., Ltd. Taixing Vichen Composite Material Co., Limited. TaiZhou Xinxing Fiberglass Products Co., Ltd. Tenglong Sealing Products Manufactory Yuyao. Texaspro (China) Company. Tianjin Bin Jin Fiberglass Products Co., Ltd. Tongxiang Suretex Composite Co., Ltd. Wallean Industries Co., Ltd. Wuhan Dinfn Industries Co., Ltd. Wuxi First Special-Type Fiberglass Co., Ltd. Wuxi Xingxiao Hi-tech Material Co., Ltd. Yuyao Feida Insulation Sealing Factory. Yuyao Tianyi Special Carbon Fiber Co., Ltd.

	Period to be reviewed
Zibo Irvine Trading Co., Ltd.	
Zibo Yao Xing Fire-Resistant and Heat Preservation Material Co., Ltd.	
Zibo Yuntai Furnace Technology Co., Ltd.	
TURKEY: Circular Welded Carbon Steel Pipes and Tubes, C-489-502	1/1/20-12/31/20
Borusan Mannesmann Boru Sanayi ve Ticaret A.S.	

Suspension Agreements

None.

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 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*,⁷ available at https://enforcement.trade.gov/frn/ 2013/1304frn/2013-08227.txt, prior to submitting factual information in this segment. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.8

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*. 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.¹⁰ 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 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

⁵ The two companies listed *i.e.*, Giti Tire (Fujian) Company Ltd. and Giti Tire (Anhui) Company Ltd. were inadvertently omitted from the initiation notice that published on April 1, 2021 (86 FR 17124). These omissions are corrected in this notice.

⁶ Cedarcoast Lumber Products and 54 Reman were inadvertently omitted from the initiation notice that published on March 4, 2021 (86 FR 12599). These omissions are corrected in this notice.

⁷ 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 https://enforcement.trade.gov/tlei/notices/factual_ info_final_rule_FAQ_07172013.pdf.

⁸ See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID-19, 85 FR 41363 (July

⁹ 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.

¹⁰ See 19 CFR 351.302.

submitting factual information in these segments.

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: April 29, 2021.

James Maeder,

Deputy Assistant Secretaryfor Antidumping and Countervailing Duty Operations.

[FR Doc. 2021-09421 Filed 5-4-21; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration [A-469-815]

Finished Carbon Steel Flanges From Spain: Final Results of Antidumping Duty Administrative Review; 2018– 2019

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) finds that sales of finished carbon steel flanges (flanges) from Spain were made at less than normal value (NV) during the period of review (POR), June 1, 2018, through May 31, 2019.

DATES: Applicable May 5, 2021.

FOR FURTHER INFORMATION CONTACT:

Marc Castillo or Mark Flessner, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0519 or (202) 482–6312, respectively.

SUPPLEMENTARY INFORMATION:

Background

On November 2, 2020, Commerce published the *Preliminary Results* of this administrative review and invited interested parties to comment on the *Preliminary Results*. These final results cover eight companies for which an

administrative review was initiated and not rescinded. On December 2, 2020, ULMA Forja, S.Coop (ULMA) submitted its case brief.² On the same day, Weldbend Corporation and Boltex Manufacturing Co., L.P. (collectively, the petitioners) submitted their case brief.³ On December 9, 2020, the petitioners submitted their rebuttal brief.⁴ On February 11, 2021, Commerce extended the deadline for these final results, until April 30, 2021.⁵

Scope of the Order 6

The scope of the *Order* covers finished carbon steel flanges from Spain. A full description of the scope of the *Order* is contained in the Issues and Decision Memorandum.⁷

Analysis of Comments Received

All issues raised in the case and rebuttal briefs filed by parties in this review are addressed in the Issues and Decision Memorandum, A list of the issues addressed in the Issues and Decision Memorandum is in the appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at https:// access.trade.gov. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the internet at http:// enforcement.trade.gov/frn/index.html.

Changes Since the Preliminary Results

Based on our analysis of the comments received, and for the reasons explained in the Issues and Decision Memorandum, we made certain changes from the *Preliminary Results*.

Final Results of Administrative Review

For these final results, we determine that the following weighted-average dumping margins exist for the period June 1, 2018, through May 31, 2019:

Exporter/manufacturer	Weighted- average dumping margin (percent)
ULMA Forja, S.Coop	1.41 1.41 1.41
Sinterizados S.A	1.41
Transglory S.A	1.41
Central Y Almacenes	1.41
Friedrich Geldbach Gmbh	1.41
Farina Group Spain	1.41

Rate for Non-Selected Respondents

For the rate for non-selected respondents in an administrative review, generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in a market economy investigation. Under section 735(c)(5)(A) of the Act, the all-others rate is normally "an amount equal to the weighted-average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero or de minimis margins, and any margins determined entirely (on the basis of facts available}." In this segment of the proceeding, we calculated a margin for ULMA that was not zero, de minimis, or based on facts available. Accordingly, we have applied the margin calculated for ULMA to the non-individually examined respondents.

Disclosure

Commerce intends to disclose the calculations performed for these final results of review within five days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Assessment

Commerce shall determine and U.S. Customs and Border Protection (CBP) shall assess antidumping duties on all appropriate entries. Commerce will instruct CBP to apply an ad valorem assessment rate of 1.41 percent to all entries of subject merchandise during the POR which were produced and/or exported by ULMA. Commerce will also instruct CBP to apply an ad valorem assessment rate of 1.41 percent to all entries of subject merchandise during the POR which were produced and/or exported by Grupo Cunado, Tubacero, S.L., Ateaciones De Metales Sinterizados S.A., Transglory S.A., Central Y Almacenes, Friedrich Geldbach Gmbh, and Farina Group Spain. Consistent with its recent

¹ See Finished Carbon Steel Flanges from Spain: Preliminary Results of Antidumping Duty Administrative Review; 2018–2019, 85 FR 69314 (November 2, 2020) (Preliminary Results); see also Memorandum, "Finished Carbon Steel Flanges from Spain, 2018–2019: Preliminary Results Federal Register Notice and Amended Briefing Schedule,' dated November 6, 2020. On October 22, 2020, Commerce published in the Federal Register the preliminary results for this administrative review of the Order for this POR (85 FR 67335). On November 2, 2020, Commerce inadvertently again published in the Federal Register the Preliminary Results; this second notice was identical to that published on October 22, 2020. In fairness to all parties and to prevent confusion, this November 2, 2020, notice is the operative notice of the Preliminary Results for this administrative review.

² See ULMA's Letter, "ULMA FORJA's Case Brief: Finished Carbon Steel Flanges from Spain POR 2," dated December 2, 2020.

³ See Petitioners' Letter, "Finished Carbon Steel Flanges from Spain: Case Brief," dated December 2, 2020.

⁴ See Petitioners' Letter, "Finished Carbon Steel Flanges from Spain: Rebuttal Brief," dated December 9, 2020.

⁵ See Memorandum, "Finished Carbon Steel Flanges from Spain: Extension of Time Limit for Final Results of Antidumping Duty Administrative Review, 2018–2019," dated February 11, 2021.

⁶ See Finished Carbon Steel Flanges from Spain: Antidumping Duty Order, 82 FR 27229 (June 14, 2017) (Order).

⁷ See accompanying Issues and Decision Memorandum.

notice,⁸ Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.*, within 90 days of publication).

Cash Deposit Requirements

The following deposit requirements for estimated antidumping duties will be effective upon publication of the notice of these final results of review for all shipments of flanges from Spain entered, or withdrawn from warehouse, for consumption on or after the date of publication as provided by section 751(a)(2) of the Act: (1) The cash deposit rate for ULMA, Grupo Cunado, Tubacero, S.L., Ateaciones De Metales Sinterizados S.A., Transglory S.A., Central Y Almacenes, Friedrich Geldbach Gmbh, and Farina Group Spain will be 1.41 percent; (2) for merchandise exported by producers or exporters not covered in this review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the original investigation, but the producer is, then the cash deposit rate will be the rate established for the most recent period for the producer of the merchandise; (4) the cash deposit rate for all other producers or exporters will continue to be 18.81 percent,9 the allothers rate established in the less-thanfair-value investigation. These cash deposit requirements shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties Regarding Administrative Protective Order

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213(h).

Dated: April 28, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary II. Background

II. Background

III. Scope of the *Order*IV. Discussion of the Issues

Comment 1: Freight Revenue Capping

Comment 2: Marine Insurance

Comment 3: Certain Offset to G&A

Expenses

V. Recommendation

[FR Doc. 2021–09413 Filed 5–4–21; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration [A-570-909]

Certain Steel Nails From the People's Republic of China: Final Results of Antidumping Duty Administrative Review, Final Determination of No Shipments and Final Partial Rescission, 2014–2015; Correction

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

ACTION: Notice; correction.

SUMMARY: The Department of Commerce (Commerce) published a notice in the **Federal Register** of March 20, 2017 in which Commerce announced the final results of the 2014–2015 administrative review of the antidumping duty (AD) order on certain steel nails (nails) from the People's Republic of China (China).

This notice contained incorrect information regarding the companies: For which Commerce rescinded the administrative review; for which Commerce made a final no shipments determination; and that Commerce assigned to the China-wide entity.

FOR FURTHER INFORMATION CONTACT: Benito Ballesteros, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–7425.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of March 20, 2017, in FR Doc. 2017–05429, on page 14345, correct the first and second paragraph of the "Final Partial Rescission of Antidumping Duty Administrative Review" section to read:

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if a party who requested the review withdraws the request within 90 days of the date of publication of notice of initiation. Mid Continent Steel & Wire, Inc. (the petitioner) withdrew its request for an administrative review on: Besco Machinery Industry (Zhejiang) Co., Ltd.; Cana (Tianjin) Hardware Industrial Co., Ltd.; Certified Products International Inc.; Chiieh Yung Metal Industrial Corporation; China Staple Enterprise (Tianjin) Co., Ltd.; Huanghua Jinhai Hardware Products Co. Ltd; Huanghua Xiong Hua Hardware Product Co., Ltd.; Huanghua Yufutai Hardware Products Limited; Jining Huarong Hardware Products; Liaocheng Minghui Hardware Products Co., Ltd.; Nanjing Yuechang Hardware Co., Ltd.; PT Enterprise Inc.; Shandong Oriental Cherry Hardware Group; Shandong Oriental Cherry Hardware Import & Export Co., Ltd.; Shandong Qingyun Hongyi Hardware Products Co., Ltd.; Shanghai Yueda Fasterners Co., Ltd.; Shanxi Tianli Enterprise Co., Ltd.; Shanxi Yuci Broad Wire Products Co., Ltd.; Smart (Tianjin) Technology Development Co., Ltd.; Tianjin Hongli Qiangsheng Import and Export Co., Ltd.; Tianjin Juxiang Metal Products Co.; Tianjin Lianda Group Ltd.¹ Tianjin Zhonglian Metals Ware Co., Ltd.; and Xi'an Metals & Minerals Import & Export Co., Ltd. No other party requested a review of these companies.2

⁸ See Notice of Discontinuation of Policy to Issue Liquidation Instructions After 15 Days in Applicable Antidumping and Countervailing Duty Administrative Proceedings, 86 FR 3995 (January 15, 2021).

⁹ See Order, 82 FR 27229.

¹We note that "Tianjin Lianda Group Co. Ltd." is subject to this review and is part of the Chinawide entity.

² The petitioner withdrew its request for: Hebei Cangzhou New Century Foreign Trade Co. Ltd; Nanjing Caiqing Hardware Co., Ltd.; Tianjin Jinghai County Hongli Industry & Business Co., Ltd.; and Tianjin Universal Machinery Import & Export Corp. However, these companies also self-requested a review. Therefore, we have not rescinded this review with respect to these four companies. The petitioner also withdrew its request for Mingguang Abundant Hardware Products Co., Ltd. However, in the *Preliminary Results*, we found Mingguang Abundant Hardware Products Co., Ltd. to be the same company as Mingguang Ruifeng Hardware

Accordingly, we are rescinding this review, in part, with respect to the companies identified above, pursuant to 19 CFR 351.213(d)(1).

In the **Federal Register** of March 20, 2017, in FR Doc 2017–05429, on page 14345, correct the first paragraph of the "Final Determination of No Shipments" section to read:

In the Preliminary Results. Commerce preliminarily determined that Zhejian Gem-Chun Hardware Accessory Co., Ltd. (Zhejian Gem-Chun) did not have any reviewable transactions during the POR.3 Consistent with Commerce's assessment practice in nonmarket economy (NME) cases, we completed the review with respect to Zhejian Gem-Chun. Based on the certifications submitted by Zhejian Gem-Chun, and our analysis of CBP information, we continue to determine that the company did not have any reviewable transactions during the POR. As noted in the "Assessment Rates" section of the Final Results, Commerce intends to issue appropriate instructions to CBP for Zheiian Gem-Chun based on the final results of this

In the **Federal Register** of March 20, 2017, in FR Doc 2017–05429, on page 14345, after the "Final Determination of No Shipments" section, add section "China-Wide Entity" to read:

In the Preliminary Results, we found that 14 companies, Cana (Tianjin) Hardware Industrial Co., Ltd., China Staple Enterprise (Tianjin) Co., Ltd., Huanghua Jinhai Hardware Products Co. Ltd, Huanghua Xiong Hua Hardware Product Co., Ltd., Huanghua Yufutai Hardware Products Limited, Liaocheng Minghui Hardware Products Co., Ltd., Mingguang Abundant Hardware Products Co., Ltd., Qingdao D&L Group Co., Ltd., Shandong Qingyun Hongyi Hardware Products Co., Ltd., Shanghai Yueda Fasterners Co., Ltd., Shanxi Tianli Enterprise Co., Ltd., Smart (Tianjin) Technology Development Co., Ltd., Tianjin Hongli Qiangsheng Import and Export Co., Ltd., and Tianjin Lianda Group Ltd., for which a review was requested had not established eligibility for a separate rate and, thus, we considered them to be part of the China-wide entity.

Products Co., Ltd. because the company changed it English name. Because Mingguang Ruifeng Hardware Products Co., Ltd. self-requested a review, we have not rescinded this review with respect to the company(ies). Similarly, we find Qingdao D&L Group, Ltd. and SDC International Australia (PTY) Ltd. to be the same as Qingdao D&L Group Co., Ltd. and SDC International Aust. PTY. Ltd., respectively, which self-requested a review. Therefore, we have not rescinded this review with respect to Qingdao D&L Group, Ltd. and SDC International Aust. PTY. Ltd.

³ In the Final Results, Commerce inadvertently included Besco Machinery Industry (Zhejiang) Co., Ltd., Jining Huarong Hardware Products, Nanjing Yuechang Hardware Co., Ltd., PT Enterprise Inc., and Shanxi Yuci Broad Wire Products Co., Ltd. in the no shipments category. However, the petitioner made a timely request to rescind the review on these companies. Therefore, Commerce has removed these companies from the no shipments category.

However, this list was incorrect.
Mingguang Abundant Hardware Products
Co., Ltd., under its new name Mingguang
Ruifeng Hardware Products Co., Ltd., and
Qingdao D&L Group Co., Ltd., under Qingdao
D&L Group Ltd., were granted separate rate
status. For the remaining companies, except
Tianjin Lianda Group Co., Ltd., Commerce
has rescinded the review, as noted above.

For the Final Results, we find that, for two companies, Suzhou Xingya Nail Co., Ltd. and Tianjin Lianda Group Co., Ltd., we have not received any information since the issuance of the Preliminary Results that provides a basis for reconsidering this preliminary determination. Therefore, Commerce continues to find that Suzhou Xingya Nail Co., Ltd. and Tianjin Lianda Group Co., Ltd. are part of the China-wide entity.

Background

On March 20, 2017, Commerce published in the **Federal Register** the final results of the 2014–2015 administrative reviews of the AD order on nails from China.⁴ This notice contained incorrect information regarding the companies for which Commerce: (1) Rescinded the administrative review; (2) made a final no shipments determination; and (3) assigned the entities to the China-wide entity.

Notification to Interested Parties

This notice is issued and published in accordance with sections 751(a)(1) and 777(i) of the Tariff Act of 1930, as amended.

Dated: April 29, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2021–09498 Filed 5–4–21; 8:45 am] BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

National Advanced Spectrum and Communications Test Network: Characterizing User Equipment Emissions

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Announcement of meeting.

SUMMARY: The National Advanced Spectrum and Communications Test Network (NASCTN) is hosting a public meeting on the conclusion of their

project Characterizing User Equipment Emissions on May 13, 2021 at 10:00 a.m.—12:30 p.m. Mountain Daylight Time. The purpose of this meeting is to bring together federal, industry, and academic stakeholders; to disseminate NASCTN's findings; and to share information.

DATES: The NASCTN meeting on Characterizing User Equipment Emissions will take place on May 13, 2021 at 10:00 a.m.–12:30 p.m. Mountain Daylight Time.

ADDRESSES: The meeting will be held via web conference. For instructions on how to participate in the meeting, please see the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Matt Briel at *matthew.briel@nist.gov* or 303–908–2747.

SUPPLEMENTARY INFORMATION: The National Advanced Spectrum and Communications Test Network (NASCTN) is hosting a public meeting on the conclusion of their project Characterizing User Equipment Emissions on May 13, 2021 at 10:00 a.m.–12:30 p.m. Mountain Daylight Time. The purpose of this meeting is to bring together federal, industry, and academic stakeholders; to disseminate NASCTN's findings; and to share information.

This project characterizes cellular emissions (LTE uplinks) to support interference models used to coordinate commercial carrier deployments in the AWS-3 band (1755-1780 MHz band) with Department of Defense systems that remain in the band. This effort consisted of two parts: (1) A Factor Screening effort which identified the key factors impacting emissions, and (2) characterization of factors impacting UE uplink emissions when closed-loop power control is enabled in the cell, and models of the emissions over operational scenarios. The output of this work can aid in the development of emissions models and interference calculations in the AWS-3 band and beyond.

More information about this project can be found on our website: https:// www.nist.gov/programs-projects/ characterizing-user-equipmentemissions.

Individuals and representatives of organizations who would like to ask questions or offer suggestions related to the test are invited to request a place on the agenda. Approximately fifteen minutes will be reserved for public comments and speaking times will be assigned on a first-come, first-served basis. Public comments can be provided via email or by web conference

⁴ See Certain Steel Nails from the People's Republic of China: Final Results of Antidumping Duty Administrative Review, Final Determination of No Shipments and Final Partial Rescission; 2014– 2015, 82 FR 14344 (March 20, 2017).

attendance. The amount of time per speaker will be determined by the number of requests received. All those wishing to speak must submit their request by email to *matthew.briel@nist.gov* by 5:00 p.m. Mountain Daylight Time, May 11, 2021. Speakers who wish to expand upon their oral statements, those who wish to speak but cannot be accommodated on the agenda, and those who are unable to attend are invited to submit written statements electronically by email to *matthew.briel@nist.gov*.

Anyone wishing to attend this meeting via web conference must register by 5:00 p.m. Mountain Daylight Time, May 11, 2021. Please submit your full name, email address, and phone number to Matt Briel at matthew.briel@nist.gov.

Authority: 15 U.S.C. 272.

Alicia Chambers,

NIST Executive Secretariat.

[FR Doc. 2021–09411 Filed 5–4–21; 8:45 am]

BILLING CODE 3510-13-P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Manufacturing Extension Partnership Advisory Board

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice of open meeting.

SUMMARY: The National Institute of Standards and Technology (NIST) announces that the Manufacturing Extension Partnership (MEP) Advisory Board will hold an open meeting on Wednesday, June 30, 2021.

DATES: The meeting will be held on Wednesday, June 30, 2021 from 9:00 a.m. to 5:00 p.m. Central Time.

ADDRESSES: The meeting will be held at the Hyatt Regency Tulsa Downtown, 100 East Second Street, Tulsa, Oklahoma, 74103. Please note admittance instructions in the SUPPLEMENTARY INFORMATION section

below. This meeting could switch to a virtual format only. Interested parties should be sure to check the NIST MEP Advisory Board website for the most upto-date information at http://www.nist.gov/mep/about/advisory-board.cfm. Everyone who registers and provides contact information will receive notice if there is a change to the meeting venue from in-person to virtual.

FOR FURTHER INFORMATION CONTACT:

Cheryl L. Gendron, Manufacturing Extension Partnership, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 4800, Gaithersburg, Maryland 20899–4800; telephone number (301) 975–2785; email: cheryl.gendron@nist.gov.

SUPPLEMENTARY INFORMATION: The MEP Advisory Board is authorized under Section 3003(d) of the America COMPETES Act (Pub. L. 110-69), as amended by the American Innovation and Competitiveness Act. Public Law 114-329 sec. 501 (2017), and codified at 15 U.S.C. 278k(m), in accordance with the provisions of the Federal Advisory Committee Act, as amended, 5 U.S.C. App. The Hollings Manufacturing Extension Partnership Program (Program) is a unique program consisting of Centers in all 50 states and Puerto Rico with partnerships at the federal, state and local levels. By statute, the MEP Advisory Board provides the NIST Director with: (1) Advice on the activities, plans and policies of the Program; (2) assessments of the soundness of the plans and strategies of the Program; and (3) assessments of current performance against the plans of the Program.

Background information on the MEP Advisory Board is available at http://www.nist.gov/mep/about/advisory-board.cfm.

Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. App., notice is hereby given that the MEP Advisory Board will hold an open meeting on Wednesday, June 30, 2021 from 9:00 a.m. to 5:00 p.m. Central Time. The meeting agenda will include an update on the MEP programmatic operations, as well as provide guidance and advice on current activities related to the MEP National NetworkTM 2017-2022 Strategic Plan. The agenda may change to accommodate Committee business. The final agenda will be posted on the MEP Advisory Board website at http://www.nist.gov/mep/ about/advisory-board.cfm.

Individuals and representatives of organizations who would like to offer comments and suggestions related to the MEP Advisory Board's business are invited to request a place on the agenda. Approximately 15 minutes will be reserved for public comments at the end of the meeting. Speaking times will be assigned on a first-come, first-served basis. The amount of time per speaker will be determined by the number of requests received but is likely to be no more than three to five minutes each. Requests must be submitted by email to cheryl.gendron@nist.gov and must be received by June 25, 2021 to be considered. The exact time for public comments will be included in the final agenda that will be posted on the MEP

Advisory Board website at http://www.nist.gov/mep/about/advisory-board.cfm. Questions from the public will not be considered during this period. Speakers who wish to expand upon their oral statements, those who wished to speak but could not be accommodated on the agenda or those who are/were unable to attend the meeting are invited to submit written statements electronically by email to cheryl.gendron@nist.gov.

Admittance Instructions: Anyone wishing to attend the MEP Advisory Board meeting must submit their name, email address and phone number to Cheryl Gendron (Cheryl.Gendron@nist.gov or 301–975–2785) no later than Friday, June 26, 2021, 5:00 p.m. Eastern Time.

Alicia Chambers,

NIST Executive Secretariat. [FR Doc. 2021–09408 Filed 5–4–21; 8:45 am] BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

National Advanced Spectrum and Communications Test Network: LTE Impacts to Aeronautical Mobile Telemetry and LTE Waveform Measurement

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Announcement of meeting.

SUMMARY: The National Advanced Spectrum and Communications Test Network (NASCTN) is hosting a public meeting on LTE impacts to Aeronautical Mobile Telemetry (AMT) as well as field and laboratory LTE waveform measurement on May 12, 2021 at 10:00 a.m.—12:30 p.m. Mountain Daylight Time. The purpose of this meeting is to bring together federal, industry, and academic stakeholders; to disseminate NASCTN's findings; and to share information.

DATES: The NASCTN meeting on LTE Impacts to AMT and LTE Waveform Measurement will take place on May 12, 2021 at 10:00 a.m.–12:30 p.m. Mountain Daylight Time.

ADDRESSES: The meeting will be held via web conference. For instructions on how to participate in the meeting, please see the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Matt Briel at *matthew.briel@nist.gov* or 303–908–2747.

SUPPLEMENTARY INFORMATION: The National Advanced Spectrum and Communications Test Network (NASCTN) is hosting a public meeting on LTE impacts to AMT as well as field and laboratory LTE waveform measurement on May 12, 2021 at 10:00 a.m.—12:30 p.m. MDT. The purpose of this meeting is to bring together federal, industry, and academic stakeholders; to disseminate NASCTN's findings; and to share information.

This project builds on and extends a previous NASCTN project that measured the out-of-band (OoB) LTE evolved Node B (eNB) and User Equipment AWS-3 emissions into adjacent L and S frequency bands of AMT systems. While the previous test measured general LTE OoB emissions, this project specifically measures the impact to AMT systems. Results can be used to improve testing protocols that protect existing federal systems during new cellular deployments. More information about this project can be found on our website: https:// www.nist.gov/programs-projects/aws-3lte-impacts-amt.

Individuals and representatives of organizations who would like to ask questions or offer suggestions related to the test are invited to request a place on the agenda. Approximately fifteen minutes will be reserved for public comments and speaking times will be assigned on a first-come, first-served basis. Public comments can be provided via email or by web conference attendance. The amount of time per speaker will be determined by the number of requests received. All those wishing to speak must submit their request by email to matthew.briel@ *nist.gov* by 5:00 p.m. Mountain Daylight Time, May 10, 2021. Speakers who wish to expand upon their oral statements, those who wish to speak but cannot be accommodated on the agenda, and those who are unable to attend are invited to submit written statements electronically by email to matthew.briel@nist.gov.

Anyone wishing to attend this meeting via web conference must register by 5:00 p.m. Mountain Daylight Time, May 10, 2021. Please submit your full name, email address, and phone number to Matt Briel at *matthew.briel@nist.gov*.

Authority: 15 U.S.C. 272.

Alicia Chambers,

NIST Executive Secretariat. [FR Doc. 2021–09410 Filed 5–4–21; 8:45 am]

BILLING CODE 3510-13-P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Visiting Committee on Advanced Technology

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice of open meeting.

SUMMARY: National Institute of Standards and Technology (NIST)'s Visiting Committee on Advanced Technology (VCAT or Committee) will meet on Tuesday, June 8, 2021, from 10:00 a.m. to 5:00 p.m. Eastern Time.

DATES: The VCAT will meet on Tuesday, June 8, 2021, from 10:00 a.m. to 5:00 p.m. Eastern Time.

ADDRESSES: The meeting will be a virtual meeting via webinar. Please note admittance instructions under the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT:

Stephanie Shaw, VCAT, NIST, 100 Bureau Drive, Mail Stop 1060, Gaithersburg, Maryland 20899–1060, telephone number 240–298–4654. Ms. Shaw's email address is stephanie.shaw@nist.gov.

SUPPLEMENTARY INFORMATION:

Authority: 15 U.S.C. 278, as amended, and the Federal Advisory Committee Act, as amended, 5 U.S.C. App.

Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. App., notice is hereby given that the VCAT will meet on Tuesday, June 8, 2021, from 10:00 a.m. to 5:00 p.m. Eastern Time. The meeting will be open to the public. The VCAT is composed of not fewer than 9 members appointed by the NIST Director, eminent in such fields as business, research, new product development, engineering, labor, education, management consulting, environment, and international relations. The primary purpose of this meeting is for the VCAT to review and make recommendations regarding general policy for NIST, its organization, its budget, and its programs within the framework of applicable national policies as set forth by the President and the Congress. The agenda will include an update on major programs, safety, and the status of the NIST Center for Neutron Research. It will also include discussions on the NIST budget and administration priorities including sessions on continuing efforts to strengthen diversity, equity, and inclusivity; NIST's role in the American Jobs Plan; and

Standards, as well as an update on ongoing actions to implement NIST's Strategic Plan. The agenda may change to accommodate Committee business. The final agenda will be posted on the NIST website at http://www.nist.gov/director/vcat/agenda.cfm.

Individuals and representatives of organizations who would like to offer comments and suggestions related to the Committee's business are invited to request a place on the agenda. Approximately one-half hour will be reserved for public comments and speaking times will be assigned on a first-come, first-serve basis. The amount of time per speaker will be determined by the number of requests received but, is likely to be about 3 minutes each. The exact time for public comments will be included in the final agenda that will be posted on the NIST website at http:// www.nist.gov/director/vcat/agenda.cfm. Questions from the public will not be considered during this period. Speakers who wish to expand upon their oral statements, those who had wished to speak but could not be accommodated on the agenda, and those who were unable to attend via webinar are invited to submit written statements to Stephanie Shaw at stephanie.shaw@

All participants will be attending via webinar and must contact Ms. Shaw at *stephanie.shaw@nist.gov* by no later than 5:00 p.m. Eastern Time, Wednesday, June 2, 2021 for detailed instructions on how to join the webinar.

Alicia Chambers,

NIST Executive Secretariat. [FR Doc. 2021–09406 Filed 5–4–21; 8:45 am] BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

National Construction Safety Team Advisory Committee Meeting

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice of open meeting.

SUMMARY: The National Construction Safety Team (NCST) Advisory Committee (Committee) will hold a virtual meeting via web conference on Thursday, June 10, 2021, from 11:00 a.m. to 3:30 p.m. Eastern Time and Friday, June 11, 2021, from 11:00 a.m. to 3:30 p.m. Eastern Time. The primary purpose of this meeting is to update the Committee on: The progress of the NCST investigation focused on the impacts of Hurricane Maria on Puerto Rico and the implementation of recommendations from previous NCST investigations, including the Joplin tornado investigation. The agenda may change to accommodate Committee business. The final agenda will be posted on the NIST website at https://www.nist.gov/topics/disaster-failure-studies/national-construction-safety-team-ncst/advisory-committee-meetings.

DATES: The NCST Advisory Committee will meet on Thursday June 10, 2021

DATES: The NCST Advisory Committee will meet on Thursday, June 10, 2021, from 11:00 a.m. to 3:30 p.m. Eastern Time and Friday, June 11, 2021, from 11:00 a.m. to 3:30 p.m. Eastern Time.

ADDRESSES: The meeting will be held via web conference. For instructions on how to participate in the meeting, please see the SUPPLEMENTARY INFORMATION section of this notice.

FOR FURTHER INFORMATION CONTACT:

Maria Dillard, Disaster and Failure Studies Program, Engineering Laboratory, NIST. Maria Dillard's email address is *Maria.Dillard@nist.gov* and her phone number is (202) 281–0908.

SUPPLEMENTARY INFORMATION: The Committee was established pursuant to Section 11 of the NCST Act (Pub. L. 107-231, codified at 15 U.S.C. 7301 et seq.). The Committee is currently composed of seven members, appointed by the Director of NIST, who were selected on the basis of established records of distinguished service in their professional community and their knowledge of issues affecting the National Construction Safety Teams. The Committee advises the Director of NIST on carrying out the NCST Act; reviews the procedures developed for conducting investigations; and reviews the reports issued documenting investigations. Background information on the NCST Act and information on the NCST Advisory Committee is available at https://www.nist.gov/topics/disasterfailure-studies/national-constructionsafety-team-ncst/advisory-committee.

Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. App., notice is hereby given that the NCST Advisory Committee will meet on Thursday, June 10, 2021, from 11:00 a.m. to 3:30 p.m. Eastern Time and Friday, June 11, 2021, from 11:00 a.m. to 3:30 p.m. Eastern Time. The meeting will be open to the public and will be held via web conference. Interested members of the public will be able to participate in the meeting from remote locations. The primary purpose of this meeting is to update the Committee on the status of the NCST investigation focused on the impacts of Hurricane Maria on Puerto Rico and the implementation of recommendations

from previous NCST investigations, including the Joplin tornado investigation. The agenda may change to accommodate Committee business. The final agenda will be posted on the NIST website at https://www.nist.gov/topics/disaster-failure-studies/national-construction-safety-team-ncst/advisory-committee-meetings.

Individuals and representatives of organizations who would like to offer comments and suggestions related to items on the Committee's agenda for this meeting are invited to request a place on the agenda. Approximately fifteen minutes will be reserved for public comments and speaking times will be assigned on a first-come, firstserved basis. Public comments can be provided via email or by web conference attendance. The amount of time per speaker will be determined by the number of requests received. Questions from the public will not be considered during this period. All those wishing to speak must submit their request by email to the attention of Peter Gale at Peter.Gale@nist.gov by 5:00 p.m. Eastern Time, Friday, June 4, 2021. Speakers who wish to expand upon their oral statements, those who wish to speak but cannot be accommodated on the agenda, and those who are unable to attend are invited to submit written statements electronically by email to Peter.Gale@nist.gov.

Anyone wishing to attend this meeting via web conference must register by 5:00 p.m. Eastern Time, Friday, June 4, 2021, to attend. Please submit your full name, email address, and phone number to Peter Gale at *Peter.Gale@nist.gov.*

Alicia Chambers,

NIST Executive Secretariat. [FR Doc. 2021–09409 Filed 5–4–21; 8:45 am] BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Open Meeting of the Information Security and Privacy Advisory Board

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice of open meeting.

SUMMARY: The Information Security and Privacy Advisory Board (ISPAB) will meet Wednesday, June 23, 2021 from 10:00 a.m. until 5:00 p.m., Eastern Time, and Thursday, June 24, 2021 from 10:00 a.m. until 5:00 p.m., Eastern Time. All sessions will be open to the public.

DATES: The meeting will be held on Wednesday, June 23, 2021 from 10:00 a.m. until 5:00 p.m., Eastern Time, and Thursday, June 24, 2021 from 10:00 a.m. until 5:00 p.m., Eastern Time.

ADDRESSES: The meeting will be a virtual meeting via webinar. Please note admittance instructions under the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Jeff Brewer, Information Technology Laboratory, National Institute of Standards and Technology, Telephone: (301) 975–2489, Email address: jeffrev.brewer@nist.gov.

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. App., notice is hereby given that the ISPAB will hold an open meeting Wednesday, June 23, 2021 from 10:00 a.m. until 5:00 p.m., Eastern Time, and Thursday, June 24, 2021 from 10:00 a.m. until 5:00 p.m. Eastern Time. All sessions will be open to the public. The ISPAB is authorized by 15 U.S.C. 278g-4, as amended, and advises the National Institute of Standards and Technology (NIST), the Secretary of Homeland Security, and the Director of the Office of Management and Budget (OMB) on information security and privacy issues pertaining to Federal government information systems, including through review of proposed standards and guidelines developed by NIST. Details regarding the ISPAB's activities are available at https://csrc.nist.gov/projects/ispab.

The agenda is expected to include the following items:

- —A Discussion with NIST on Critical Software.
- —A Briefing from NIST on Supply Chain Risk Management Guidance,
- —A Briefing from DHS on Threat Information Sharing,
- —A Briefing from NIST on Zero Trust Architectures,
- —A Briefing from GSA on a Federal Cloud Security Strategy,—A Discussion on Secure Software
- Development Practices,

 —A Discussion on Software Security
- Testing Tools, —A Briefing on the Use of a Software
- Bill of Materials,

 —Update on the NIST Information
- —Update on the NIST Information Technology Laboratory.

Note that agenda items may change without notice. The final agenda will be posted on the ISPAB event page at: https://csrc.nist.gov/Events/2021/ispabjune-meeting.

Public Participation: Written questions or comments from the public are invited and may be submitted electronically by email to Jeff Brewer at the contact information indicated in the **FOR FURTHER INFORMATION CONTACT** section of this notice by 5 p.m. on June 21, 2021.

The ISPAB agenda will include a period, not to exceed thirty minutes, for submitted questions or comments from the public (Wednesday, June 23, 2021, between 4:30 p.m. and 5:00 p.m.). Submitted questions or comments from the public will be selected on a first-come, first-served basis and limited to five minutes per person.

Members of the public who wish to expand upon their submitted statements, those who had wished to submit a question or comment but could not be accommodated on the agenda, and those who were unable to attend the meeting via webinar are invited to submit written statements. In addition, written statements are invited and may be submitted to the ISPAB at any time. All written statements should be directed to the ISPAB Secretariat, Information Technology Laboratory by email to: jeffrey.brewer@nist.gov.

Admittance Instructions: All participants will be attending via webinar and must register on ISPAB's event page at: https://csrc.nist.gov/Events/2021/ispab-june-meeting by 5 p.m. Eastern Time, June 21, 2021.

Alicia Chambers,

NIST Executive Secretariat. [FR Doc. 2021–09407 Filed 5–4–21; 8:45 am] BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XB059]

Council Coordination Committee Meeting

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

ACTION: Notice of a public meeting; information regarding the agenda.

SUMMARY: The National Marine
Fisheries Service, Office of Sustainable
Fisheries will host a virtual meeting of
the Council Coordination Committee
(CCC), consisting of the Regional
Fishery Management Council (Council)
chairs, vice chairs, and executive
directors from May 18 to May 20, 2021.
The intent of this meeting is to discuss
issues of relevance to the Councils and
NMFS, including issues related to the
implementation of the MagnusonStevens Fishery Conservation and

Management Reauthorization Act (MSA).

DATES: The meeting will begin at 1:30 p.m. Eastern Daylight Time (EDT) on Tuesday, May 18, 2021, recess at 5:30 p.m., reconvene at 1:30 p.m. EDT on Wednesday, May 19, 2021, recess at 5:30 p.m., and reconvene on the final day at 1:30 p.m. EDT, Thursday, May 20, 2021, adjourning at 5:30 p.m.

ADDRESSES: The meeting will be held online via WebEx. Attendees can find information on how to join at https://www.fisheries.noaa.gov/national/partners/council-coordination-committee and http://

www.fisherycouncils.org/ccc-meetings.

FOR FURTHER INFORMATION CONTACT:

Nicholas Pieper by email at *Nicholas.Pieper@noaa.gov* or at (301) 427–8500.

SUPPLEMENTARY INFORMATION: The 2007 reauthorization of the MSA established the CCC. The CCC consists of the chairs, vice chairs, and executive directors of each of the eight Regional Fishery Management Councils, or their respective proxies. All sessions are open to the public and time will be set aside for public comments at the end of each day and after specific sessions at the discretion of the meeting Chair. The meeting Chair will announce public comment times and instructions to provide comment at the start of each meeting day. Updates to this meeting and additional information will be posted on https:// www.fisheries.noaa.gov/national/

partners/council-coordinationcommittee and http:// www.fisherycouncils.org/ when available.

Proposed Agenda

Tuesday, May 18, 2021—1:30 p.m.–5:30 p.m. EDT

- 1. Welcome and Introduction
- 2. Approval of Agenda and Minutes
- 3. NMFS Update and Upcoming Priorities
- 4. NMFS Fisheries Science Update
- 5. Legislative Outlook
- 6. Integration of Endangered Species Act Section 7 with MSA
- 7. Public Comment
- 8. Adjourn Day 1

Wednesday, May 19, 2021—1:30 p.m.–5:30 p.m. EDT

- 1. Welcome
- 2. Recent Executive Orders
- 3. Offshore Wind Development
- 4. MSA National Standard1 Draft
 Technical Memorandum on
 managing with annual catch limits
 (ACLs) for data-limited stocks and
 update on working group products

- 5. CCC Committees
- 6. Public Comment
- 7. Adjourn Day 2

Thursday, May 20, 2021—1:30 p.m.–5:30 p.m. EDT

- 1. Welcome
- 2. Seafood Competitiveness, Marketing, and Economic Growth
- 3. Electronic Monitoring
- 4. Policy and Procedural Directives on Guidance for Financial Disclosures and Recusals
- 5. Public Comment
- 6. Wrap-up and Other Business
- 7. Adjourn Day 3

The order in which the agenda items are addressed may be adjusted by the meeting Chair to stay on time. The CCC will meet as late as necessary to complete scheduled business.

Special Accommodations

If you have particular access needs please contact Nicholas Pieper at *Nicholas.Pieper@noaa.gov* prior to the meeting for accommodation.

Dated: April 30, 2021.

Jennifer M. Wallace,

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

[FR Doc. 2021–09493 Filed 5–4–21; 8:45 am] BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XB044]

Fisheries of the Gulf of Mexico and Atlantic; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

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

ACTION: Notice of SEDAR 68 Assessment Webinar V for Gulf of Mexico and Atlantic scamp grouper.

SUMMARY: The SEDAR 68 assessment process of Gulf of Mexico and Atlantic scamp will consist of a series of data and assessment webinars, and a Review Workshop. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 68 Assessment Webinar V will be held May 24, 2021, from 10 a.m. to 1 p.m., Eastern Time.

ADDRESSES: The meeting will be held via webinar. The webinar is open to members of the public. Those interested in participating should contact Julie A. Neer at SEDAR (see FOR FURTHER INFORMATION CONTACT) to request an

invitation providing webinar access information. Please request webinar invitations at least 24 hours in advance of each webinar.

SEDAR address: 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Julie A. Neer, SEDAR Coordinator; (843) 571–4366; email: Julie.neer@safmc.net

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region, SEDAR is a multistep process including: (1) Data Workshop, (2) a series of assessment webinars, and (3) A Review Workshop. The product of the Data Workshop is a report that compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The assessment webinars produce a report that describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The product of the Review Workshop is an Assessment Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, HMS Management Division, and Southeast Fisheries Science Center. Participants include data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and NGO's; International experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion during the Assessment Webinar are as follows:

- 1. Using datasets and initial assessment analysis recommended from the data webinars, panelists will employ assessment models to evaluate stock status, estimate population benchmarks and management criteria, and project future conditions.
- 2. Participants will recommend the most appropriate methods and configurations for determining stock status and estimating population parameters.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see **ADDRESSES**) at least 5 business days prior to each workshop.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: April 29, 2021.

Tracey L. Thompson,

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

[FR Doc. 2021–09417 Filed 5–4–21: 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XB061]

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council's Research Steering Committee (RSC) will hold a meeting.

DATES: The meeting will be held on Wednesday, June 2, 2021, beginning at 9 a.m. and conclude by 12 p.m. For agenda details, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The meeting will be held via webinar. Details on the proposed agenda, webinar listen-in access, and briefing materials will be posted at the MAFMC's website: www.mafmc.org.

Council address: Mid-Atlantic Fishery Management Council, 800 N State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331; www.mafmc.org.

FOR FURTHER INFORMATION CONTACT:

Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The purpose of this RSC meeting is to discuss redevelopment of the research set-aside program. In doing so, the RSC will also discuss the outcomes of the March 2021 meeting, the Scientific and Statistical Committee Economic Working Group involvement, workshop participants, and future workshop agendas.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kathy Collins at the Mid-Atlantic Council Office, (302) 526–5253, at least 5 days prior to the meeting date.

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

Dated: April 30, 2021.

Tracey L. Thompson,

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

[FR Doc. 2021–09502 Filed 5–4–21; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XA962]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Ferry Berth Improvements in Tongass Narrows, Alaska

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

ACTION: Notice; issuance of renewal incidental harassment authorization.

SUMMARY: In accordance with the regulations implementing the Marine Mammal Protection Act (MMPA), as amended, notification is hereby given that NMFS has issued a Renewal incidental harassment authorization (IHA) to the Alaska Department of Transportation and Public Facilities (ADOT&PF) to incidentally harass marine mammals incidental to Phase I of the two-part ferry berth improvements and construction in Tongass Narrows, near Ketchikan, AK. **DATES:** This authorization is effective from date of issuance through February 28, 2022.

FOR FURTHER INFORMATION CONTACT:

Dwayne Meadows, Ph.D., Office of Protected Resources, NMFS, (301) 427–8401. Electronic copies of the original application, Renewal request, and supporting documents (including NMFS Federal Register notices of the original proposed and final authorizations, and the previous IHA), as well as a list of the references cited in this document, may be obtained online at: https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-undermarine-mammal-protection-act. In case of problems accessing these documents, please call the contact listed above.

SUPPLEMENTARY INFORMATION:

Background

The MMPA prohibits the "take" of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 et seq.) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are proposed or, if the taking is limited to harassment, a notice of a proposed incidental take authorization 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 such species or stocks for taking for certain subsistence uses (referred to here as "mitigation measures"). Monitoring and reporting of such takings are also required. The meaning of key terms such as "take," "harassment," and "negligible impact" can be found in section 3 of the MMPA (16 U.S.C. 1362) and the agency's regulations at 50 CFR 216.103.

NMFS' regulations implementing the MMPA at 50 CFR 216.107(e) indicate that IHAs may be renewed for additional periods of time not to exceed 1 year for each reauthorization. In the notice of proposed IHA for the initial authorization, NMFS described the circumstances under which we would

consider issuing a Renewal for this activity, and requested public comment on a potential Renewal under those circumstances. Specifically, on a caseby-case basis, NMFS may issue a onetime one-year Renewal IHA following notice to the public providing an additional 15 days for public comments when (1) up to another year of identical or nearly identical activities as described in the Detailed Description of Specific Activity section of the initial IHA issuance notice is planned or (2) the activities as described in the Detailed Description of Specific Activity section of the initial IHA issuance notice would not be completed by the time the initial IHA expires and a Renewal would allow for completion of the activities beyond that described in the Dates and Duration section of the initial IHA issuance notice, provided all of the following conditions are met:

(1) A request for renewal is received no later than 60 days prior to the needed Renewal IHA effective date (recognizing that the Renewal IHA expiration date cannot extend beyond one year from expiration of the initial IHA);

(2) The request for renewal must include the following:

- An explanation that the activities to be conducted under the requested Renewal IHA are identical to the activities analyzed under the initial IHA, are a subset of the activities, or include changes so minor (e.g., reduction in pile size) that the changes do not affect the previous analyses, mitigation and monitoring requirements, or take estimates (with the exception of reducing the type or amount of take); and
- A preliminary monitoring report showing the results of the required monitoring to date and an explanation showing that the monitoring results do not indicate impacts of a scale or nature not previously analyzed or authorized; and

(3) Upon review of the request for Renewal, the status of the affected species or stocks, and any other pertinent information, NMFS determines that there are no more than minor changes in the activities, the mitigation and monitoring measures will remain the same and appropriate, and the findings in the initial IHA remain valid.

An additional public comment period of 15 days (for a total of 45 days), with direct notice by email, phone, or postal service to commenters on the initial IHA, is provided to allow for any additional comments on the proposed Renewal. A description of the Renewal process may be found on our website at: www.fisheries.noaa.gov/national/

marine-mammal-protection/incidental-harassment-authorization-renewals.

History of Request

On March 1, 2020, NMFS issued two, consecutive IHAs to ADOT&PF to take marine mammals incidental to Phase I and II activity related to ferry berth improvements and construction in Tongass Narrows, near Ketchikan, AK (85 FR 673; January 7, 2020), the first one (for Phase 1) effective from March 1, 2020 through February 28, 2021. On December 28, 2020, NMFS received an application for the Renewal of the initial Phase I IHA. As described in the application for Renewal IHA, the activities for which incidental take is requested consist of activities that were covered by the initial Phase I authorization but were not completed prior to its expiration. As required, the applicant also provided a preliminary monitoring report (available at https:// www.fisheries.noaa.gov/action/ incidental-take-authorization-alaskadepartment-transportation-ferry-berthimprovements) which confirms that the applicant has implemented the required mitigation and monitoring, and which also shows that no impacts of a scale or nature not previously analyzed or authorized have occurred as a result of the activities conducted. The notice of the proposed Renewal incidental harassment authorization was published on March 5, 2021 (86 FR 12918).

Description of the Specified Activities and Anticipated Impacts

ADOT&PF's planned construction activities includes a subset of the work activities under the 2020 initial IHA (Phase I) on the ferry berths in Tongass Narrows. The project is comprised of four permanent project components, identical to those described in the initial IHA: New Revilla ferry berth, new Gravina Island Shuttle Ferry Berth and Terminal Improvements, Gravina Airport Ferry Layup Facility, and the Gravina Freight.

This project will improve the reliability of the transportation system as well as access to Gravina Island and Ketchikan International Airport. This renewal authorization allows the completion of Phase I activities beyond the initial IHA's expiration, February 28, 2021.

ADOT&PF's renewal request initially included one minor change to the specified activity described in the initial IHA (other than the removal of the activities that have already been completed), specifically, the request described a higher maximum number of piles that may be installed per day via impact and vibratory driving (up from a

max of three to eight piles). Following consideration of comments from the Marine Mammal Commission (MMC) during the public comment period as discussed below, we determined that the request to increase the number of piles that may be installed per day via impact and vibratory driving from a max of three to eight piles does not meet the requirements of a Renewal IHA described above and ADOT&PF withdrew their request to make this change on April 16, 2021.

As described in the proposed Renewal, we noted a small increase in the number of days of temporary pile driving work that it took to complete the work that occurred at one site under the initial IHA. However, that change does not affect or change the previous analysis of the temporary pile driving work to be conducted at the remaining three sites under this Renewal.

Regarding the analysis of impacts, NMFS identified two changes in NMFS' recommended methods (not the applicant's activity) since the initial IHA that neither change the determinations nor change the take estimates in a manner such that they exceed those analyzed and authorized by the initial IHA. First, as noted by the MMC during the public comment period (see below), NMFS has updated its analytical method for assessing the impacts of down-the-hole (DTH) pile installation since the initial IHA was issued and newer methods were not applied in the proposed Renewal. While applying the alternative method would result in somewhat larger Level A harassment zones, as described below, a re-analysis of this activity under the alternative approach is not necessary or warranted in this situation, and therefore does not affect the analysis or findings from the initial IHA or the Renewal conditions being met.

Second, as previously described in the proposed Renewal, the driving of DTH holes for one of the structures (tension anchors) utilized in the applicant's activity and described in the initial IHA, was initially assessed by the applicant and NMFS as unlikely to result in the take of marine mammals because of the size of the holes, which are smaller than the holes for the structures specifically associated with take in the initial IHA (rock sockets). However, new sound source measurement data indicate source levels from DTH driving of tension anchors high enough to potentially result in the take of marine mammals. Accordingly, take from DTH driving of tension anchors is appropriately characterized and quantified the same as the DTH driving for rock sockets addressed in the

initial IHA (though impacts are thought to be less, given the small size of the holes, which are 6-8 inches, as opposed to the smallest 24-in rock socket). Take in the initial IHA and Renewal IHA is estimated based on days of in-water work. Some of the driving days used to calculate take in the initial IHA included DTH for tension anchors, but where DTH drilling of tension anchors may occur on days without other driving, driving days have been added in the Renewal. Nonetheless, the total days of driving under the Renewal are still fewer than the total days of driving under the initial IHA, tension anchor driving activity was discussed in the initial IHA, quantitatively the impacts on marine mammals under the Renewal are less than those from the rock socket DTH under the initial IHA, and the mitigation for DTH remains the same and appropriate.

In summary, the activity is identical to the initial IHA and includes four methods of pile installation: Vibratory and impact hammers, DTH holes created for rock sockets for the piles and smaller DTH holes for the installation of tension anchors at some locations (see Tables 1 and 2). Moreover, Phase II activities will only begin upon the completion of Phase I, as stated in the 2020 initial IHA and proposed renewal (so there will be no overlap between the remaining Phase I activities under the Renewal IHA and the Phase II activities).

The amount of take requested for the Renewal IHA reflects the amount of remaining work under Phase I, the methods in the initial IHA (which remain appropriate for this Renewal), and consideration of marine mammal monitoring data from the 2020 construction activities indicating detection of notably fewer marine mammals within harassment zones than were authorized to be taken in the initial IHA. The potential effect of ADOT&PF's activities is to take a small number of eight species of marine mammals (Steller sea lion, harbor seal, harbor porpoise, Dall's porpoise, Pacific white-sided dolphin, killer whale, humpback whale, and minke whale) by Level B harassment and three (harbor seal, harbor porpoise, and Dall's porpoise), by Level A harassment incidental to underwater noise resulting from construction associated with the planned activities.

Detailed Description of the Activity

As discussed earlier, this is a Renewal to complete the subset of the activity not completed under the initial IHA (85 FR 673; January 7, 2020). Due to construction schedule delays,

designated work was only conducted on 56 of the estimated 101 days of the initial IHA. ADOT&PF installed 11 temporary piles (of which one has already been removed) and 41 permanent piles over approximately 23 construction days in 2020. As of the submission of their Renewal request, ADOT&PF expected to drive pile for 40 more days and complete installation of 27 24-inch trestle piles, 5 24-inch bridge abutment piles, 15 24-inch floating fender dolphin piles, 27 remaining sheet piles, and 10 30-inch steel float piles for the Revilla New Ferry Berth and Upland Improvements between January 4 and February 28, 2021 under the 2020 initial

As of February 2, 2021, the following work remains to be completed during the one-year 2021 Renewal IHA: Installation of 192 piles, 73 rock sockets, and 78 tension anchors and installation (38) and removal (40) of temporary piles. This work is expected to take no more than 90 days of in-water piling activities. Although some work may have been completed between February 2 and the expiration of the initial IHA (February 28), the applicant requested authorization for the work remaining as of February 2 outlined in Tables 1 and 2. The Renewal IHA will be effective through February 28, 2022.

The effects of DTH driving were fully assessed in the initial IHA. At the time the initial IHA analysis was conducted, the DTH driving of the relatively smaller holes for tension anchors was described, but was not anticipated to produce sound levels that would result in the incidental take of marine mammals. However, NMFS' consideration of new monitoring data from the White Pass & Yukon Route project (Reyff, 2020) now suggests that sound levels from the DTH driving of the 6 to 8-inch holes for these particular structures may be high enough to result in take, and the take estimate in this Renewal considers this. as described above.

Regarding the number of days of temporary pile driving, the initial IHA application specified 7-11 total days of temporary pile driving would be needed to complete all projects during Phase I. The temporary pile driving at the Revilla New Ferry Berth required 7 days, instead of the 2-3 days listed in the IHA application, because of subsurface boulders and weather conditions. It is expected that, therefore, more total days than initially anticipated will be needed to complete the temporary pile driving over the entire Phase I period. However, the renewal application describes 5-8 days of temporary pile installation to complete the three remaining

component projects, which is identical to what was described in the initial IHA.

Considering the information above, the total number of days of pile driving remaining (90) under the Renewal IHA is still fewer than included in the initial IHA (101).

The mitigation and monitoring will be identical to that of the 2020 initial IHA,

with the indicated mitigation for the DTH driving of 24-in piles applied to DTH driving of the smaller tension anchors. A detailed description of the construction activities may be found in the notices of the proposed (84 FR 34134; July 17, 2019) and final initial IHAs (85 FR 673; January 7, 2020). All documents associated with the 2020

initial IHA (i.e., the IHA application, proposed IHA, final IHA, public comments, monitoring reports, etc.) can be found on NMFS's website, https://www.fisheries.noaa.gov/action/incidental-take-authorization-alaska-department-transportation-ferry-berth-improvements.

TABLE 1—PERMANENT PILE DETAILS AND ESTIMATED EFFORT REQUIRED FOR PILE INSTALLATION DURING 2021 RENEWAL

Project component/pile type	Number of piles	Number of rock sockets	Number of tension anchors	Average vibratory duration per pile (minutes)	Average strikes per pile for DTH for rock sockets and tension anchors	Impact strikes per pile	Average duration (minutes) per pile for vibratory	Average piles per day (range)	Days of installation
Revilla New Ferry Berth and									
Upland Improvements:	45	_	10	00	NI/A	000	00	4.5 (4.0)	00
24" Pile Diameter	15 2	0	12 14	30 30	N/A N/A	200 200	30 30	1.5 (1–3)	36 12
30" Sheet Pile	0	Completed	14	30	IN/A	200	30	1.5 (1–3)	12
New Gravina Island Shuttle	U	Completed							
Ferry Berth/Related Terminal									
Improvements:									
24" Pile Diameter	65	52	25	15	25,000	50	15	1.5 (1–3)	44
30" Pile Diameter	8	4	4	15	25,000	50	15	1.5 (1–3)	5
27.6" Sheet Pile	74	N/A	N/A	15	N/A	N/A	15	6 (6–12)	12
Gravina Airport Ferry Layup Fa-								((),	·-
cility:									
18" Pile Diameter	3	0	0	15	N/A	50	15	1.5 (1-3)	2
30" Pile Diameter	12	12	10	15	25,000	50	15	1.5 (1–3)	8
Gravina Freight Facility:									
20" Pile Diameter	6	0	6	15	N/A	50	15	1.5 (1–3)	4
24" Pile Diameter	3	3	3		25,000	50	15	1.5 (1–3)	2
30" Pile Diameter	4	2	4	15	25,000	50	15	1.5 (1–3)	3
Phase I total	192	73	78						a 128

a Identically to the initial IHA, the assumption that two pieces of equipment are to be used concurrently on 30 percent of planned driving days reduces in-water construction to 90 days.

TABLE 2—Numbers of Temporary Piles Planned To Be Installed and Removed for Each Project Component in 2021

Project component	Number of temporary piles	Average vibratory duration per pile for installation (minutes)	Average vibratory duration per pile for removal (minutes)	Days of installation	Days of removal	Piles per day
Revilla New Ferry Berth and Upland Improvements.	8	0-currently installed	15	0	2 to 3	4 to 6
New Gravina Island Shuttle Ferry Berth/Related Ter- minal Improvements.	12	15	15	2 to 3	2 to 3	4 to 6
Gravina Airport Ferry Layup Facility.	8	15	15	1 to 2	0.75 to 2	4 to 6
Gravina Freight Facility	12	15	15	2 to 3	2 to 3	4 to 6
Total	40	480 (8 hrs)	600 (10 hrs)	5–8	7–11	

Description of Marine Mammals

A description of the marine mammals in the area of the activities for which take is authorized here, including information on abundance, status, distribution, and hearing, may be found in the **Federal Register** notices of the proposed (84 FR 34134; July 17, 2019) and final (85 FR 673; January 7, 2020)

IHAs for the initial authorization. NMFS has reviewed the monitoring data from the initial IHA, recent draft Stock Assessment Reports (SARs), information on relevant Unusual Mortality Events, and other scientific literature. As discussed in the notice of the proposed renewal, the 2020 SARs indicated the estimated abundance of the West Coast

Transient and Northern Resident Killer whale stocks and Steller sea lion Eastern U.S. stock have increased slightly, whereas the Clarence Strait harbor seal stock decreased slightly. However, we have determined that neither the above, nor any other new information, affects which species or stocks have the potential to be affected or the pertinent

information in the Description of the Marine Mammals in the Area of Specified Activities sections contained in the supporting documents for the initial IHA.

Potential Effects on Marine Mammals and Their Habitat

A description of the potential effects of the specified activity on marine mammals and their habitat for the activities for which take is authorized may be found in the Federal Register notices of the proposed (84 FR 34134; July 17, 2019) and Final (85 FR 673; January 7, 2020) IHAs for the initial authorization. NMFS has reviewed the monitoring data from the initial IHA, recent draft SARs, information on relevant Unusual Mortality Events, and other scientific literature, and determined that neither this nor any other new information affects our initial analysis of impacts on marine mammals and their habitat. The applicant submitted the required preliminary monitoring results and the monitoring

to date does not contradict the original take calculations or indicate impacts of a scale or nature not previously analyzed or authorized.

Estimated Take

A detailed description of the methods and inputs used to estimate take for the specified activity are found in the Federal Register notices of the proposed (84 FR 34134; July 17, 2019) and final (85 FR 673; January 7, 2020) IHAs for the initial authorization. Specifically, the days of operation, and marine mammal density/occurrence data applicable to this authorization remain unchanged from the previously issued IHA, with the exception of the fact that there are fewer days of operation since this activity is a subset of that covered in the initial IHA. Only the inclusion of the DTH driving of tension anchors (which was described in the initial IHA) as a potential source of take has changed, but this is not outside the scope of what was previously analyzed in the initial IHA. Specifically, the take

from DTH driving of these structures is calculated identically to that of the 24-inch DTH driving (though the holes and impacts are smaller), the number of total driving days (90) is fewer than the initial IHA (101), and the authorized take does not exceed that included in the initial IHA. Similarly, the stocks taken, methods of take, and types of take remain unchanged from the previously issued IHA.

The rationale and take estimates presented in the initial proposed IHA (which were based on the likelihood of an individual or group entering the area some number of times during the activity, as opposed to being based on a species' density) remain applicable (Table 3). Further, the marine mammal detections reported in the preliminary monitoring report, which were very low as compared to the number authorized in relation to the activities conducted, do not suggest impacts of a scale or nature not previously analyzed or authorized.

TABLE 3—TAKE NUMBERS TO BE AUTHORIZED BY SPECIES/STOCK

Species	DPS/stock	Estimated number of exposures to level B harassment	Estimated number of exposures to level A harassment	Total estimated exposures (level A and level B harassment)	
Steller sea lion	Eastern DPS	1,800	0	1,800	
Harbor seal	Clarence Strait	765	18	783	
Harbor porpoise	Southeast Alaska	109	15	124	
Dall's porpoise	Alaska	317	15	332	
Pacific white-sided dolphin	North Pacific	92	0	92	
Killer whale	Alaska Resident	144	0	144	
	Northern Resident				
	West Coast Transient				
Humpback whale 1	Hawaii DPS	238	0	238	
•	Mexico DPS	15	0	15	
Minke whale	Alaska	7	0	7	

Note: DPS = distinct population segment.

Description of Mitigation, Monitoring and Reporting Measures

The mitigation, monitoring, and reporting measures included as requirements in this authorization are identical to those included in the Federal Register notice announcing the issuance of the initial IHA (with minor clarifications on DTH terminology and applicability of terms to DTH driving where it was previously unclear), and the same mitigation identified for DTH drilling of 24-inch rock sockets will be applied to the DTH driving of the smaller (6-8-inch) tension anchors. The discussion of the least practicable adverse impact included in the notices of the proposed initial IHA (84 FR

34134; July 17, 2019) and issuance of the initial IHA remains accurate. As noted previously, the applicant withdrew the request to increase the maximum number of piles per day from three to eight, so the discussion of increased Level A zones in the proposed Renewal no longer applies.

Mitigation Measures

The following measures are included in this renewal:

• Conduct briefings between construction supervisors and crews and the monitoring team prior to the start of all pile driving activity, and when new personnel join the work, to explain responsibilities, communication procedures, marine mammal monitoring protocol, and operational procedures;

- For in-water heavy machinery work other than pile driving/removal and drilling (e.g., use of barge-mounted excavators, or dredging), if a marine mammal comes within 10 m, operations must cease and vessels must reduce speed to the minimum level required to maintain steerage and safe working conditions. This type of work could include the following activities: (1) Movement of the barge to the pile location; or (2) positioning of the pile on the substrate via a crane (i.e., stabbing the pile);
- Work must only occur during daylight hours, when visual monitoring of marine mammals can be conducted;

¹ Assumes that 6.1 percent of humpback whales exposed are members of the Mexico DPS (Wade et al. 2016).

- For any marine mammal species for which take by Level B harassment has not been requested or authorized, inwater pile installation/removal and drilling will shut down immediately when the animals are sighted; and
- If take by Level B harassment reaches the authorized limit for an authorized species, pile installation will be stopped as these species approach the Level B harassment zone to avoid additional take of them.

Establishment of Shutdown Zone for Level A Harassment—For all pile driving/removal and DTH activities, ADOT&PF will establish a shutdown zone. 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 within the zone (or in anticipation of an animal entering the defined area). Shutdown zones will vary based on the activity type, marine mammal hearing group, and in the case of impact pile driving, additional details about the activity including the expected number of pile strikes required, size of the pile, and number of piles to be driven during that day (See

Table 4). The placement of protected species observers (PSOs) during all pile driving, pile removal, and drilling activities will ensure that the entire shutdown zone is visible during pile installation.

The shutdown zones shown in Table 4 apply when a single piece of equipment is in use. In addition, ADOT&PF will implement a shutdown zone of 100 m for each vibratory hammer on days when it is anticipated that multiple vibratory hammers will be used.

TABLE 4—SHUTDOWN ZONES DURING USE OF A SINGLE PIECE OF EQUIPMENT

Activity	Pile or hole size (inches)	Minutes per pile or strikes per pile	Piles installed or removed per day	Level B harassment isopleth (m)	Shutdown distances (m)				
•					LF	MF	HF	PW	OW
Vibratory Installation	30	30 min	3 3 10	6,310 5,420 4,650			50		
Vibratory Removal	24, 16	30 min	5	5,420					
DTH Rock Sockets and Tension Anchors.	30	25,000 strikes	3	12,030	70	50	60	50	50
	24, 8	25,000 strikes	3		60	50	50	50	50
Impact Installation	30	50 strikes	3	2,160	250	50	250	150	50
			2		200		200	100	
			1		100		150	100	
		200 strikes	3		550		650	300	
			2		400		500	250	
			1		300		300	150	
	24	50 strikes	3	1,000	150		150	100	
			2		100		150	50	
		000 1.1	1		100		100	50	
		200 strikes	3		300		350	200	
			2		250		300	150	
	10	EO atrikas	1		150		200	100	
	18	50 strikes	2		150 100		150 150	100 50	
			4		100			50	
			'		100		100	50	

Establishment of Monitoring Zones for Level B Harassment—ADOT&PF will establish monitoring zones (see Table 3 of the initial final IHA and proposed Renewal IHA), based on the Level B harassment zones which are areas where sound pressure levels (SPLs) are equal to or exceed the 160 dB rms (decibel root mean square) threshold for impact driving and the 120 dB rms threshold during vibratory driving, vibratory removal, and DTH. Monitoring zones provide utility for observing marine mammals by establishing monitoring protocols for areas adjacent to the shutdown zones. Monitoring zones enable observers to be aware of and communicate the presence of marine mammals in the project area outside the shutdown zone and thus prepare for a potential halt of activity should the animal enter the shutdown zone. On days and at times when a single piece of pile installation or removal equipment will be used, the Level B

harassment zone will be monitored and implemented according to pile size, type, and installation method. The largest Level B harassment zone extends to a radius of 12,023 m in at least one direction up or down Tongass Narrows when a single piece of driving equipment is being utilized, making it impracticable for the PSOs to consistently view the entire harassment area. Due to this, detections of exposures above the Level B harassment thresholds will be recorded and takes will be estimated based upon the number of these observed detections and the percentage of the Level B harassment zone that was not visible.

When two or more pieces of equipment are used simultaneously, and the noise they produce is not continuous or is a combination of continuous and impulsive, Table 4, above, will be followed to define the Level A and Level B harassment monitoring zones for each piece of equipment.

On days when multiple pieces of equipment that produce continuous noise are used simultaneously, source levels will be determined as shown in Table 9, Table 10, Table 11, and Table 12 of the initial final IHA (85 FR 673; January 7, 2020) with the resulting harassment zones being defined in Table 4 of the final initial IHA and proposed Renewal IHA. The calculated source level will be used to determine the Level B harassment monitoring zones in accordance with values depicted in Table 14 of the initial final IHA (85 FR 673; January 7, 2020). The assumption stands that a minimum of two pieces of equipment will be used on 30 percent of construction days; therefore, decreasing the total number of pile installation days from 128 to 90 days as well as the number of days when the Level B harassment zone size could exceed 12,023 m.

Soft Start—The use of a soft-start procedure provides 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 will be required to provide an initial set of strikes from the hammer at reduced percent energy, each strike followed by no less than a 30-second waiting period. This procedure will be conducted a total of three times before impact pile driving begins. Soft Start is not required during vibratory pile driving and removal activities. If a marine mammal is present within the Level A harassment zone, soft start will be delayed until the animal leaves the Level A harassment zone. Soft start will begin only after the PSO has determined, through sighting, that the animal has moved outside the Level A harassment zone or has not been observed for 15 minutes. If a marine mammal is present in the Level B harassment zone, soft start may begin and a take by Level B harassment will be recorded. Soft start up may occur when these species are in the Level B harassment zone, whether they enter the Level B harassment zone from the Level A harassment zone or from outside the

Pre-Activity Monitoring—Prior to the start of daily in-water construction activity, or whenever a break in pile driving of 30 minutes or longer occurs, the PSO will observe the shutdown and monitoring zones for a period of 30 minutes. The shutdown zone will be 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 Level B harassment 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 Level B harassment zone. When a marine mammal permitted for take by Level B harassment is present in the Level B harassment zone, piling activities may begin and take by Level B harassment will be recorded. As stated above, if the entire Level B harassment zone is not visible at the start of construction, piling or drilling activities can begin. If work ceases for more than 30 minutes, the pre-activity monitoring of both the Level B harassment and shutdown zone will commence.

Timing Restrictions—ADOT&PF plans to implement the Essential Fish Habitat (EFH) Conservation Recommendations developed by NMFS. These include a no in-water work timing window for three project components, Revilla New Ferry Berth and Upland Improvements, Gravina Airport Ferry Layup Facility, and Revilla Refurbish Existing Ferry Berth Facility, with no in-water work occurring between March 1 and June 15. Implementation of this timing window will likely reduce exposure/take of marine mammals to levels below what has been predicted, because some project locations will be able to install piles when other locations may not.

Based on our evaluation of the applicant's required measures NMFS has determined that the mitigation measures provide the means of effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Monitoring and Reporting

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 action; 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 would be conducted 30 minutes before, during, and 30 minutes after pile driving/removal and drilling activities. In addition, observers shall

record all incidents of marine mammal occurrence), and shall document any behavioral reactions in concert with distance from piles being driven or removed. Pile driving activities include the time to install or remove a single pile or series of piles, as long as the time elapsed between uses of the pile driving equipment is no more than 30 minutes.

There will be at least one PSO present at or near each construction site during in-water pile installation and removal so that all Level A harassment zones and shutdown zones are monitored by a dedicated PSO at all times. PSOs will not perform duties for more than 12 hours in a 24-hour period. PSOs will be land-based observers, positioned at the best practical vantage points. At least one other PSO for each active worksite will begin at the central worksite and travel along the Tongass Narrows until they have reached the edges of the monitoring zones, based on the Level B harassment zones. These PSOs will then monitor the edges of the monitoring zone and as much as possible of the rest of the monitoring zone, looking for animals entering the Level B harassment zone. If waters exceed a sea state that restricts the PSO's ability to make observations within the Level A harassment zones (e.g., excessive wind or fog), pile installation and removal must cease. Pile driving must not be reinitiated until the entire relevant Level A harassment zones are visible.

When combinations of one DTH hammer with a vibratory hammer, two DTH hammers, or two DTH hammers with a vibratory hammer are used simultaneously, creating a Level B harassment zone that is greater than 12,023 m in radius, one additional PSO (at least two total) will be stationed at the northernmost land-based location at the entrance to Tongass Narrows. One PSO will focus on Tongass Narrows, specifically watching for marine mammals that could approach or enter Tongass Narrows and the project area. The second PSO will look out into Clarence Strait, watching for marine mammals that could swim through the ensonified area. This monitoring requirement for concurrent driving scenarios was not included in the proposed initial IHA, but was included in the final initial IHA. No additional PSOs will be required at the southernmost monitoring location because the Level B harassment zones are truncated to the southeast by islands, which prevent propagation of sound in that direction beyond the confines of Tongass Narrows. Takes by Level B harassment will be recorded by PSOs and extrapolated based upon the number of observed takes and the

percentage of the Level B harassment zone that was not visible.

With this configuration, PSOs can have a full view of the Level A harassment zone and awareness of as much of the Level B harassment zone as possible. This monitoring will provide information on marine mammal occurrence within Tongass Narrows and how these marine mammals are impacted by pile installation and removal.

All PSOs will be trained in marine mammal identification and behaviors and are required to have no other project-related tasks while conducting monitoring. In addition, monitoring will be conducted by qualified observers, who will 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. Qualified observers are trained and/or experienced professionals, with the following minimum qualifications:

- Independent observers (i.e., not construction personnel);
- Observers must have their Curriculum Vitae/resumes submitted to and approved by NMFS;
- · Advanced education in biological science or related field (i.e., undergraduate degree or higher). Observers may substitute experience or training for education;
- Experience and ability to conduct field observations and collect data according to assigned protocols (this may include academic experience);
- At least one observer must have prior experience working as an observer;
- Experience or training in the field identification of marine mammals, including the identification of behaviors;
- Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;
- Writing skills sufficient to prepare a report of observations including but not limited to the number and species of marine mammals observed: dates and times when in-water construction activities were conducted; dates, times, and reason for implementation of mitigation (or why mitigation was no implemented when required); and marine mammal behavior; and
- Ability to communicate orally, by radio or in person, with project personnel to provide real-time information on marine mammals observed in the area as necessary.

Reporting

NMFS is requiring that ADOT&PF submit a preliminary marine mammal monitoring report for the work covered under the initial IHA and this renewal at least 4 months prior to beginning the work covered under their second IHA, referred to as Phase II (85 FR 673; January 7, 2020). This preliminary report must contain all items that would be included in the draft final report (see below). This will allow NMFS to assess the impact of the activities relative to the analysis presented here, and modify the IHA for Phase II if the preliminary monitoring report shows unforeseen impacts on marine mammals in the area. If needed, NMFS will publish an amended proposed IHA, describing any changes but referencing the original IHA for Phase II, and include an opportunity for the public to comment on the amended proposed authorization.

In addition to the preliminary monitoring report discussed above, separate draft marine mammal monitoring reports must be submitted to NMFS within 90 days after the completion of both Phase I and Phase II pile driving, pile removal, and drilling activities. These reports will include an overall description of work completed, a narrative regarding marine mammal sightings, and associated PSO data sheets. Specifically, the reports must include:

- Date and time that monitored activity begins and ends;
- Construction activities occurring during each daily observation period;
- Weather parameters (e.g., percent cover, visibility);
- Water conditions (e.g., sea state, tide state);
- Species, numbers, and, if possible, sex and age class of marine mammals;
- Description of any observable marine mammal behavior patterns, including bearing and direction of travel and distance from pile driving activity;
- Distance from pile driving/removal activities to marine mammals and distance from the marine mammals to the observation point;
- Locations of all marine mammal observations; and
- · An estimate of total take based on proportion of the monitoring zone that was observed.

If no comments are received from NMFS within 30 days, that phase's draft final report will constitute the final report. If comments are received, a final report for the given phase addressing NMFS comments must be submitted within 30 days after receipt of comments.

In the event that personnel involved in the construction activities discover

an injured or dead marine mammal, ADOT&PF shall report the incident to the Office of Protected Resources, NMFS and to the Alaska Regional Stranding Coordinator as soon as feasible. The report must include the following information:

• Time, date, and location (latitude/ longitude) of the first discovery (and updated location information if known and applicable);

• Species identification (if known) or description of the animal(s) involved;

 Condition of the animal(s) (including carcass condition if the animal is dead);

• Observed behaviors of the animal(s), if alive;

 If available, photographs or video footage of the animal(s); and

• General circumstances under which the animal was discovered.

Public Comments

A notice of NMFS' proposal to issue a Renewal IHA to ADOT&PF was published in the **Federal Register** on March 5, 2021 (86 FR 12918). That notice either described, or referenced descriptions of, the ADOT&PF's activity, the marine mammal species that may be affected by the activity, the anticipated effects on marine mammals and their habitat, proposed amount and manner of take, and proposed mitigation, monitoring and reporting measures. NMFS received a comment letter from the MMC. A summary of the comments and our responses are provided below, and the comment letter is available online at https:// www.fisheries.noaa.gov/action/ incidental-take-authorization-alaska-

department-transportation-ferry-berthimprovements.

Comment: The Commission recommended that NMFS deny ADOT&PF's request to renew its IHA for Phase I activities, based on its assessment that the renewal issuance criteria were not met. First, they assert that the renewal request was not received 60 days prior to when the renewal is needed, as required, noting that while we indicated that ADOT&PF requested their renewal on December 28, we posted materials dated January 12. Second, they assert that the request did not meet the requirement that any changes in the activity are minor, specifically noting the applicant's change to the activity from 3 piles/day to 8 piles/day, and also a change in NMFS' general approach to analyzing Level A harassment for DTH piling (i.e., considering it an impulsive source), and further suggesting that the required mitigation and PSOs would be inadequate given the increased zones.

Third, the MMC asserted that the requirement that preliminary monitoring results do not indicate impacts of a scale or nature not previously analyzed was not met, specifically citing the fact that ADOT&PF did not "extrapolate" takes as required in areas that were not visually monitored.

Response: Regarding the date ADOT&PF requested the renewal, it is our responsibility to work with applicants to ensure that adequate and complete information is included in applications and renewal requests. ADOT&PF submitted their initial renewal request on December 28, 2020 and then revised their request, providing updated information on the date indicated, January 12, 2021. There is no requirement in the MMPA or our regulations to post all versions of applications on our website and we have not typically done so. We further note that while the requirement to notify NMFS of the need for a renewal 60 days in advance of the needed effective date is presented as a renewal condition on our website, the MMC's comments have alerted us to the fact that the purpose of this requirement may not be clear. The 60-day deadline has nothing to do with ensuring the appropriateness of the project for renewal. The intention is to put renewal requesters on notice that they should request a renewal at least 60 days prior to the desired effective date to ensure we have adequate time to process the request, including publication of the proposed Renewal IHA and providing the additional 15 days for public comment. The intent is not to disqualify requesters from the renewal process if they are later than 60 days from the requested effective date of the Renewal IHA, but rather to provide potential requesters notice that we typically need at least 60 days to process their request and cannot ensure completion of the Renewal process in fewer than 60 days.

As the MMC notes one of the conditions of a Renewal IHA is that there are no more than minor changes in the applicant's activities from those described and analyzed in the initial IHA. As described above, ADOT&PF withdrew their request to increase the maximum number of piles that could be installed by impact driving in a day.

Regarding the change in the DTH calculation methods for Level A harassment raised by the MMC, we first note that it is not a change in the applicant's planned activity, but rather a change in NMFS' approach since the initial IHA was issued. As a general matter, renewal conditions are focused on ensuring the activity is identical, or

has no more than minor changes, and the absence of new information suggesting impacts of a nature or scale not initially analyzed and affecting the initial findings, not on changes in NMFS recommended methods.

As described in more detail in our recent response to a similar comment for the CTJV Renewal (86 FR 14609, March 17, 2021), the DTH data available to inform the analytical approach are limited and the updated interim methodology adopted by NMFS moving forward, and referenced in the MMC's comment, takes the most conservative approach to both Level A and Level B harassment estimation, with the expectation that take is likely overestimated using this method. The fact that NMFS is using the new approach moving forward does not mean the prior approach is unsound. Here, while the Level A harassment zones would be somewhat larger using the updated methodology, it would not change the take estimates for any species or stock, the nature of the expected impacts, or any of our findings. The take estimates in the initial IHA were based on the prediction that a very small number of three species may occasionally potentially approach close enough within a given amount of days/months (which are still fewer for this renewal than for the initial IHA) and stay long enough to incur PTS, rather than upon any density/area calculations. It is highly unlikely that a change in the Level A harassment zones would result in any change in the potential for any of this to occur. Further, as described below, the monitoring to date indicates that far fewer marine mammals are entering the activity area than expected, and the mitigation measures described in the initial IHA remain adequate and appropriate. Accordingly, as required under the Renewal conditions, upon review of the request for Renewal, the status of the affected species or stocks, the preliminary monitoring report, and any other pertinent information, we have determined that there are no changes in the activities, the mitigation and monitoring measures will remain the same and appropriate, and the findings in the initial IHA remain valid.

Regarding the preliminary monitoring information provided by the current IHA Holder and applicant for the Renewal, significantly fewer marine mammals of all species were detected and reported within harassment zones than were predicted and authorized (17 reported takes, less than 1 percent of the total take authorized across species, and no more than 3 percent of any species or stock) given the amount of activity

conducted. Regarding the MMC's comment that ADOT&PF was required to extrapolate take based on the unseen portion of the zones, the requirement does not apply in this case because PSOs positioned themselves along the Narrows in a manner that enabled a full view of the entire Level B harassment zones. The Level B harassment zones were completely visible throughout the work conducted to date, and so extrapolation was not necessary as there were no unseen portions of the zones. The preliminary monitoring data provided by the applicant clearly does not indicate impacts of a scale or nature not previously analyzed or authorized.

As described above, despite development of an alternative approach to DTH pile driving since the initial IHA that is not necessary to apply here, this project qualifies for a renewal in that the applicant proposes to complete a subset of the initially analyzed activities with no changes, the preliminary monitoring shows no impacts of a scale or nature beyond those previously analyzed (in fact they were significantly less than that predicted), the total number of days of driving and the amount of take authorized are both less than that in the initial IHA, the mitigation and monitoring measures remain the same, and upon review NMFS has determined that the findings in the initial IHA remain valid. We therefore decline to accept the Commission's recommendation that we deny the renewal request.

Comment: The MMC further notes that NMFS did not abide by one of the basic tenets of its process that it will provide direct notice of a proposed renewal by email, phone, or postal service (in this order) to persons who commented on the proposed initial authorization because it did not inform the MMC of the renewal request.

Response: NMFS acknowledges that our inadvertent lack of direct notice to the MMC was an error in our current practice and we have taken steps to ensure that we do not miss notifying the MMC about future proposed Renewal IHA notices. Nonetheless, our oversight in providing the MMC with direct notice of the proposed Renewal does not necessitate the denial of the renewal, which otherwise qualifies for issuance based on the renewal conditions. Because the MMC was the only person or entity that commented on the initial proposed IHA, there is no one else who did not receive direct notice. In addition, the MMC received notice of the proposed Renewal IHA through the March 5, 2021 Federal Register notice and was able to review the proposed Renewal notice and provide its

comments within the needed timeframe. We likewise were able to fully consider the MMC's comments within the needed timeframe. Therefore, our inadvertent failure to provide the MMC with direct notice was functionally harmless in this case.

Comment: The MMC asserts that NMFS wrongly considered the two phases of ADOT&PF's project and that we ignored the possibility that ADOT&PF would conduct both phases simultaneously.

Response: We considered this issue in the proposed renewal notice. On page 12920 (86 FR 12918; March 5, 2021) we noted that Phase I and Phase II of the work would not occur simultaneously. We have emphasized this again in this final Renewal IHA notice.

Comment: Based on the asserted and perceived problems noted above, the MMC recommends that NMFS formally revoke its authorization renewal process

Response: NMFS does not agree with the MMC's recommendation, and does not adopt it. First, as noted above, we have concurred with the MMC's interpretation of the increase in the maximum number of piles per day from 3 to 8, and, following our recommendation, ADOT&PF rescinded the request for this change. Additionally, as discussed above the MMC asserted numerous problems that in fact were not true, were based on the MMC's opinion, or did not appreciably impact the MMC's ability to comment on the proposed Renewal, and thus do not establish problems with this Renewal IHA or systemic problems with the renewal process and its compliance with Section 101(a)(5)(D) of the MMPA

Further, we note in prior responses to comments about IHA Renewals (e.g., 84 FR 52464; October 2, 2019, 85 FR 53342; August 28, 2020; and 86 FR 14606; March 17, 2021), NMFS has explained how the renewal process, as implemented, is consistent with the statutory requirements contained in section 101(a)(5)(D) of the MMPA, provides additional efficiencies beyond the use of abbreviated notices, and, further, promotes NMFS' goals of improving conservation of marine mammals and increasing efficiency in the MMPA compliance process. Therefore, we intend to continue implementing the Renewal process and will adjust its conditions and implementation as needed.

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 determined that the issuance of the IHA Renewal qualifies to be categorically excluded from further NEPA review.

Determinations

NMFS has concluded that there is no new information suggesting that our analysis or findings should change from those reached for the initial IHA. This includes consideration of all information discussed above, as well as stock abundance information. The estimated abundance of the West Coast Transient and Northern Resident Killer whale stocks and Steller sea lion Eastern U.S. stock have increased slightly, whereas, the Clarence Strait harbor seal stock decreased slightly. Based on the information and analysis contained here and in the referenced documents, NMFS has determined the following: (1) The required mitigation measures will effect the least practicable impact on marine mammal species or stocks and their habitat; (2) the authorized takes will have a negligible impact on the affected marine mammal species or stocks; (3) the authorized takes represent small numbers of marine mammals relative to the affected stock abundances; (4) ADOT&PF's activities will not have an unmitigable adverse impact on taking for subsistence purposes as no relevant subsistence uses of marine mammals are implicated by this action, and; (5) appropriate monitoring and reporting requirements are included.

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 NMFS' Alaska Regional Office.

NMFS' Alaska Region issued a revised Biological Opinion to NMFS' Office of Protected Resources on December 19, 2019 which concluded that issuance of IHAs to ADOT&PF is not likely to jeopardize the continued existence of Mexico DPS humpback whales. Since then, the regional office determined that issuance of the renewal IHA will not alter take or require re-initiation of the consultation.

Renewal

As a result of these determinations, NMFS has issued a Renewal IHA to ADOT&PF for the taking of marine mammals incidental to the remaining activities of Phase I of the two-phase ferry berth improvements and construction in Tongass Narrows, near Ketchikan, AK from the date of issuance through February 28, 2022, provided the previously described mitigation, monitoring, and reporting requirements are incorporated. The IHA can be found at https://www.fisheries.noaa.gov/ national/marine-mammal-protection/ incidental-take-authorizationsconstruction-activities.

Dated: April 28, 2021.

Catherine Marzin,

Acting Director, Office of Protected Resource, National Marine Fisheries Service.

[FR Doc. 2021–09451 Filed 5–4–21; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XB016]

South Atlantic 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 South Atlantic Fishery Management Council (Council) will hold a meeting of its Private Recreational Reporting Workgroup evaluating reporting alternatives for the private recreational snapper grouper fishery.

DATES: The Workgroup meeting will be held via webinar from 9 a.m. to 12 p.m. on Wednesday, May 26, 2021.

ADDRESSES: *Meeting address:* The meeting will be held via webinar.

Webinar registration is required. Details are included in **SUPPLEMENTARY INFORMATION**.

Council address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N. Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, SAFMC; phone: (843) 302–8440 or toll free: (866) SAFMC–10; fax: (843) 769–4520; email: kim.iverson@safmc.net.

SUPPLEMENTARY INFORMATION: Meeting information, including the webinar link, agenda, and briefing book materials will be posted on the Council's website at: http://safmc.net/safmc-meetings/ council-meetings/.

Agenda items include:

- 1. Review recreational reporting by Highly Migratory Species anglers
- 2. Review recreational reporting for Mid-Atlantic Tilefish anglers
- 3. Review NOAA Fisheries Marine Recreational Information Program's (MRIP) Large Pelagic Survey
- 4. Identify topics for discussion or presentation at the next meeting

Written comments may be submitted electronically via the Council's website at http://safmc.net/safmc-meetings/council-meetings/. Comments become part of the Administrative Record of the meeting and will automatically be posted to the website and available for Council consideration.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the Council office (see ADDRESSES) 5 days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: April 29, 2021.

Tracey L. Thompson,

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

[FR Doc. 2021-09420 Filed 5-4-21; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XB050]

Pacific 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 Pacific Fishery
Management Council's (Pacific Council)
Ad Hoc Climate and Communities Core
Team (CCCT) is holding an online
meeting, which is open to the public.

DATES: The online meeting will be held Friday, May 21, 2021, beginning at 1:30 p.m., Pacific Time and continuing until business is completed.

ADDRESSES: This meeting will be held online. Specific meeting information, including directions on how to join the meeting and system requirements will be provided in the meeting announcement on the Pacific Council's website (see www.pcouncil.org). You may send an email to Mr. Kris Kleinschmidt (kris.kleinschmidt@noaa.gov) or contact him at (503) 820–2412 for technical assistance.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

SUPPLEMENTARY INFORMATION: At this meeting, the CCCT will discuss the drafting of a final report for the Fishery Ecosystem Plan Climate and Communities Initiative. The report will be based on a review of information generated during the Initiative and make recommendations on tools, products, and processes to build consideration of, and adaption to, climate change into ongoing Council processes. The report is scheduled for Council consideration at its September 2021 meeting. The CCCT will also discuss additional activities, including future meetings, related to completion of the report and the Initiative.

A meeting agenda will be posted on the Pacific Council website at least one week before the meeting date.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section

305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt, (kris.kleinschmidt@noaa.gov; (503) 820–2412), at least 10 business days prior to the meeting date.

Dated: April 29, 2021.

Tracey L. Thompson,

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

[FR Doc. 2021-09418 Filed 5-4-21; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XB062]

Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of public online meeting.

SUMMARY: The Pacific Fishery
Management Council's (Pacific Council)
Scientific and Statistical Committee's
(SSC's) Economics and Groundfish
Subcommittees will meet to review a
new Quota Share Owners' Cost Survey
to inform decisions on the west coast
limited entry trawl catch shares program
and to do some initial planning on an
upcoming review of the limited entry
fixed gear sablefish program.

DATES: The online meeting will be held Wednesday, May 26, 2021, from 9 a.m.to 1 p.m., Pacific Daylight Time.

ADDRESSES: This meeting will be held online. Specific meeting information, including directions on how to join the meeting and system requirements will be provided in the meeting announcement on the Pacific Council's website (see www.pcouncil.org). You may send an email to Mr. Kris Kleinschmidt (kris.kleinschmidt@noaa.gov) or contact him at (503) 820—2412 for technical assistance.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: John DeVore, Staff Officer, Pacific Council; telephone: (503) 820–2413.

SUPPLEMENTARY INFORMATION: The purpose of the SSC Economics and Groundfish Subcommittees' meeting will be to review a new Quota Shares Owners' Cost Survey proposed by the Northwest Fisheries Science Center to inform future management decisions on the west coast limited entry trawl catch shares program. The SSC Economics and Groundfish Subcommittees will also work with Pacific Council staff to plan the upcoming review of the limited entry fixed gear sablefish program. The SSC Economics and Groundfish Subcommittees' reports are scheduled to be presented to the full SSC and the Pacific Council at the June 2021 Pacific Council meeting.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt, (kris.kleinschmidt@noaa.gov; (503) 820–2412), at least 10 days prior to the meeting date.

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

Dated: April 30, 2021.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service. [FR Doc. 2021–09503 Filed 5–4–21; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 048-XB034]

Fisheries of the South Atlantic; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

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

ACTION: Notice of SEDAR webinar I for SEDAR Procedural Workshop 8: Fishery Independent Index Development under changing survey design.

SUMMARY: The SEDAR Procedural Workshop 8 for Fishery Independent Index Development will consist of a series of webinars, and an in-person workshop. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR Procedural Workshop 8 webinar I will be held May 20, 2021, from 1 p.m. to 3 p.m., Eastern. **ADDRESSES:**

Meeting address: The meeting will be held via webinar. The webinar is open to members of the public. Those interested in participating should contact Julie A. Neer at SEDAR (see FOR FURTHER INFORMATION CONTACT) to request an invitation providing webinar access information. Please request webinar invitations at least 24 hours in advance of each webinar.

SEDAR address: 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Julie A. Neer, SEDAR Coordinator; (843) 571–4366; email: Julie.neer@safmc.net.

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a multistep process including: (1) Data Workshop; (2) Assessment Process utilizing webinars; and (3) Review Workshop. The product of the Data Workshop is a data report that compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The product of the Assessment Process is a stock assessment report that describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The assessment is independently peer reviewed at the Review Workshop. The product of the Review Workshop is a Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, HMS Management Division, and Southeast Fisheries Science Center. Participants include data collectors and database managers; stock assessment scientists, biologists, and researchers;

constituency representatives including fishermen, environmentalists, and NGO's; International experts; and staff of Councils, Commissions, and state and federal agencies.

Item(s) for discussion:

Participants will discuss what data available for use in SEDAR Procedural Workshop 8.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations: The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see ADDRESSES) at least 10 business days prior to each workshop.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: April 29, 2021.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service. [FR Doc. 2021–09416 Filed 5–4–21; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF EDUCATION

National Advisory Committee on Institutional Quality and Integrity (NACIQI)

AGENCY: National Advisory Committee on Institutional Quality and Integrity (NACIQI), U.S. Department of Education.

ACTION: Request for student nominees for appointment to serve on the National Advisory Committee on Institutional Quality and Integrity (NACIQI).

SUMMARY: At least one member of the National Advisory Committee on Institutional Quality and Integrity (NACIQI) must be a student who, at the time of the appointment by the Secretary of Education, is attending an institution of higher education.

DATES: Nominations must be received no later than Friday, May 28, 2021.

ADDRESSES: You may submit nomination(s), including attachments,

via email to: cmtemgmtoffice@ed.gov. (Please specify in the email subject line "NACIQI Student Nomination.")

For questions, please contact the U.S. Department of Education, Committee Management Office at (202) 401–3677. SUPPLEMENTARY INFORMATION: NACIQI's Statutory Authority and Function: The NACIQI is established under Section 114 of the HEA and is composed of 18 members who are appointed—

(A) On the basis of the individuals' experience, integrity, impartiality, and

good judgment.

(B) From among individuals who are representatives of, or knowledgeable concerning, education and training beyond secondary education, representing all sectors and types of institutions of higher education; and

(C) On the basis of the individuals' technical qualifications, professional standing, and demonstrated knowledge in the fields of accreditation and administration of higher education.

The NACIQI meets at least twice a year and advises the Secretary of Education with respect to:

- The establishment and enforcement of the standards of accrediting agencies or associations under subpart 2 of part H of Title IV, HEA.
- The recognition of specific accrediting agencies or associations.
- The preparation and publication of the list of nationally recognized accrediting agencies and associations.
- The eligibility and certification process for institutions of higher education under Title IV of the HEA, together with recommendations for improvements in such process.
- The relationship between (1) accreditation of institutions of higher education and the certification and eligibility of such institutions, and (2) State licensing responsibilities with respect to such institutions.

• Any other advisory functions relating to accreditation and institutional eligibility that the Secretary may prescribe by regulation.

Nomination Process: Interested persons, stakeholders, or organizations may nominate a qualified student(s). To nominate a student(s) or self-nominate for appointment to serve on the NACIQI, please submit the following information to the U.S. Department of Education:

- A cover letter addressed to the Secretary of Education as follows: Honorable Miguel Cardona, Secretary of Education, U.S. Department of Education, 400 Maryland Avenue SW, Washington, DC 20202. In the letter, please note your reason(s) for submitting the nomination.
- A copy of the nominee's current resume.

• Contact information for the nominee (name, address, contact phone number, and email address).

In addition, the cover letter must include a statement affirming the nominee (if you are nominating someone other than yourself) has agreed to be nominated and is willing to serve on the NACIQI if appointed by the Secretary of Education. Student nominees should be broadly knowledgeable about higher education and accreditation.

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.

Miguel Cardona,

Secretary of Education.

[FR Doc. 2021–09514 Filed 5–4–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 12740-008]

Jordan Hydroelectric Limited Partnership, Virginia; Notice of Application for Amendment of License, Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

- a. *Type of Proceeding:* Amendment of License.
 - b. Project No.: 12740-008.
 - c. Date Filed: March 10, 2021.
- d. *Licensee:* Jordan Hydroelectric Limited Partnership, Virginia.¹

- e. *Name of Project:* Flannagan Hydroelectric Project.
- f. Location: The project is located at the U.S. Army Corps of Engineers' (Corps) John W. Flannagan Dam and Reservoir, which is on the Pound River, near the Town of Clintwood, in Dickenson County, Virginia.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Licensee Contact*: Mr. James B. Price, President, General Partner Jordan Hydroelectric Limited Partnership, P.O. Box 903 Gatlinburg, TN 37738, (803) 215–4165, *jimpricehydro@bellsouth.net*.

215–4165, jimpricehydro@bellsouth.net. i. FERC Contact: Jeremy Jessup, (202) 502–6779, Jeremy.Jessup@ferc.gov.

j. Deadline for filing comments, motions to intervene, and protests, is 30 days from the issuance date of this notice by the Commission.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at http://www.ferc.gov/docs-filing/ efiling.asp. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at http:// www.ferc.gov/docs-filing/ ecomment.asp. You must include your name and contact information at the end of your comments. 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 $\bar{\text{U.S.}}$ 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, MD 20852. The first page of any filing should include docket number P-12740-008. Comments emailed to Commission staff are not considered part of the Commission record.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. Description of Request: The applicant proposes to redesign the

¹On March 12, 2021, subsequent to filing the amendment application, Jordan Hydroelectric Limited Partnership and Flannagan Hydro, LLC filed an Application for Approval of Transfer of License. Commission staff is reviewing the transfer of license under a separate proceeding.

project to have four smaller Turgo-type turbine-generators in lieu of the approved two Francis-type turbinegenerators. The design change would decrease the project capacity from 1.8 megawatts (MW) to 1.4 MW and decreases the hydraulic capacity from 180 cubic feet per second (cfs) to 150 cfs. The licensee states that this redesign will better align with the existing features of the Flannagan Dam and produce more energy on a yearly basis than the previous design. The licensee states that it is not proposing changes to any other aspects of the project and that the environmental impact of the project will not change from previously analyzed.

1. Locations of the Application: This filing may be viewed on the Commission's website at http:// www.ferc.gov using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at http:// www.ferc.gov/docs-filing/ esubscription.asp to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email FERCOnlineSupport@ferc.gov, for TTY, call (202) 502-8659. Agencies may obtain copies of the application directly from the applicant.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. Comments, Protests, or Motions to *Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. Filing and Service of Documents: Any filing must (1) bear in all capital letters the title "COMMENTS". "PROTEST", or "MOTION TO INTERVENE" as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001

through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

Dated: April 29, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021-09515 Filed 5-4-21; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2360-272]

Allete, Inc.; Notice of Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and **Protests**

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

- a. Application Type: Amendment of Project Boundary.
 - b. Project No: 2360-272.
- c. Date Filed: December 22, 2020, and supplemented on April 27, 2021.
 - d. Applicant: Allete, Inc.
- e. Name of Project: St. Louis River Hydroelectric Project.
- f. Location: Island Lake Reservoir, Fish Lake Reservoir, and Whiteface Reservoir in St. Louis County, Minnesota.
- g. Filed Pursuant to: Federal Power Act, 16 U.S.C. 791a-825r.
- h. Applicant Contact: Greg Prom, Minnesota Power, 30 West Superior Street, Duluth, Minnesota 55802-2093, $(218)\ 355-3191.$
- i. FERC Contact: Mark Carter, (678) 245-3083, mark.carter@ferc.gov.
- j. Deadline for filing comments, motions to intervene, and protests: May 31, 2021.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at http://www.ferc.gov/docs-filing/ efiling.asp. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at http:// www.ferc.gov/docs-filing/ ecomment.asp. You must include your name and contact information at the end of your comments. 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. The first page of any filing should include docket number P-2360-272. Comments emailed to Commission staff are not considered part of the Commission record.

k. Description of Request: Allete, Inc. (licensee) is proposing to amend its project boundary at three of the project's reservoirs (i.e., Island Lake Reservoir, Fish Lake Reservoir, and Whiteface Reservoir) to more accurately reflect the lands needed for project purposes. The licensee would remove approximately 191 acres of land around the reservoirs that are currently leased to individuals for private, residential use, while preserving an upland buffer area around the reservoirs. Additionally, the licensee would add 469 acres of land around the three reservoirs to be managed as Natural Character Areas for scenic and environmental protection uses. The proposed project boundary adjustment would result in a net increase of 423 acres of project lands including the removal of residential lands, addition of environmental protection lands, as well as other additions to reflect actual acreages of islands and recreation areas inside the project boundary.

l. Locations of the Application: In addition to publishing the full text of this document in the Federal Register, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (http://www.ferc.gov) using the "elibrary" link. Enter the docket number excluding the last three digits in the document field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID-19), issued by the President on March 13, 2020. For assistance, contact FERC at FERCOnlineSupport@ferc.gov or call toll-free, (886) 208-3673 or TYY, (202) 502-8659. Agencies may obtain copies of the application directly from the applicant.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. Comments, Protests, or Motions to *Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. Filing and Service of Documents: Any filing must (1) bear in all capital letters the title "COMMENTS" "PROTEST", or "MOTION TO INTERVENE" as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385,2010.

Dated: April 29, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–09516 Filed 5–4–21; 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 rate filings:

Docket Numbers: ER18–1174–001. Applicants: Imperial Valley Solar 2, LLC.

Description: Notice of Non-Material Change in Status of Imperial Valley Solar 2, LLC.

Filed Date: 4/28/21.

Accession Number: 20210428–5353. Comments Due: 5 p.m. ET 5/19/21.

Docket Numbers: ER21–1165–001. Applicants: Purge Energy LLC. Description: Tariff Amendment: Tariffs and Agreements to be effective 4/28/2021.

Filed Date: 4/28/21.

Accession Number: 20210428–5291. Comments Due: 5 p.m. ET 5/19/21.

Docket Numbers: ER21–1789–000. Applicants: Southwest Power Pool,

Description: Notice of cancellation of Network Integration Transmission Service Agreement and Network Operating Agreement of Southwest Power Pool, Inc.

Filed Date: 4/28/21.

Accession Number: 20210428–5263. Comments Due: 5 p.m. ET 5/19/21.

Docket Numbers: ER21–1791–000. Applicants: Mid-Atlantic Interstate

Transmission, LLC, PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: MAIT submits ECSA No. 5940 to be effective 6/29/2021.

Filed Date: 4/29/21.

Accession Number: 20210429–5042. Comments Due: 5 p.m. ET 5/20/21.

Docket Numbers: ER21–1792–000. Applicants: Southwest Power Pool,

Description: § 205(d) Rate Filing: 2198R30 Kansas Power Pool NITSA NOA to be effective 4/1/2021.

Filed Date: 4/29/21.

Accession Number: 20210429–5044. Comments Due: 5 p.m. ET 5/20/21.

Docket Numbers: ER21–1793–000. Applicants: Southern California Edison Company.

Description: § 205(d) Rate Filing: UFA Yellow Pine 2 Project TOT796AFS SA No. 261 to be effective 4/30/2021. Filed Date: 4/29/21.

Accession Number: 20210429–5081. Comments Due: 5 p.m. ET 5/20/21.

Docket Numbers: ER21–1794–000. Applicants: White Oak Energy LLC. Description: Baseline eTariff Filing:

Reactive Power Compensation Filing to be effective 6/28/2021.

Filed Date: 4/29/21.

Accession Number: 20210429–5128. Comments Due: 5 p.m. ET 5/20/21. Docket Numbers: ER21–1795–000. Applicants: Oakland Power Company

LLC.

Description: § 205(d) Rate Filing: Request for Authorization of Payment Pursuant to Section 7.5 of RMR Agreement to be effective 6/29/2021.

Filed Date: 4/29/21.

Accession Number: 20210429–5236. Comments Due: 5 p.m. ET 5/20/21.

Docket Numbers: ER21–1796–000. Applicants: Transource Oklahoma, LLC, Southwest Power Pool, Inc. Description: § 205(d) Rate Filing: Transource Oklahoma, LLC Formula Rate to be effective 7/1/2021.

Filed Date: 4/29/21.

Accession Number: 20210429–5242. Comments Due: 5 p.m. ET 5/20/21.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES21-41-000.

Applicants: Southwestern Electric Power Company.

Description: Application under Section 204 of the Federal Power Act for Authorization to Issue Securities for Southwestern Electric Power Company.

Filed Date: 4/29/21.

Accession Number: 20210429–5063. Comments Due: 5 p.m. ET 5/20/21.

Take notice that the Commission received the following electric reliability filings:

Docket Numbers: RR20-5-001.

Applicants: North American Electric Reliability Corporation.

Description: Compliance Filing of The North American Electric Reliability Corporation on The Revised Delegation Agreements With Regional Entities.

Filed Date: 4/29/21.

Accession Number: 20210429–5087. Comments Due: 5 p.m. ET 5/20/21.

The filings are accessible in the Commission's eLibrary system (https://elibrary.ferc.gov/idmws/search/fercgensearch.asp) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: http://www.ferc.gov/docs-filing/efiling/filing-req.pdf. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: April 29, 2021.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2021–09481 Filed 5–4–21; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC21-27-000]

Commission Information Collection Activities; (FERC-65, FERC-65A, AND FERC-65B); Consolidated Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, the Federal **Energy Regulatory Commission** (Commission or FERC) is soliciting public comment on the currently approved information collections, FERC-65 (Notice of Holding Company Status), FERC-65A (Exemption Notification of holding Company Status), and FERC-65B (Waiver Notification of Holding Company Status), which will be submitted to the Office of Management and Budget (OMB) for a review of the information collection requirements.

DATES: Comments on the collection of information are due July 6, 2021.

ADDRESSES: You may submit comments (identified by Docket No. IC21–27–000) by either of the following methods:

Electronic filing through *http://www.ferc.gov*, is preferred.

- *Électronic Filing:* Documents must be filed in acceptable native applications and print-to-PDF, but not in scanned or picture format.
- For those unable to file electronically, comments may be filed by USPS mail or by hand (including courier) delivery:
- Mail via U.S. Postal Service Only:
 Addressed to: Federal Energy
 Regulatory Commission, Secretary of the
 Commission, 888 First Street NE,
 Washington, DC 20426.
- Hand (Including Courier) Delivery to: Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: http://www.ferc.gov. For user assistance, contact FERC Online Support by email at ferconlinesupport@ferc.gov, or by phone at (866) 208–3676 (toll-free).

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at http://www.ferc.gov.

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at *DataClearance@FERC.gov*, telephone at (202) 502–8663.

SUPPLEMENTARY INFORMATION:

Title: FERC–65 (Notice of Holding Company Status), FERC–65A (Exemption Notification of Holding Company Status), and FERC–65B (Waiver Notification of Holding Company Status).

OMB Control No.: 1902-0218.

Type of Request: Three-year extension of the FERC–65, FERC–65A and FERC–65B information collection requirements with no changes to the current reporting requirements.

Abstract:

FERC-65 (Notice of Holding Company Status)

The Pursuant to section 366.4 of the Commission's rules and regulations, persons who meet the definition of a holding company shall provide the Commission notification of holding company status. The FERC-65 is a onetime informational filing outlined in the Commission's regulations at 18 Code of Federal Regulations (CFR) 366.4. The FERC-65 must be submitted within 30 days of becoming a holding company.1 While the Commission does not require the information to be reported in a specific format, the filing needs to consist of the name of the holding company, the name of public utilities, the name of natural gas companies in the holding company system, and the names of service companies. In addition, the Commission requires the filing to include the names of specialpurpose subsidiaries (which provide non-power goods and services) and the names of all affiliates and subsidiaries (and their corporate interrelationship) to each other. Filings may be submitted in hardcopy or electronically through the Commission's eFiling system.

FERC-65A (Exemption Notification of Holding Company Status)

While noting the previously outlined requirements of the FERC-65, the Commission has allowed for an exemption from the requirement of providing the Commission with a FERC-65 if the books, accounts, memoranda, and other records of any person are not relevant to the jurisdictional rates of a public utility or natural gas company; or if any class of transactions is not relevant to the jurisdictional rates of a public utility or natural gas company. Persons seeking this exemption file the FERC-65A, which must include a form of notice suitable for publication in the **Federal** Register. Those who file a FERC-65A in good faith will have a temporary exemption upon filing, after 60 days if the Commission has taken no action, the exemption will be deemed granted. Commission regulations within 18 CFR 366.3 describe the criteria in more specificity.

FERC-65B (Waiver Notification of Holding Company Status)

If an entity meets the requirements in 18 CFR 366.3(c), they may file a FERC-65B waiver notification pursuant to the procedures outlined in 18 CFR 366.4. Specifically, the Commission waives the requirement of providing it with a FERC-65 for any holding company with respect to one or more of the following: (1) Single-state holding company systems; (2) holding companies that own generating facilities that total 100 MW or less in size and are used fundamentally for their own load or for sales to affiliated end-users; or (3) investors in independent transmissiononly companies. Filings may be made in hardcopy or electronically through the Commission's website.

Type of Respondent: Public utility companies, natural gas companies, electric wholesale generators, foreign utility holding companies.

Estimate of Annual Burden: ² The Commission estimates the annual public reporting burden for the information collection as:

¹ Persons that meet the definition of a holding company as provided by § 366.1 as of February 8, 2006 shall notify the Commission of their status as a holding company no later than June 15, 2006. Holding companies formed after February 8, 2006 shall notify the Commission of their status as a holding company, no later than the latter of June 15, 2006 or 30 days after they become holding companies.

² Burden is defined as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. Refer to 5 CFR 1320.3 for additional information.

FERC-65 (NOTIFICATION OF HOLDING COMPANY STATUS), FERC-65A (EXEMPTION NOTIFICATION OF HOLDING
COMPANY STATUS), AND FERC-65B (WAIVER NOTIFICATION OF HOLDING COMPANY STATUS)

	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden & cost per response 3	Total annual burden hours & total annual cost (\$)	Cost per respondent (\$)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
FERC-65	12 4 4	1 1.25 1.75	12 5 7	3; \$249.00 1; \$83.00 1; \$83.00	36; \$2,988 5; \$415.00 7; \$581.00	\$249.00 103.75 145.25
Total			24		48; 3,984.00	

Comments: Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate 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.

Dated: April 29, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–09517 Filed 5–4–21; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Numbers: RP95–408–088.
Applicants: Columbia Gas

Transmission, LLC.

Description: Annual Report on Sharing Profits from Base Gas Sales with Customers of Columbia Gas

Transmission, LLC.

Filed Date: 4/26/21.
Accession Number: 2

Accession Number: 20210426–5152. Comments Due: 5 p.m. ET 5/10/21.

Docket Numbers: RP21-752-000. Applicants: ANR Storage Company.

Description: Compliance filing 2021 Operational Purchases and Sales Report. Filed Date: 4/27/21.

Accession Number: 20210427–5094. Comments Due: 5 p.m. ET 5/10/21.

Docket Numbers: RP21–753–000. Applicants: Discovery Gas

Transmission LLC.

Description: Imbalance Cash-out Report for 2020 Annual Fuel Activity for Discovery Gas Transmission LLC. Filed Date: 4/27/21.

Accession Number: 20210427–5138. Comments Due: 5 p.m. ET 5/10/21.

Docket Numbers: RP21-754-000.

Applicants: Carolina Gas

Transmission, LLC.

Description: Compliance filing CGT— April 28, 2021 Service Agreement Termination Notice.

Filed Date: 4/28/21.

Accession Number: 20210428–5032. Comments Due: 5 p.m. ET 5/10/21.

Docket Numbers: RP21–755–000.

Applicants: Cameron Interstate Pipeline, LLC.

Description: Annual Report of Penalty Revenues of Cameron Interstate Pipeline, LLC.

Filed Date: 4/28/21.

Accession Number: 20210428-5293.

Comments Due: 5 p.m. ET 5/10/21. Docket Numbers: RP21–756–000.

Applicants: Cameron Interstate

Pipeline, LLC.

Description: Annual Report of Transportation Imbalances and Cash-Out Activity of Cameron Interstate Pipeline, LLC.

Filed Date: 4/28/21.

Accession Number: 20210428–5294. Comments Due: 5 p.m. ET 5/10/21.

The filings are accessible in the Commission's eLibrary system (https://elibrary.ferc.gov/idmws/search/fercgensearch.asp) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: http://www.ferc.gov/docs-filing/efiling/filing-req.pdf. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: April 29, 2021.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2021-09482 Filed 5-4-21; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. IC21-19-000, RD21-4-000]

Commission Information Collection Activities (FERC-725A); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission, Department of Energy.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collection, FERC-725A (Mandatory Reliability Standards for the Bulk-Power System). This notice includes the burden totals for proposed Reliability Standard FAC-008-5.

³ The Commission staff estimates that the average respondent for this collection is similarly situated to the Commission, in terms of salary plus benefits. Based on FERC's 2020 annual average of \$172,329 (for salary plus benefits), the average hourly cost is \$22 (hour).

DATES: Comments on the collection of information are due July 6, 2021.

ADDRESSES: You may submit copies of your comments (identified by Docket No. IC21–19–000) by one of the following methods:

Electronic filing through *http://www.ferc.gov*, is preferred.

- *Electronic Filing:* Documents must be filed in acceptable native applications and print-to-PDF, but not in scanned or picture format.
- For those unable to file electronically, comments may be filed by USPS mail or by hand (including courier) delivery:
- Mail via U.S. Postal Service Only:
 Addressed to: Federal Energy
 Regulatory Commission, Secretary of the Commission, 888 First Street NE,
 Washington, DC 20426.
- Hand (Including Courier) Delivery:
 Deliver to: Federal Energy Regulatory
 Commission, 12225 Wilkins Avenue,
 Rockville, MD 20852.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: http://www.ferc.gov. For user assistance, contact FERC Online Support by email at ferconlinesupport@ferc.gov, or by phone at (866) 208–3676 (toll-free).

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at http://www.ferc.gov.

FOR FURTHER INFORMATION CONTACT:

Ellen Brown may be reached by email at *DataClearance@FERC.gov*, telephone at (202) 502–8663.

SUPPLEMENTARY INFORMATION:

Title: FERC–725A (Mandatory Reliability Standards for the Bulk-Power System).

OMB Control No.: 1902–0244.

Type of Request: Three-year extension of the FERC–725A information collection requirements with no changes to the current reporting requirements.

Abstract: On August 8, 2005, the Electricity Modernization Act of 2005, which is Title XII, Subtitle A, of the Energy Policy Act of 2005 (EPAct 2005), was enacted into law. EPAct 2005 added a new section 215 to the FPA, which requires a Commission-certified

electric reliability organization (ERO) (FERC–725) to develop mandatory and enforceable Reliability Standards, which are subject to Commission review and approval. Once approved, the Reliability Standards may be enforced by the ERO, subject to Commission oversight or the Commission can independently enforce Reliability Standards (FERC–725A).²

On February 3, 2006, the Commission issued Order No. 672, implementing section 215 of the FPA.³ Pursuant to Order No. 672, the Commission certified one organization, NERC, as the ERO.⁴ The ERO is required to develop Reliability Standards, which are subject to Commission review and approval. The Reliability Standards will apply to users, owners and operators of the Bulk-Power System, as set forth in each Reliability Standard.

On March 16, 2007, the Commission issued Order No. 693, a Final Rule adding part 40, a new part, to the Commission's regulations. The Final Rule states that this part applies to all users, owners and operators of the Bulk-Power System within the United States (other than Alaska or Hawaii). It also requires that each Reliability Standard identify the subset of users, owners and operators to which that particular Reliability Standard applies. The new regulations also require that each Reliability Standard that is approved by the Commission will be maintained on the ERO's internet website for public inspection.

In order that the Commission is able to perform its oversight function with regard to Reliability Standards that are proposed by the ERO and established by the Commission, it is essential that the Commission receive timely information regarding all or potential violations of Reliability Standards. While section 215 of the FPA contemplates the filing of the record of an ERO or Regional Entity

enforcement action, FERC needs information regarding violations and potential violations at or near the time of occurrence. Therefore, it will work with the ERO and regional reliability organizations to be able to use the electronic filing of information so the Commission receives timely information. The new regulations also require that each Reliability Standard that is approved by the Commission will be maintained on the ERO's internet website for public inspection. In accordance with section 39.5 of the Commission's regulations, the ERO must file each Reliability Standard or a modification to a Reliability Standard with the Commission. The filing is to include a concise statement of the basis and purpose of the proposed Reliability Standard, either a summary of the Reliability development proceedings conducted by the ERO or a summary of the Reliability Standard development proceedings conducted by a Regional Entity together with a summary of the Reliability Standard review proceedings of the ERO and a demonstration that the proposed Reliability Standard is "just, reasonable, not unduly discriminatory or preferential, and in the public interest.

RD21-4 (FAC-008-05)

The proposed information collection changes in Docket No. RD21–4–000 relate to the proposed Reliability Standard FAC–008–05 (Facility Ratings) developed by the North American Electric Reliability Corporation (NERC), and submitted to the Commission for approval. The Commission received NERC's petition to approve the proposed Reliability Standards.

On February 19, 2021, NERC filed a petition seeking approval of proposed Reliability Standard FAC-008-5. NERC states that proposed Reliability Standard FAC-008-5 reflects the retirement of Requirement R7 of the currently effective standard. NERC notes that this proposal was recommended following the first phase of work under the NERC Standards Efficiency Review and that in its Order No. 873 remanding a previously proposed version of the FAC-008 Reliability Standard, the Commission agreed that the retirement of Requirement R7 from the standard would not result in a reliability gap.

¹Energy Policy Act of 2005, Public Law 109–58, Title XII, Subtitle A, 119 Stat. 594, 941 (2005), to be codified at 16 U.S.C. 8240.

^{2 16} U.S.C. 824o(e)(3).

³Rules Concerning Certification of the Electric Reliability Organization; Procedures for the Establishment, Approval and Enforcement of Electric Reliability Standards, Order No. 672, 71 FR 8662 (February 17, 2006), FERC Stats. & Regs. ¶31,204 (2006), order on reh'g, Order No. 672–A, 71 FR 19814 (April 18, 2006), FERC Stats. & Regs. ¶31,212 (2006).

⁴ North American Electric Reliability Corp., 116 FERC ¶ 61,062 (ERO Certification Order), order on reh'g & compliance, 117 FERC ¶ 61,126 (ERO Rehearing Order) (2006), order on compliance, 118 FERC ¶ 61,030 (2007) (January 2007 Compliance Order)

In June 2019, following the conclusion of the standard development process, NERC submitted a series of standard retirement proposals to the Commission. Among the proposals, NERC submitted for Commission approval proposed Reliability Standard FAC-008-4, in which NERC proposed to retire Requirements R7 and R8 of currently effective Reliability Standard FAC-008-3. In September 2020, the Commission issued Order No. 873 regarding NERC's retirement proposals. In this order, the Commission remanded proposed Reliability Standard FAC-008-4 to NERC for further consideration, citing concerns with the proposed retirement of Requirement R8 of the currently effective standard. The standard drafting team determined to develop a new version of the Reliability Standard, proposed Reliability Standard FAC-008-5, in which only Requirement R7 of the currently effective standard would be proposed for retirement. Reliability Standard FAC-008-3 Requirement R7 requires Generator Owners and Transmission Owners to provide certain information to requesting Reliability Coordinator(s), Planning Coordinator(s), Transmission Planner(s), Transmission Owner(s), and

Transmission Operator(s) regarding their Facilities, as follows:

R7. Each Generator Owner shall provide Facility Ratings (for its solely and jointly owned Facilities that are existing Facilities, new Facilities, modifications to existing Facilities and re-ratings of existing Facilities) to its associated Reliability Coordinator(s), Planning Coordinator(s), Transmission Planner(s), Transmission Owner(s) and Transmission Operator(s) as scheduled by such requesting entities.

In the years since Reliability Standard FAC-008-3 was developed, NERC has developed other Reliability Standards that render the data provision obligations of Requirement R7 redundant. Specifically, Reliability Standards MOD-032-1, IRO-010-2, and TOP-003-3 contain provisions to help ensure that the entities that have the responsibility to plan and operate the Bulk Power System have the data they need from Generator Owners and Transmission Owners for operations and planning. Requirement R1 of Reliability Standard MOD-032-1-Data for Power System Modeling and Analysis requires the Planning Coordinator and Transmission Planner to develop modeling data requirements and reporting procedures including the

data listed in Attachment 1 to the standard. This data would include information on power capabilities and Facility Ratings. Requirement R2 requires the Generator Owner and Transmission Owner to provide the requested information. Requirement R1 of Reliability Standard IRO-010-2-Reliability Coordinator Data Specification and Collection requires the Reliability Coordinator to maintain a documented specification for the data necessary to perform its Operational Planning Analyses, Real-time monitoring, and Real-time Assessments. This data necessarily includes Facility Ratings as inputs to System Operating Limit monitoring. Requirement R3 requires the Transmission Owner and Generator Owner to provide requested data. Similarly, Requirement R1 of Reliability Standard TOP-003-3-Operational Reliability Data requires the Transmission Operator to maintain a documented data specification (Requirement R1) and for the Transmission Owner and Generator Owner to provide the requested data (Requirement R5).

Estimate of Annual Burden: ⁵ The Commission estimates the burden and cost ⁶ for this information collection as follows.

PROPOSED CHANGES TO BURDEN DUE TO DOCKET NO. RD20-4-000 ADJUSTMENTS AND CLARIFICATIONS

Reliability standard & Number of respondents ents & type of entity		Annual number of responses per respondent	Annual number of responses	Average burden hrs. per response	Total annual burden hours				
	(1)	(1) (2)		(4)	(3) * (4) = (5)				
	RD21-4 Net Changes to FERC-725A, OMB Control No. 1902-0244								
FAC-008-05 (Facility 1,003 (No Change) Ratings) 7.		1	1,003 (No Change)	-10 hrs. (Reduction)	-10,030 hrs. (Reduction).				

⁵ Burden is defined as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, refer to 5 CFR part 1320.

⁶ The Commission staff thinks that the average respondent for this collection is similarly situated to the Commission, in terms of salary plus benefits. Based on FERC's 2020 annual average of \$172,329 (for salary plus benefits), the average hourly cost is \$23/hour.

⁷The type of entity effect is the NERC registered GO = Generator Owners (1,003). This reduction for 725A represent a decrease in burden but the GOs still have other obligations, so the 1,003 is included for information purpose but does not affect the overall number of entities in 725A.

IC21-19-000 Renewal of 725A

The following table represents the current burden associated with all

Mandatory Reliability Standards that fall under FERC–725A.

Reliability standard & requirement	Number of entity ⁸	Number of annual responses per entity	Total number of responses	Average number of burden hours per response	Total burden hours
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)
		FERC-725A			
Mandatory Reliability Standards for Bulk	(3,420)	1	3,420	428.86	1,466,716 hrs.
Power System. RD21–4 Net Changes	1,003 (No change)	1	1,003 (No Change)	-10	- 10,030 hrs. (Reduction).
Total for FERC-725A					1,456,686 hrs.

Note: FAC-008-05 is a part of the Bulk Power System burden totals. The net changes for the responses and hours will affect the totals for the row stated "Mandatory Reliability Standards for Bulk Power System".

Comments: Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate 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.

Dated: April 29, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021-09519 Filed 5-4-21; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2242-125]

Eugene Water and Electric Board; Notice of Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

- a. *Application Type:* Amended Recreation and Aesthetics Management Plan.
 - b. Project No: 2242-125.
 - c. Date Filed: January 8, 2021.
- d. *Applicant:* Eugene Water and Electric Board.
- e. *Name of Project:* Carmen-Smith Hydroelectric Project.
- f. Location: The project is located on the McKenzie River in Lane and Linn counties, Oregon and occupies 624.56 acres of federal lands administered by the U.S. Forest Service.
- g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.
- h. Applicant Contact: Scarlett Philibosian, Eugene Water and Electric Board, 500 East 4th Avenue, Eugene, OR 97440; telephone (541) 685–7120; or email scarlett.philibosian@eweb.org.
- i. FERC Contact: Mark Ivy, (202) 502–6156, or mark.ivy@ferc.gov.
- j. Deadline for filing comments, motions to intervene, and protests: June 1, 2021.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at http://www.ferc.gov/docs-filing/efiling.asp. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the

eComment system at http://www.ferc. gov/docs-filing/ecomment.asp. You must include your name and contact information at the end of your comments. 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. The first page of any filing should include the docket number P-2242-125. Comments emailed to Commission staff are not considered part of the Commission record.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. Description of Request: The licensees filed an amended Recreation and Aesthetics Management Plan (plan) which incorporates changes requested by the U.S. Forest Service to align the plan with current agency management strategies and proposes additional modifications, for Commission approval. The recreation facilities available at many recreation sites would

⁸ This is a list of NERC registered entities who under 725A need to follow the NERC Standards. BA = Balancing Authority (99); DP = Distribution Provider (373); GP = Generator Owner (1,003); Generator Operator (937); PA PC Planning Authority Planning Coordinator (65); RC = Reliability Coordinator (11); RP = Resource Planner (160); RSG = Reserve Sharing Group (11); FRSG Frequency Response Sharing Group (1); TO = Transmission Owner (321); TOP = Transmission Operator (167); TP = Transmission Provided (201); TSP = Transmission Service Provider (71); for a sum total of (3,420). The same entity may have multiple registration obligation to follow under 725A so an individual entity's obligation increases based on registration functions. These values were derived from the NERC Compliance data of February 5, 2021 using only unique United States registered entities.

be revised to match existing conditions, the existing and planned recreation facilities accessible to persons with disability would be updated, the implementation schedule for developing recreation facilities would be modified, and the public would no longer be notified of planned high flow releases in the bypass reaches.

l. In addition to publishing the full text of this document in the Federal Register, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (http:// ferc.gov) using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID-19), issued by the President on March 13, 2020. For assistance, contact FERC at FERCOnlineSupport@ferc.gov or call toll-free, (886) 208-3676 or TYY, (202) 502–8659. Agencies may obtain copies of the application directly from the applicant.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission

of the Commission.

n. Comments, Protests, or Motions to *Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. Filing and Service of Documents:
Any filing must (1) bear in all capital letters the title "COMMENTS",
"PROTEST", or "MOTION TO
INTERVENE" as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must

set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

Dated: April 29, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021-09520 Filed 5-4-21; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER21-1768-000]

Light Power & Gas LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Light Power & Gas LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is May 19, 2021.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at http://www.ferc.gov. To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the Federal Register, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (http:// www.ferc.gov) using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID-19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at FERCOnlineSupport@ferc.gov or call toll-free, (886) 208-3676 or TYY, (202) 502-8659.

Dated: April 29, 2021.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2021-09479 Filed 5-4-21; 8:45 am]

BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-10020-14-OMS]

Privacy Act of 1974; System of Records

AGENCY: Office of Land and Emergency Management (OLEM), Environmental Protection Agency (EPA).

ACTION: Notice of a modified system of records.

SUMMARY: The U.S. Environmental Protection Agency's (EPA), Office of Land and Emergency Management (OLEM) is giving notice that it proposes to modify a system of records pursuant to the provisions of the Privacy Act of 1974. Environmental Assessments of Residential Properties (EARP) is being modified to clarify the nature of the information, and the ways in which that information may be used and shared with parties who are part of the evaluation and coordination process. This system of records contains information of individuals that is collected in the course of response and environmental assessment actions, including actions taken under a variety of EPA authorities. The information maintained under this System of

Records Notice (SORN) is needed to support EPA's decision-making process on what actions may be necessary to address potential environmental impacts at residential properties, including necessary investigation and cleanup activities. This information is collected to ensure an appropriate and cohesive response to situations that may require EPA response activities, and to protect the health and welfare of residents who may be affected by conditions that present a potential environmental or public health threat. The information is maintained as needed for consideration and coordination of environmental response activities. This information may include individuals' contact information, information related to their address or place of residence, correspondence, and related environmental and public health information collected in the course of investigation, sampling, and cleanup work, as described in further detail below. All exemptions and provisions included in the previously published SORN for EARP will transfer to the modified SORN for EARP.

DATES: Persons wishing to comment on this system of records notice must do so by June 4, 2021. New routine uses for this modified system of records will be effective June 4, 2021.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OLEM-2021-0038, by one of the following methods:

Federal eRulemaking Portal: www.regulations.gov. Follow the online instructions for submitting comments.

Email: docket_oms@epa.gov. Include the Docket ID number in the subject line of the message.

Fax: 202–566–1752.

Mail: OMS Docket, Environmental Protection Agency, Mail Code: 2822T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

Hand Delivery: OMS Docket, EPA/DC, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC 20460. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA-HQ-OLEM-2021-0038. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Controlled Unclassified Information (CUI) or other information

for which disclosure is restricted by statute. Do not submit information that you consider to be CUI or otherwise protected through www.regulations.gov. The www.regulations.gov website is an "anonymous access" system for the EPA, which means the EPA will not know your identity or contact information. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. If you send an email comment directly to the EPA without going through www.regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about the EPA public docket, visit the EPA Docket Center homepage at https:// www.epa.gov/dockets.

Docket: All documents in the docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, e.g., CUI or other information for which disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in

www.regulations.gov or in hard copy at the OMS Docket, EPA/DC, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington. DC 20460. The Public Reading Room is normally open from 8:30 a.m. to 4:30 p.m., Monday through Friday excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OMS Docket is (202) 566–1752.

Temporary Hours During COVID-19

Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are closed to the public, with limited exceptions, to reduce the risk of transmitting COVID–19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via https://www.regulations.gov/ or email, as there may be a delay in processing mail and faxes. Hand deliveries and couriers may be received by scheduled appointment only. For further information on EPA

Docket Center services and the current status, please visit us online at https://www.epa.gov/dockets.

FOR FURTHER INFORMATION CONTACT:

Joseph Schaefer, Office of Land and Emergency Management (OLEM), Office of Superfund Remediation and Technology Information (OSRTI), Mail Code 205A–ERT, Raritan Depot, 2890 Woodbridge Avenue, Edison, NJ 08837; telephone number (732) 906–6920; Schaefer.Joe@epa.gov.

SUPPLEMENTARY INFORMATION: EPA created a Privacy Act system of records to allow the agency to maintain records that are necessary to conduct environmental assessments at residential properties in order to respond to emergency situations and during environmental assessment activities conducted by EPA under many different programs including Superfund (42 U.S.C. 9601 *et seq.*), the Resource Conservation and Recovery Act (42 U.S.C. 6901 et seq.), and the Safe Drinking Water Act (42 U.S.C. 300f et seq.). This system of records promotes transparency, efficiency, and improved environmental and health outcomes by encompassing all records associated with EPA residential assessment and response work, including the database repositories, field documentation, and analytical reports.

The original notice highlighted that EPA is often required to support or work closely with state and local agencies or other federal agencies evaluating the health and welfare of affected communities. This cooperation and coordination also extends to tribes and

tribal agencies. The original notice included a list of the types of information commonly gathered in environmental assessments and responses, including: Names of residents; address information; phone number or other contact information; test results from environmental sampling; information about the building structure, such as the age of the structure, information about the service lines, plumbing and pipe information, and building materials in the structure; information about the length of residence or ownership of the structure; and geographic information system (GIS) coordinates. This modified notice provides further examples of typical types of information that may be gathered: Age; medical and health information; property ownership and property management information; information about physical dimensions of the property and structures present on the property; information about wells on the property; information about how the property is used; information about

sampling locations; and information about prior environmental issues at the property, including prior test results and actions taken. Other site-specific data elements may also be collected if needed for the environmental assessment or response activity.

As described in more detail in the original notice, information and data collected in environmental assessments and responses will generally be stored in an agency-approved electronic database, which will be managed by EPA system administrators. Other associated records may also be stored in other agency-approved electronic or paper formats, such as Microsoft Excel spreadsheets, Microsoft Word documents or tables, or in file folders in secure locations. During the course of the assessment and response, records may also be temporarily stored off site in secure facilities such as incident command posts or EPA field offices which are maintained and secured by EPA staff.

The original notice identified the EPA staff and contractors who might have access to the information in the system of records. The notice also stated that in appropriate circumstances, limited access to the database systems may be provided to state and local public health authorities in conformity with federal, state, and local laws when necessary to protect the environment or public health or safety. To clarify and emphasize the value of intergovernmental coordination and communication, the original notice is now modified to allow for disclosure to any appropriate federal, state, local, and tribal authorities when necessary to protect the environment or public health or safety, including carrying out an investigation or response. Information may also be shared with state agencies and with the public as part of their participation in the Superfund evaluation and decisionmaking process. This may include public disclosure of addresses where EPA determines cleanup actions are required. In cases of emergency, EPA may also need to share information with members of the public to assure protection of the environment, and public health and safety.

SYSTEM NAME AND NUMBER:

Environmental Assessments of Residential Properties (EARP), EPA-74.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

The system will be managed by the EPA's Office of Emergency Response,

OLEM, 1200 Pennsylvania Ave. NW, Mail Code 5103 T, Washington, DC 20460. Information maintained pursuant to this notice may be located at EPA Headquarters Offices or at EPA Regional Offices, or at field offices established as part of the residential assessment field work, depending upon the location where the environmental assessment is conducted or where computer resources are located. Databases may be hosted at the EPA's National Computer Center located at 109 T.W. Alexandra Drive, Durham, NC 27709, or in OLEM's emergency response cloud hosting environment.

SYSTEM MANAGER(S):

Joseph Schaefer, Office of Land and Emergency Management (OLEM), Office of Superfund Remediation and Technology Information (OSRTI), Mail Code 205A–ERT, Raritan Depot, 2890 Woodbridge Avenue, Edison, NJ 08837; telephone number (732) 906–6920; Schaefer.Joe@epa.gov.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Resource Conservation and Recovery Act (RCRA), 42 U.S.C. 6981;
Comprehensive Environmental
Response, Compensation and Liability
Act (CERCLA), 42 U.S.C. 9604, 9660;
Clean Air Act (CAA), 42 U.S.C. 7403;
Safe Drinking Water Act (SDWA), 42
U.S.C. 300i; 300j–1; Federal Water
Pollution Control Act, (FWPCA) 33
U.S.C. 1254, 1318, 1321; Toxic
Substances Control Act (TSCA), 15
U.S.C. 2609; Federal Insecticide,
Fungicide, and Rodenticide Act,
(FIFRA) 7 U.S.C. 136r.

PURPOSE(S) OF THE SYSTEM:

The EPA has created a Privacy Act system of records to allow EPA to maintain records that are necessary to conduct environmental assessments at residential properties in order to respond to emergency situations and during environmental assessment activities conducted by EPA under many different programs including Superfund, RCRA, and the SDWA. This system of records promotes transparency, efficiency, and improved environmental and health outcomes by encompassing all of the records associated with EPA residential assessment and response work, including the database repositories, field documentation and analytical reports. Over the course of these assessments EPA is often required to support or work closely with state and local agencies or other federal agencies to evaluate the health and welfare of affected communities. EPA's environmental assessment activities at

residential properties include: Obtaining and tracking legal access to the properties; gathering environmental data through sampling activities, such as sampling air, water, soil, or other environmental media at sites; collecting structural information such as the age of the structure, information about the service lines, plumbing and pipe information, and building materials in the structure, information about the length of residence or ownership of the structure, and GIS coordinates; and collecting residential contact information such as name, address, and phone number to allow response teams to correspond with individuals affected by environmental contamination.

CATEGORIES OF INDIVIDUALS COVERED BY SYSTEM:

Members of the public such as residents, property owners, property managers, and other individuals who may be associated with a property whose information needs to be collected as part of EPA's environmental assessment and response activities. In addition, EPA staff, contractors, grantees, or any other individuals engaged in response activities (including state, local, and tribal employees) may have their information in the system such as name, office address, and contact information to facilitate assessment and response activities.

CATEGORIES OF RECORDS IN THE SYSTEM:

The types of data collected in environmental assessments and responses include names of residents; names of property owners; tenant information; names of property managers; address information; phone number or other contact information; test results from environmental sampling; medical and health information; information about residential structures such as the age of the structure, information about the service lines, plumbing and pipe information, and building materials in the structure; information about the length of residence or ownership of the structure; GIS coordinates; age; property ownership and management information; information about physical dimensions of the property and structures present on the property; information about wells on the property; information about uses of the property; information about sampling locations; and information about prior environmental issues at the property, including prior test results and actions taken. Other site-specific data elements may also be collected if needed for the

environmental assessment or emergency response activity.

RECORD SOURCE CATEGORIES:

Records within this system of records are obtained by EPA employees, contractors, or grantees collecting environmental assessment data and sample information at residential sites, or from state or local governments who have collected environmental assessment information as part of their response authorities. Environmental assessment data is received from interviews with residents, property owners, property managers, and other individuals who may be associated with a property, local public records such as property tax data, from inspections of residential properties, from residential property records or other public records, and from other on-site sources such as EPA or contracted laboratories and EPA or contracted GIS systems.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

The routine uses below are both related to and compatible with the original purpose for which the information was collected. The following general routine uses apply to this system (73 FR 2245):

A. Disclosure for Law Enforcement Purposes: Information may be disclosed to the appropriate Federal, State, local, tribal, or foreign agency responsible for investigating, prosecuting, enforcing, or implementing a statute, rule, regulation, or order, if the information is relevant to a violation or potential violation of civil or criminal law or regulation within the jurisdiction of the receiving entity.

B. Disclosure Incident to Requesting Information: Information may be disclosed to any source from which additional information is requested (to the extent necessary to identify the individual, inform the source of the purpose of the request, and to identify the type of information requested,) when necessary to obtain information relevant to an agency decision concerning retention of an employee or other personnel action (other than hiring,) retention of a security clearance, the letting of a contract, or the issuance or retention of a grant, or other benefit.

D. Disclosure to Office of Management and Budget: Information may be disclosed to the Office of Management and Budget at any stage in the legislative coordination and clearance process in connection with private relief legislation as set forth in OMB Circular No. A–19.

E. Disclosure to Congressional Offices: Information 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.

F. Disclosure to Department of Justice: Information may be disclosed to the Department of Justice, or in a proceeding before a court, adjudicative body, or other administrative body before which the Agency is authorized to appear, when:

1. The Agency, or any component

2. Any employee of the Agency in his or her official capacity;

3. Any employee of the Agency in his or her individual capacity where the Department of Justice or the Agency have agreed to represent the employee;

4. The United States, if the Agency determines that litigation is likely to affect the Agency or any of its components.

Is a party to litigation or has an interest in such litigation, and the use of such records by the Department of Justice or the Agency is deemed by the Agency to be relevant and necessary to the litigation provided, however, that in each case it has been determined that the disclosure is compatible with the purpose for which the records were collected.

G. Disclosure to the National Archives: Information may be disclosed to the National Archives and Records Administration in records management inspections.

H. Disclosure to Contractors,
Grantees, and Others: Information may
be disclosed to contractors, grantees,
consultants, or volunteers performing or
working on a contract, service, grant,
cooperative agreement, job, or other
activity for the Agency and who have a
need to have access to the information
in the performance of their duties or
activities for the Agency. When
appropriate, recipients will be required
to comply with the requirements of the
Privacy Act of 1974 as provided in 5
U.S.C. 552a(m).

K. Disclosure in Connection With Litigation: Information from this system of records may be disclosed in connection with litigation or settlement discussions regarding claims by or against the Agency, including public filing with a court, to the extent that disclosure of the information is relevant and necessary to the litigation or discussions and except where court orders are otherwise required under section (b)(11) of the Privacy Act of 1974, 5 U.S.C. 552a(b)(11).

The two routine uses below (L and M) are required by OMB Memorandum M–17–12.

L. Disclosure to Persons or Entities in Response to an Actual or Suspected Breach of Personally Identifiable Information: To appropriate agencies, entities, and persons when (1) the Agency suspects or has confirmed that there has been a breach of the system of records, (2) the Agency has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the Agency (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 the Agency's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

M. Disclosure to Assist Another Agency in Its Efforts to Respond to a Breach of Personally Identifiable Information: To another Federal agency or Federal entity, when the Agency 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 remedying 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.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

These records are maintained electronically on computer storage devices such as computer tapes and disks. The computer storage devices are located at EPA, Office of Emergency Response, OLEM. Backup will be maintained at a disaster recovery site. Computer records are maintained in a secure password protected environment. Access to computer records is limited to those who have a need to know. Permission level assignments will allow users access only to those functions for which they are authorized. All records are maintained in secure, accesscontrolled areas or buildings.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Information may be retrieved by any collected data element, such as a resident's name or address, or information may be retrieved by GIS coordinates or by identifying numbers assigned to a person, sampling location, or residence.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records maintained in this system are subject to record schedule 1036, which is still being finalized.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Security controls used to protect personal sensitive data in Environmental Assessments of Residential Properties are commensurate with those required for an information system rated MODERATE for confidentiality, integrity, and availability, as prescribed in National Institute of Standards and Technology (NIST) Special Publication, 800–53, "Security and Privacy Controls for Federal Information Systems and Organizations," Revision 5.

Administrative Safeguards: For documents in EPA database systems, those systems have a single point of access via a front-end Portal. All users are required to complete a new user form (signed by their supervisor) and take online security training before they are provided with access. All authorized users of the EARP application are required to take an annual security training identifying the user's role and responsibilities for protecting the Agency's information resources, as well as, consequences for not adhering to the policy. Similarly, those documents maintained on Agency computers prior to placement in EARP are protected by passwords and/or Personal Identity Verification, and all agency users are required to complete a new user form (signed by their supervisor) and take computer security training.

Technical Safeguards: Electronic records are maintained in a secure, password protected electronic system.

Physical Safeguards: Paper files are maintained in locked file cabinets when not in use by EPA emergency response staff. All records are maintained in secure, access-controlled areas or buildings.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information in this system of records about themselves are required to provide adequate identification (e.g., driver's license, military identification card, employee badge or identification card). Additional identity verification procedures may be required, as warranted. Requests must meet the requirements of EPA regulations that implement the Privacy Act of 1974, at 40 CFR part 16.

CONTESTING RECORDS PROCEDURES:

Requests for correction or amendment must identify the record to be changed

and the corrective action sought. Complete EPA Privacy Act procedures are described in EPA's Privacy Act regulations at 40 CFR part 16.

NOTIFICATION PROCEDURE:

Any individual who wants to know whether this system of records contains a record about him or her, should make a written request to the EPA, Attn: Agency Privacy Officer, MC 2831T, 1200 Pennsylvania Ave. NW, Washington, DC 20460, privacy@epa.gov.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

The original SORN for the EARP (EPA-74) was published in the **Federal Register** on April 21, 2016 (81 FR 23488–23490).

Vaughn Noga,

Senior Agency Official for Privacy. [FR Doc. 2021–09403 Filed 5–4–21; 8:45 am] BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2016-0141; FRL-10023-39]

Notice of Requests to Voluntarily Cancel Uses for Dicloran (DCNA)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is issuing a notice of receipt of requests by registrants to voluntarily cancel certain dicloran (DCNA) registrations. EPA intends to grant these requests at the close of the comment period for this announcement unless the Agency receives substantive comments within the comment period that would merit its further review of the requests, or unless the registrants withdraw its requests. If these requests are granted, any sale, distribution, or use of products listed in this notice will be permitted after the registrations have been cancelled only if such sale, distribution, or use is consistent with the terms as described in the final order.

DATES: Comments must be received on or before June 4, 2021.

Users of these products who desire continued use on crops or sites being deleted should contact the applicable registrant on or before June 4, 2021.

ADDRESSES: Submit your withdrawal request, identified by docket

identification (ID) number EPA-HQ-OPP-2016-0141, by one of the following methods:

Federal eRulemaking Portal: http://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.

Mail: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.

Hand Delivery: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at http://www.epa.gov/dockets/contacts.html.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit https://www.epa.gov/dockets.

FOR FURTHER INFORMATION CONTACT: Kent Fothergill, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (703) 347–8299; email address: fothergill.kent@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides.

B. How can I get copies of this document and other related information?

The docket for this action, identified by docket ID number EPA-HQ-OPP-2016-0141, is available either electronically through http://www.regulations.gov or in hard copy at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460-0001. Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote

customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit https://www.epa.gov/dockets.

II. What action is the Agency taking?

This notice announces receipt by the Agency of applications from registrants

to delete uses in certain pesticide registrations. These registrations are listed in Table 1 of this unit by registration number, product name, active ingredient, and specific uses deleted.

Unless a request is withdrawn by the registrant or if the Agency determines

that there are substantive comments that warrant further review of this request, EPA intends to issue an order in the **Federal Register** canceling the affected registrations.

TABLE 1—PRODUCT REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION

EPA registration No.	Product name	Active ingredient	Delete from label
10163–195	Botran 75-W Fungicide Botran Technical Botran 5F Fungicide Botran P 5F Fungicide	Dicloran	Geraniums and hydrangeas.
10163–226		Dicloran	Geraniums and hydrangeas.

Table 2 of this unit includes the names and addresses of record for all registrants of the products listed in Table 1 of this unit, in sequence by EPA company number.

TABLE 2—REGISTRANTS REQUESTING VOLUNTARY CANCELLATION

EPA company No.	Company name and address
10163	Gowan Company, P.O. Box 5569, Yuma, AZ 85366-5569.

III. What is the Agency's authority for taking this action?

Section 6(f)(1) of FIFRA (7 U.S.C. 136d(f)(1)) provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be amended to delete one or more uses. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**.

Section 6(f)(1)(B) of FIFRA (7 U.S.C. 136d(f)(1)(B)) requires that before acting on a request for voluntary cancellation, EPA must provide a 30-day public comment period on the request for voluntary cancellation or use termination. In addition, FIFRA section 6(f)(1)(C) (7 U.S.C. 136d(f)(1)(C)) requires that EPA provide a 180-day comment period on a request for voluntary cancellation or termination of any minor agricultural use before granting the request, unless:

- 1. The registrants request a waiver of the comment period, or
- 2. The EPA Administrator determines that continued use of the pesticide would pose an unreasonable adverse effect on the environment.

The registrants listed in Table 2 of Unit II have requested that EPA waive the 180-day comment period. Accordingly, EPA will provide a 30-day comment period on the proposed requests.

IV. Procedures for Withdrawal of Request

Registrants who choose to withdraw a request for use deletion must submit the withdrawal in writing to the person listed under FOR FURTHER INFORMATION CONTACT using the methods in ADDRESSES. If the products have been subject to a previous cancellation action, the effective date of cancellation and all other provisions of any earlier cancellation action are controlling.

V. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of registered pesticide products that are currently in the United States and that were packaged, labeled, and released for shipment prior to the effective date of the cancellation action.

In any order issued in response to these requests for cancellation of product registrations EPA proposes to include the following provisions for the treatment of any existing stocks of the products listed in Table 1 of Unit II.

For all voluntary product cancellations, listed in Table 1 of Unit II, the registrants will be permitted to sell and distribute existing stocks of voluntarily canceled products for 1 year after the effective date of the cancellation, which will be the date of publication of the cancellation order in the **Federal Register**. Thereafter, registrants will be prohibited from selling or distributing the products

identified in Table 1 of Unit II, except for export consistent with FIFRA section 17 (7 U.S.C. 1360) or for proper disposal.

Persons other than the registrant may sell, distribute, or use existing stocks of the canceled products until supplies are exhausted, provided that such sale, distribution, or use is consistent with the terms of the previously approved labeling on, or that accompanied, the canceled products.

Authority: 7 U.S.C. 136 et seq.

Dated: April 28, 2021.

Mary Reaves,

Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.

[FR Doc. 2021–09485 Filed 5–4–21; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-10022-04-OAR]

Disclosure of Information Claimed as, or Determined by EPA To Be, Confidential Business Information in Renewable Fuel Standard (RFS) Small Refinery Exemption Petitions and All RFS Related Information in EPA's Moderated Transaction System (EMTS)

AGENCY: Environmental Protection

Agency (EPA).

ACTION: Notice.

SUMMARY: The U.S. Environmental Protection Agency ("EPA" or "Agency") is providing notice of disclosure to all obligated parties under the Renewable Fuel Standard ("RFS") program that have petitioned for a small refinery exemption and to all parties whose RFS information otherwise resides in EPA's Moderated Transaction System ("EMTS"). In response to a request by the U.S. Government Accountability Office ("GAO"), EPA will disclose information to GAO which has been submitted to the Agency that is claimed to be, or has been determined to be, confidential business information (collectively "CBI"). The information to be disclosed includes all documents, information, and data related to all small refinery exemption petitions received by EPA from the start of the RFS program through the present. These records include, but are not limited to: (a) All materials submitted by the small refineries as part of its petition; (b) any documentation sent by the Department of Energy ("DOE") to EPA stating DOE's findings and score(s) associated with the petition(s) and any EPA responses thereto; (c) any EPA record addressing the subject of the exemption petition(s), including any analysis that EPA conducted in addition to DOE's findings; and (d) EPA's final exemption decision sent to the refinery. EPA also intends to disclose to GAO all RFS related transaction-level data contained in EMTS, including Renewable Identification Number ("RIN") transactions under the RFS. This information is being produced to GAO pursuant to EPA's regulations pertaining to disclosure.

DATES: EPA will disclose the material discussed in this document to GAO, including any CBI therein, no later than 16 calendar days after publication of this notice in the **Federal Register**. All CBI-claimed documents will be destroyed, deleted, or returned to EPA at the conclusion of GAO's review.

FOR FURTHER INFORMATION CONTACT:

Karen Nelson, Environmental Protection Specialist, Compliance Division, Office of Transportation and Air Quality at ComplianceInfo@epa.gov or (734) 214–4362.

SUPPLEMENTARY INFORMATION:

I. Background

In connection with a review by the U.S. Government Accountability Office ("GAO"), the U.S. Environmental Protection Agency ("EPA" or "Agency") received a request under 40 CFR 2.209(b) from GAO for records submitted to EPA under the Renewable Fuel Standard ("RFS") program from

the start of the program through the present. The information that will be disclosed to GAO includes all documents, information, and data related to all small refinery exemption petitions received by EPA from the start of the RFS program through the present. These records include, but are not limited to: (a) All materials submitted by the small refineries as part of its petition; (b) any documentation sent by the Department of Energy ("DOE") to EPA stating DOE's findings and score associated with the petition; (c) any analysis that EPA conducted in addition to DOE's findings; and (d) EPA's final exemption decision sent to the refinery. The request also includes all RFS related transaction-level data contained in EPA's Moderated Transaction System ("EMTS"), including Renewable Identification Number ("RIN") transactions under the RFS. This notice is being provided pursuant to 40 CFR 2.209(b)(2) to inform potentially affected businesses that EPA intends to transmit certain documents, which may contain information submitted by oil refiners and refineries, or any company associated therewith, that is claimed to be, or has been determined to be, confidential business information (collectively "CBI") to GAO in response to its request for information. The disclosure of CBI is limited to GAO and further disclosure is generally restricted by 31 U.S.C. 716(e) and subject to criminal penalties under 18 U.S.C. 1905. Any objections to EPA's disclosure must be raised within 15 calendar days from publication of this notice.

Dated: April 29, 2021.

Byron Bunker,

Director, Compliance Division, Office of Transportation and Air Quality, Office of Air and Radiation.

[FR Doc. 2021–09467 Filed 5–4–21; 8:45 am]

BILLING CODE 6560-50-P

EXPORT-IMPORT BANK

[Public Notice: 2021-6008]

Agency Information Collection
Activities: Final Collection; Comment
Request

AGENCY: Export-Import Bank of the United States.

ACTION: Submission for OMB review and comments request.

SUMMARY: The Export-Import Bank of the United States (EXIM), as a part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal Agencies to comment on the proposed

information collection, as required by the Paperwork Reduction Act of 1995. **DATES:** Comments should be received on or before July 6, 2021 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on www.Regulations.gov or by mail to Donna Schneider, Export-Import Bank of the United States, 811 Vermont Ave. NW, Washington, DC 20571.

The form can be viewed at: https://www.exim.gov/sites/default/files/pub/

pending/eib11-04.pdf.

FOR FURTHER INFORMATION CONTACT: To request additional information, please Donna Schneider. 202–565–3612.

SUPPLEMENTARY INFORMATION: This collection of information is necessary, pursuant to 12 U.S.C. 635(a)(1), to determine eligibility of the export sales for insurance coverage. The Report of Premiums Payable for Financial Institutions Only is used to determine the eligibility of the shipment(s) and to calculate the premium due to Ex-Im Bank for its support of the shipment(s) under its insurance program. Export-Import Bank customers will be able to submit this form on paper or electronically.

This form will enable EXIM to identify the specific details of the proposed co-financing transaction between a U.S. exporter, EXIM, and a foreign export credit agency; the information collected includes vital facts such as the amount of U.S.-made content in the export, the amount of financing requested from EXIM, and the proposed financing amount from the foreign export credit agency. These details are necessary for approving this unique transaction structure and coordinating our support with that of the foreign export credit agency to ultimately complete the transaction and support U.S. exports—and U.S. jobs.

Titles and Form Number: EIB11-04, Co-Financing with Foreign Export Credit Agency.

OMB Number: 3048–0037.

Type of Review: Regular.
Need and Use: The information
collected will provide information
needed to determine compliance and
creditworthiness for transaction
requests submitted to the Export Import
Bank under its insurance, guarantee,
and direct loan programs.

Affected Public: This form affects entities involved in the export of U.S.

goods and services.

Annual Number of Respondents: 60. Estimated Time per Respondent: 15 minutes.

Annual Burden Hours: 15 hours. Frequency of Reporting or Use: As needed. Government Expenses:

Reviewing Time per Year: 15 hours. Average Wages per Hour: \$42.50. Average Cost per Year: \$637.50 (time

* wages).

Benefits and Overhead: 20%. Total Government Cost: \$765.

Bassam Doughman,

IT Specialist.

[FR Doc. 2021-09395 Filed 5-4-21; 8:45 am]

BILLING CODE 6690-01-P

EXPORT-IMPORT BANK

[Public Notice: 2021-6007]

Agency Information Collection Activities: Comment Request

AGENCY: Export-Import Bank of the United States.

ACTION: Submission for OMB review and comments request.

SUMMARY: The Export-Import Bank of the United States (EXIM), 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 collection, as required by the Paperwork Reduction Act of 1995.

DATES: Comments must be received on or before July 6, 2021 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on www.Regulations.Gov or by mail to Donna Schneider, Export-Import Bank of the United States, 811 Vermont Ave. NW, Washington, DC 20571.

The information collection tool can be reviewed at: https://www.exim.gov/sites/default/files/pub/pending/eib10-05.pdf.

FOR FURTHER INFORMATION CONTACT: To request additional information, please Donna Schneider. 202–565–3612.

SUPPLEMENTARY INFORMATION: Pursuant to the Export-Import Bank Act of 1945, as amended (12 U.S.C. 635, et seq.), the Export-Import Bank of the United States (EXIM), facilitates the finance of the export of U.S. goods and services by providing insurance or guarantees to U.S. exporters or lenders financing U.S. exports. By neutralizing the effect of export credit insurance or guarantees offered by foreign governments and by absorbing credit risks that the private sector will not accept, EXIM enables U.S. exporters to compete fairly in foreign markets on the basis of price and product. In the event that a borrower defaults on a transaction insured or guaranteed by EXIM, the insured or guaranteed exporter or lender may seek

payment from EXIM by the submission of a claim.

Title and Form Number: EIB 10–05 Notice of Claim and Proof of Loss, Medium Term Guarantee.

OMB Number: 3048–0034. Type of Review: Regular.

Need and Use: This collection of information is necessary, pursuant to 12 U.S.C. 635(a)(1), to determine if such claim complies with the terms and conditions of the relevant guarantee.

Affected Public: This form affects entities involved in the export of U.S. goods and services.

Annual Number of Respondents: 65. Estimated Time per Respondent: 11/2 hours.

Annual Burden Hours: 97.5 hours. Frequency of Reporting of Use: As needed to request a claim payment.

Government Expenses: Reviewing time per year: 65 hours. Average Wages per Hour: \$42.50. Average Cost per Year: \$2,762 (time * yages).

Benefits and Overhead: 20%. Total Government Cost: \$3,315.

Bassam Doughman,

IT Specialist.

[FR Doc. 2021–09393 Filed 5–4–21; 8:45 am]

BILLING CODE 6690-01-P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060-0180; FRS 24362]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of

information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before July 6, 2021. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov*.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0180. Title: Section 73.1610, Equipment Tests.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other forprofit entities; Not-for-profit institutions.

Number of Respondents and Responses: 500 respondents; 500 responses.

Estimated Hours per Response: 0.5 hours.

Frequency of Response: On occasion reporting requirement.

Total Annual Burden: 250 hours. Total Annual Cost: None.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in Section 154(i) of the Communications Act of 1934, as amended.

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Privacy Impact Assessment: No impact(s).

Needs and Uses: The information collection requirements contained in 47 CFR 73.1610 require the permittee of a new broadcast station to notify the FCC of its plans to conduct equipment tests for the purpose of making adjustments and measurements as may be necessary to assure compliance with the terms of

the construction permit and applicable engineering standards. FCC staff use the data to assure compliance with the terms of the construction permit and applicable engineering standards.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary. [FR Doc. 2021–09509 Filed 5–4–21; 8:45 am] BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

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

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 et seq.) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at https://www.federalreserve.gov/foia/ request.htm. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments 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 June 4, 2021.

- A. Federal Reserve Bank of Dallas (Karen Smith, Director, Applications) 2200 North Pearl Street, Dallas, Texas 75201–2272:
- 1. A.N.B. Holding Company, Ltd., Terrell, Texas; to acquire additional voting shares up to 38.5 percent of The ANB Corporation, and thereby indirectly acquire voting shares of The American National Bank of Texas, both of Terrell, Texas.

Board of Governors of the Federal Reserve System, April 30, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board. [FR Doc. 2021–09487 Filed 5–4–21; 8:45 am] BILLING CODE 6210–01–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 May 20, 2021.

A. Federal Reserve Bank of Atlanta (Kathryn Haney, Assistant Vice President) 1000 Peachtree Street NE, Atlanta, Georgia 30309. Comments can also be sent electronically to Applications.Comments@atl.frb.org:

- 1. Eureka Homestead Employee Stock Ownership Plan, Metairie, Louisiana; to acquire additional voting shares of Eureka Homestead Bancorp, Inc., and thereby indirectly acquire voting shares of Eureka Homestead, both of Metairie, Louisiana.
- B. Federal Reserve Bank of Dallas (Karen Smith, Director, Applications) 2200 North Pearl Street, Dallas, Texas 75201–2272:
- 1. Gus K. Eifler, Houston, Texas; to acquire voting shares of Central Bancshares, Inc., by becoming a trustee of both the Carolyn J. Young 2012 Trust

and John H. Young 2020 Trust, and thereby indirectly acquire voting shares of Central Bank, all of Houston, Texas, and to become a member of the Young Family Control Group, a group acting in concert.

C. Federal Reserve Bank of Richmond (Adam M. Drimer, Assistant Vice President) 701 East Byrd Street, Richmond, Virginia 23219. Comments can also be sent electronically to Comments.applications@rich.frb.org:

1. Kenneth R. Lehman, Fort Lauderdale, Florida; to acquire voting shares of Affinity Bancshares, Inc., and thereby indirectly acquire voting shares of Affinity Bank, both of Covington, Georgia.

Board of Governors of the Federal Reserve System, April 29, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board. [FR Doc. 2021–09405 Filed 5–4–21; 8:45 am] BILLING CODE P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, with revision, the Government Securities Dealers Reports (FR 2004; OMB No. 7100–0003). The revisions will be effective with the first applicable as of date, January 5, 2022.

FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829.

Office of Management and Budget (OMB) Desk Officer—Shagufta Ahmed—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.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the PRA to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. Boardapproved collections of information are incorporated into the official OMB inventory of currently approved collections of information. The OMB

inventory, as well as copies of the PRA Submission, supporting statements, and approved collection of information instrument(s) are available at https:// www.reginfo.gov/public/do/PRAMain. These documents are also available on the Federal Reserve Board's public website at https://www.federal reserve.gov/apps/reportforms/ review.aspx or may be requested from the agency clearance officer, whose name appears above.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, With Revision, of the Following **Information Collection**

Report title: Government Securities Dealers Reports: Weekly Report of Dealer Positions (FR 2004A), Weekly Report of Cumulative Dealer Transactions (FR 2004B), Weekly Report of Dealer Financing and Fails (FR 2004C), Weekly Report of Specific Issues (FR 2004SI), Daily Report of Specific Issues (FR 2004SD), Supplement to the Daily Report of Specific Issues (FR 2004SD ad hoc), Daily Report of Dealer Activity in Treasury Financing (FR 2004WI), Settlement Cycle Report of Dealer Fails and Transaction Volumes: Class A (FR 2004FA), Settlement Cycle Report of Dealer Fails and Transaction Volumes: Class B (FR 2004FB), Settlement Cycle Report of Dealer Fails and Transaction Volumes: Class C (FR 2004FC), and Settlement Cycle Report of Dealer Fails and Transaction Volumes (FR 2004FM).

Agency form number: FR 2004. OMB control number: 7100–0003. Effective date: The revisions will be effective with the first applicable as of date, January 5, 2022.

Frequency: Weekly, daily, monthly. Respondents: Dealers in the U.S. government securities market.

Estimated number of respondents: 24. Estimated average hours per response: FR 2004A, 3.0; FR 2004B, 3.7; FR 2004C, 4.1; FR 2004SI, 2.2; FR 2004SD, 2.2; FR 2004SD ad hoc, 2.0; FR 2004WI, 1.0; FR 2004FA, 1.0; FR 2004FB, 1.0; FR 2004FC, 1.0; and FR 2004FM, 1.5.

Estimated annual burden hours: FR 2004A, 3,744; FR 2004B, 4,618; FR 2004C, 5,117; FR 2004SI, 2,746; FR 2004SD, 2,112; FR 2004SD ad hoc, 1,248; FR 2004WI, 3,840; FR 2004FA, 288; FR 2004FB, 288; FR 2004FC, 288; FR 2004FM, 432.

General description of report: The Federal Reserve Bank of New York (FRBNY), on behalf of the Federal Reserve System, collects data from primary dealers in the U.S. government securities market. Filing of these data is required to obtain the benefit of primary dealer status. The Federal Reserve uses

these data to (1) monitor the condition of the U.S. government securities market in its Treasury market surveillance and analysis of the market and (2) assist and support the U.S. Department of the Treasury (Treasury) in its role as fiscal agent for Treasury financing operations. In addition, these data are used in the analysis of broad financial conditions and a range of financial stability issues.

Legal authorization and confidentiality: The information collected on the FR 2004 series of reports is generally authorized under sections 2A, 12A(c), 14, and 15 of the Federal Reserve Act. Section 2A requires that the Board and the Federal Open Market Committee "maintain long run growth of the monetary and credit aggregates commensurate with the economy's long run potential to increase production, so as to promote effectively the goals of maximum employment, stable prices, and moderate long-term interest rates" (12 U.S.C. 225a). Section 12A(c) further provides that the time, character, and volume of open market operations "shall be governed with a view to accommodating commerce and business and with regard to their bearing upon the general credit situation of the country" (12 U.S.C. 263(c)). Additionally, section 14 authorizes the Federal Reserve Banks to engage in open market operations (12 U.S.C. 353-359). Finally, section 15 permits the Federal Reserve Banks, at the direction of the Secretary of the Treasury, to act as fiscal agents of the United States (12 U.S.C. 391). The Board has implicit authority to collect data to carry out the requirements of the foregoing statutory provisions.¹ Filing the FR 2004 series is a condition of obtaining and retaining primary dealer status. Thus, the obligation to respond is "required to obtain or retain a benefit" because being a primary dealer allows a firm to act as a trading counterparty of the FRBNY in the implementation of its monetary policy.²

While aggregate data from certain of the forms in the FR 2004 series will be published, individually identifying information may be kept confidential under exemption 4 and, in certain circumstances, exemption 8 of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(4) and (b)(8)). Individual

respondent data collected through the FR 2004 may be considered confidential pursuant to FOIA exemption 4 to the extent these responses contain nonpublic commercial or financial information, which is both customarily and actually treated as private by the respondent. Moreover, to the extent that the information is "contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of [the Board]," the information may be withheld by the Board under FOIA exemption 8.

Current actions: On December 14, 2020, the Board published a notice in the Federal Register (85 FR 80786) requesting public comment for 60 days on the extension, with revision, of the FR 2004. The Board proposed to revise the FR 2004 with four additions and two modifications by:

(1) Adding a row to the FR 2004A, B, SI, SD, and WI to account for the new 20 year Treasury bond,

(2) adding a row to the FR 2004A and two rows to FR 2004B to separately capture Mortgage-Backed Securities (MBS) To-Be-Announced (TBA) and specified pool classifications,

(3) adding 18 columns to the FR 2004C to capture a split by clearing venue, with maturity tenor applied to

each venue classification,

(4) adding 5 lines to the FR 2004C to separately capture Federal Agency and Government-Sponsored Enterprise (GSE) Residential MBS and Federal Agency and GSE Commercial MBS, and to separate Total lines for Repo and Other Financing Activities,

(5) revising the FR 2004FA, FB, and FM to capture Federal National Mortgage Association (FNMA) and Federal Home Loan Mortgage Corporation (FHLMC) Uniform MBS (UMBS) and FNMA non-UMBS eligible securities settlement fails and transactions, separate from FHLMC non-UMBS eligible securities settlement fails and transactions, and

(6) modifying the instructions to provide additional guidance on report consolidation rules for primary dealers when the legal entity serving as a primary dealer is a branch or agency of a foreign banking organization (FBO) as well as some other minor corrections and edits for improved clarity.

The comment period for this notice expired on February 12, 2021. The Board received 2 comment letters from industry trade associations related to the changes to the FR 2004 reports. Both commenters requested that the effective date of the changes be extended, with one commenter requesting a phased approach beginning in the fourth quarter 2021 and the other commenter

¹ Additionally, depending upon the survey respondent, a more precise statute may authorize the data collection. For example, the Board is authorized to collect information from bank holding companies (and their subsidiaries) under section 5(c) of the Bank Holding Company Act of 1956 (12 U.S.C. 1844(c)) and from depository institutions under section 11(a) of the Federal Reserve Act (12 U.S.C. 248(a)).

² See 5 CFR 1320.8(b)(3)(iv).

recommending a January 2022 effective date. The Board agreed and clarified that the changes will become effective with the first applicable as of date, January 5, 2022. One commenter recommended that the FR 2004 report instructions and FAQs be updated to reflect the proposed changes. The revised report forms, instructions, and FAQ document will be made available in final form on the Board's public website. Aside from the changes discussed above, the Board will adopt the extension, with revision, of the FR 2004 as originally proposed.

Board of Governors of the Federal Reserve System, April 29, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board. [FR Doc. 2021–09459 Filed 5–4–21; 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, with revision, the International Applications and Prior Notifications under Subparts A and C of Regulation K (FR K–1; OMB No. 7100–

DATES: Comments must be submitted on or before July 6, 2021.

0107).

ADDRESSES: You may submit comments, identified by *FR K-1*, by any of the following methods:

- Agency Website: https:// www.federalreserve.gov/. Follow the instructions for submitting comments at https://www.federalreserve.gov/apps/ foia/proposedregs.aspx.
- Email: regs.comments@ federalreserve.gov. Include the OMB number in the subject line of the message.
- Fax: (202) 452–3819 or (202) 452–3102.
- Mail: Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue 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 identifying or contact information. Public comments may also be viewed electronically or in paper in Room 146, 1709 New York Avenue NW, Washington, DC 20006, between 9:00 a.m. and 5:00 p.m. on weekdays. 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—Shagufta Ahmed—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 Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the 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.

A copy of the Paperwork Reduction Act (PRA) OMB submission, including the reporting form and instructions, supporting statement, and other documentation will be available at https://www.reginfo.gov/public/do/PRAMain, if approved. These documents will also be made available on the Board's public website at https://www.federalreserve.gov/apps/reportforms/review.aspx or may be requested from the agency clearance officer, whose name appears above.

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, With Revision, the Following Information Collection

Report title: International Applications and Prior Notifications under Subparts A and C of Regulation K

Agency form number: FR K-1. *OMB control number:* 7100–0107. *Frequency:* On occasion.

Respondents: Member banks, Edge and agreement corporations, bank holding companies (BHCs), and certain investments by foreign organizations.

Estimated number of respondents:
Reporting: Attachments A and B, 6;
Attachments C through G, 13;
Attachments H and I, 10; Attachment J,
2; Attachment K, 1; Section 211.5(c)(4)
requirements, 1; Section 211.10
requirements, 1; Section 211.11
requirements, 1. Disclosure: Attachment
F, 13. Recordkeeping: Section 211.13
requirement, 70.

Estimated average hours per response: Reporting: Attachments A and B, 11.5; Attachments C through G, 9; Attachments H and I, 15.5; Attachment J, 10; Attachment K, 20; Section 211.5(c)(4) requirements, 1; Section 211.8 requirements, 0.25; Section 211.10 requirements, 8; Section 211.11 requirements, 5. Disclosure: Attachment F, 1. Recordkeeping: Section 211.13 requirement, 1.

¹References to Edge corporations are inclusive of agreement corporations. An agreement corporation is a corporation that has entered into an agreement with the Board that it will not exercise any power that is impermissible for an Edge corporation. 12 CFR 211.5(g)(1).

Estimated annual burden hours: Reporting: Attachments A and B, 138; Attachments C through G, 234; Attachments H and I, 465; Attachment J, 20; Attachment K, 20; Section 211.5(c)(4) requirements, 1; Section 211.8 requirements, 0; Section 211.10 requirements, 8; Section 211.11 requirements, 5. Disclosure: Attachment F, 26. Recordkeeping: Section 211.13 requirement, 70.

General description of report: Subpart A of Regulation K—International Banking Operations, governs the foreign investments and activities of member banks, Edge and agreement corporations, BHCs, and certain investments by foreign organizations. Subpart C of Regulation K governs investments in export trading companies by eligible investors.² The FR K–1 information collection contains eleven attachments for the application and notification requirements in Subparts A and C of Regulation K. The Board requires these applications for regulatory and supervisory purposes and to allow the Board to fulfill its statutory obligations under the Federal Reserve Act (FRA) and the Bank Holding Company Act of 1956 (BHC Act). The applications are eventgenerated and provide the Federal Reserve with information necessary to evaluate each of the proposed transactions.

Proposed revisions: The Board proposes to revise the FR K-1 information collection to account for several reporting and recordkeeping provisions in sections 211.5, 211.8, 211.10, 211.11, and 211.13 of Regulation K that have not been previously cleared by the Board under the PRA. The Board is not proposing to create additional attachments to the FR K-1 to address these provisions.

Legal authorization and confidentiality: The Board is authorized to collect the information required on the FR K–1 under sections 25 and 25A of the FRA,³ and sections 4(c)(13), 4(c)(14), and 5(c) of the BHC Act.⁴ Section 25 of the FRA authorizes the Board to approve applications to establish agreement corporations, establish foreign branches, and invest in foreign banks in accordance with regulations prescribed by the Board. Section 25 also authorizes the Board to require reports concerning the condition of these entities. Section 25A of the FRA

authorizes the Board to approve the establishment of Edge corporations, to issue rules and regulations relating to these entities, and to require reports from these entities. Section 4(c)(13) of the BHC Act authorizes the Board, by regulation or order, to determine that BHCs may invest in companies that do business abroad. Section 4(c)(14) of the BHC Act authorizes BHCs to invest in export trading companies, subject to a notice requirement and disapproval by the Board. Section 5(c) of the BHC Act grants the Board reporting and examination authorities.

The applications and notifications comprising FR K-1 are required to obtain a benefit. Individual respondents may request that information submitted to the Board through the FR K-1 be kept confidential. If a respondent requests confidential treatment, the Board will determine whether the information is entitled to confidential treatment on a case-by-case basis. To the extent a respondent submits nonpublic commercial or financial information, which is both customarily and actually treated as private by the respondent, the respondent may request confidential treatment pursuant to exemption 4 of the Freedom of Information Act (FOIA).⁵ To the extent a respondent submits personal, medical, or similar files, the disclosure of which would constitute an unwarranted invasion of privacy, the respondent may request confidential treatment pursuant to exemption 6 of the FOIA.6 To the extent that the Board obtains information as part of the examination process, the information may be confidential pursuant to exemption 8 of the FOIA.7

Board of Governors of the Federal Reserve System, April 29, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board. [FR Doc. 2021–09426 Filed 5–4–21; 8:45 am] BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, without revision, the Survey of

Consumer Finances (FR 3059; OMB 7100–0287).

FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829.

Office of Management and Budget (OMB) Desk Officer—Shagufta Ahmed—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.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the PRA to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. Boardapproved collections of information are incorporated into the official OMB inventory of currently approved collections of information. The OMB inventory, as well as copies of the PRA Submission, supporting statements, and approved collection of information instrument(s) are available at https:// www.reginfo.gov/public/do/PRAMain. These documents are also available on the Federal Reserve Board's public website at https://www.federal reserve.gov/apps/reportforms/ review.aspx or may be requested from the agency clearance officer, whose name appears above.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, Without Revision, of the Following Information Collection

Report title: Survey of Consumer Finances (SCF).

Agency form number: FR 3059. OMB control number: 7100–0287. Frequency: Triennial.

Respondents: U.S. families. Estimated number of respondents: Pretest, 150; Main survey, 7,000.

Estimated average hours per response: Pretest, 100 minutes; Main survey, 100 minutes.

Estimated annual burden hours: Pretest, 250 hours; Main survey, 11,667 hours.

General description of report: This triennial survey is the only source of representative information on the structure of U.S. families' finances. The survey would collect data on the assets, debts, income, work history, pension rights, use of financial services, and attitudes of a sample of U.S. families. Because the ownership of some assets is relatively concentrated in a small

² Eligible investors are BHCs, Edge and agreement corporations that are subsidiaries of bank holding companies but are not subsidiaries of banks, banker's banks, and foreign banking organizations. 12 CFR 211.32(d).

³ 12 U.S.C. 601-604(a) and 611-631.

^{4 12} U.S.C. 1843(c)(13), 1843(c)(14), and 1844(c).

^{5 5} U.S.C. 552(b)(4).

⁶⁵ U.S.C. 552(b)(6).

⁷⁵ U.S.C. 552(b)(8).

number of families, the survey would make a special effort to ensure proper representation of such assets by systematically oversampling wealthier families.

Legal authorization and confidentiality: Section 2A of the Federal Reserve Act (FRA) requires that the Board and the Federal Open Market Committee (FOMC) maintain long run growth of the monetary and credit aggregates commensurate with the economy's long run potential to increase production, so as to promote effectively the goals of maximum employment, stable prices, and moderate long-term interest rates.1 In addition, under section 12A of the FRA, the FOMC is required to implement regulations relating to the open market operations conducted by Federal Reserve Banks. Those transactions must be governed with a view to accommodating commerce and business and with regard to their bearing upon the general credit situation of the country.2 The Board and the FOMC use the information obtained from the FR 3059 to help fulfill these obligations. The FR 3059 is a voluntary survey.

It is expected that the data collected would be published in summary form in the Federal Reserve Bulletin. A version of the microdata, which would be altered to protect the identity of individual respondents, would be made available to the public through the Board's public website. None of the pretest data would be released to the public. The information collected on the FR 3059 that identifies the individual respondents may be exempt from disclosure under exemption 6 of the Freedom of Information Act, which protects information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.3

Current actions: On February 3, 2021, the Board published a notice in the **Federal Register** (86 FR 8016) requesting public comment for 60 days on the extension, without revision, of the Survey of Consumer Finances. The comment period for this notice expired on April 5, 2021. The Board did not receive any comments.

Board of Governors of the Federal Reserve System, April 29, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–09465 Filed 5–4–21; 8:45 am]

BILLING CODE 6210-01-P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, without revision, the Senior Financial Officer Surveys (FR 2023; OMB No. 7100–0223).

FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829.

Office of Management and Budget (OMB) Desk Officer—Shagufta Ahmed—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.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the PRA to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. Boardapproved collections of information are incorporated into the official OMB inventory of currently approved collections of information. The OMB inventory, as well as copies of the PRA Submission, supporting statements, and approved collection of information instrument(s) are available at https:// www.reginfo.gov/public/do/PRAMain. These documents are also available on the Federal Reserve Board's public website at https://www.federal reserve.gov/apps/reportforms/ review.aspx or may be requested from the agency clearance officer, whose name appears above.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, Without Revision, of the Following Information Collection

Report title: Senior Financial Officer Surveys.

Agency form number: FR 2023.

OMB control number: 7100–0223.

Frequency: Up to four times a year.

Respondents: Domestically chartered large depository institutions and foreign banking organizations.

Estimated number of respondents: 80. Estimated average hours per response:

Estimated annual burden hours: 960.

General description of report: The Board uses the surveys in this collection to gather qualitative and limited quantitative information about liability management, the provision of financial services, and the functioning of key financial markets. Responses are obtained from a senior officer at each participating institution, usually through an electronic submission. Although a survey may not be collected in a given year, the Board may conduct up to four surveys per year when informational needs arise and cannot be met from existing data sources. The survey does not have a fixed set of questions; each survey consists of a limited number of questions directed at topics of timely interest.

Legal authorization and confidentiality: The FR 2023 is authorized by sections 2A, 12A, and 11 of the Federal Reserve Act ("FRA").1 Section 2A of the FRA requires that the Board and the Federal Open Market Committee ("FOMC") maintain long run growth of the monetary and credit aggregates commensurate with the economy's long run potential to increase production, so as to promote effectively the goals of maximum employment, stable prices, and moderate long-term interest rates.2 Section 12A of the FRA further requires the FOMC to implement regulations relating to the open market operations conducted by Federal Reserve Banks with a view to accommodating commerce and business and with regard to their bearing upon the general credit situation of the country.3 Section 11 of the FRA authorizes the Board to require reports from each member bank as it may deem necessary and authorizes the Board to prescribe reports of liabilities and assets from insured depository institutions to enable the Board to discharge its responsibility to monitor and control monetary and credit aggregates.4 The Board and FOMC use the information obtained through the FR 2023 to discharge these responsibilities. Survey submissions under the FR 2023 are voluntary.

The questions asked on each survey will vary. The Board's ability to keep confidential responses to the FR 2023 must therefore be determined on a case-by-case basis. Much of the information collected is likely to constitute nonpublic commercial or financial information, which is both customarily and actually treated as private by the respondent, and may be kept

¹ 12 U.S.C. 225a.

² 12 U.S.C. 263.

^{3 5} U.S.C. 552(b)(6).

^{1 31} U.S.C. 5364(a).

² 12 U.S.C. 225a.

^{3 12} U.S.C. 263.

^{4 12} U.S.C. 248(a).

confidential by the Board pursuant to exemption 4 of the Freedom of Information Act ("FOIA").⁵ Some survey responses may also contain information contained in or related to an examination of a financial institution, which may be kept confidential under exemption 8 of FOIA.⁶ Responses to the FR 2023 are tabulated and summarized at the Board and the Federal Reserve Bank of New York. This aggregate information is not considered confidential, and a report containing summary data is published on the Board's public website.⁷

Current actions: On February 3, 2021, the Board published a notice in the **Federal Register** (86 FR 8015) requesting public comment for 60 days on the extension, without revision, of the Senior Financial Officer Surveys. The comment period for this notice expired on April 5, 2021. The Board did not receive any comments.

Board of Governors of the Federal Reserve System, April 29, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–09466 Filed 5–4–21; 8:45 am] BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, without revision, the Quarterly Report of Assets and Liabilities of Large Foreign Offices of U.S. Banks (FR 2502q; OMB No. 7100–0079).

FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829.

Office of Management and Budget (OMB) Desk Officer—Shagufta Ahmed—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.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the PRA to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. Boardapproved collections of information are incorporated into the official OMB inventory of currently approved collections of information. The OMB inventory, as well as copies of the PRA Submission, supporting statements, and approved collection of information instrument(s) are available at https:// www.reginfo.gov/public/do/PRAMain. These documents are also available on the Federal Reserve Board's public website at https://www.federal reserve.gov/apps/reportforms/ review.aspx or may be requested from the agency clearance officer, whose name appears above.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, Without Revision, of the Following Information Collection

Report title: Quarterly Report of Assets and Liabilities of Large Foreign Offices of U.S. Banks.

Agency form number: FR 2502q. OMB control number: 7100–0079. Frequency: Quarterly.

Respondents: U.S. commercial banks, bank holding companies (including financial holding companies), and Edge Act and agreement corporations.

Estimated number of respondents: 23. Estimated average hours per response:

Estimated annual burden hours: 92. General description of report: U.S. commercial banks, bank holding companies, and Edge Act and agreement corporations are required to file the FR 2502q reporting form, on a quarterly basis, for their large branches (those that have assets of \$2 billion or more) and banking subsidiaries (those that have assets of \$2 billion or more and deposits of \$10 million or more) that are located in the United Kingdom or the Caribbean. The Board has an interest in knowing the amounts of the claims and liabilities of U.S.-chartered banks with respect to residents of individual countries.

Legal authorization and confidentiality: The Board is authorized to collect the information in FR 2502q from (1) bank holding companies pursuant to section 5 of the Bank Holding Company Act, which authorizes the Board to require a bank holding company and any subsidiary to submit reports; (2) Edge Act and agreement corporations pursuant to

sections 25(4) 25A(17) of the Federal Reserve Act (FRA),² which authorize the Board to require Edge and agreement corporations to make reports to the Board; and (3) depository institutions pursuant to sections 11(a)(1) and (2) of the FRA,³ which authorize the Board to require reports from each member bank as it may deem necessary and to require reports of liabilities and assets from insured depository institutions to enable the Board to discharge its responsibility to monitor and control monetary and credit aggregates.

The FR 2502q report is mandatory. To the extent that the information from this collection obtained by the Board constitutes nonpublic commercial or financial information, which is both customarily and actually treated as private by the financial institution, the financial institution may request confidential treatment pursuant to exemption 4 of the Freedom of Information Act.⁴

Current actions: On February 3, 2021, the Board published a notice in the Federal Register (86 FR 8014) requesting public comment for 60 days on the extension, without revision, of the Quarterly Report of Assets and Liabilities of Large Foreign Offices of U.S. Banks. The comment period for this notice expired on April 5, 2021. The Board received one comment.

Detailed Discussion of Public Comments

The U.S. Department of Commerce Bureau of Economic Analysis provided comment that it was in strong support of the continued collection of the FR 2502q data.

Board of Governors of the Federal Reserve System, April 29, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board. [FR Doc. 2021–09460 Filed 5–4–21; 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, with revision, the Report of

⁵ 5 U.S.C. 552(b)(4).

⁶ 5 U.S.C. 552(b)(8).

⁷ Survey reports are available at www.federalreserve.gov/data/sfos/sfos.htm.

¹ 12 U.S.C. 1844(c).

² 12 U.S.C. 602 and 12 U.S.C. 625.

^{3 12} U.S.C. 248(a)(1) and (2).

⁴⁵ U.S.C. 552(b)(4).

Selected Money Market Rates (FR 2420; OMB No. 7100–0357).

DATES: Comments must be submitted on or before July 6, 2021.

ADDRESSES: You may submit comments, identified by FR 2420, by any of the following methods:

- Agency Website: https:// www.federalreserve.gov/. Follow the instructions for submitting comments at https://www.federalreserve.gov/apps/ foia/proposedregs.aspx.
- Email: regs.comments@ federalreserve.gov. Include the OMB number in the subject line of the message.
- Fax: (202) 452–3819 or (202) 452–3102.
- Mail: Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue 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 identifying or contact information. Public comments may also be viewed electronically or in paper in Room 146, 1709 New York Avenue NW, Washington, DC 20006, between 9:00 a.m. and 5:00 p.m. on weekdays. 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—Shagufta Ahmed—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 Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the 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.

A copy of the Paperwork Reduction Act (PRA) OMB submission, including the reporting form and instructions, supporting statement, and other documentation will be available at https://www.reginfo.gov/public/do/PRAMain, if approved. These documents will also be made available on the Board's public website at https://www.federalreserve.gov/apps/reportforms/review.aspx or may be requested from the agency clearance officer, whose name appears above.

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, With Revision, the Following Information Collection

Report title: Report of Selected Money Market Rates.

Agency form number: FR 2420. OMB control number: 7100–0357. Frequency: Daily.

Respondents: Commercial banks, savings associations, branches and agencies of foreign banks, international banking facilities, and significant banking organizations representing entities actively participating in the federal funds and/or other money markets.

Estimated number of respondents: 181 commercial banks, savings associations, U.S. branches and agencies of foreign banks, and significant banking organizations; 77 international banking facilities.

Estimated average hours per response: 2.0 commercial banks, savings associations, U.S. branches and agencies of foreign banks, and significant banking organizations; 1.1 international banking facilities.

Estimated annual burden hours: 90,500 commercial banks, savings associations, U.S. branches and agencies of foreign banks, and significant banking organizations; 21,175 international banking facilities.

General description of report: The FR 2420 is a transaction-based report that collects daily liability data on federal funds purchased, selected borrowings from non-exempt entities,1 Eurodollar transactions, and time deposits and certificates of deposits (CDs) from (1) domestically chartered commercial banks and savings associations that have \$18 billion or more in total assets as well as those that have total assets above \$5 billion but less than \$18 billion and meet the activity threshold, (2) U.S. branches and agencies of foreign banks with total third-party assets of \$2.5 billion or more, and (3) significant banking organizations that are active participants in money markets. The FR 2420 also collects daily data on Eurodollar transactions from International Banking Facilities (IBFs) of the above-referenced institutions. The FR 2420 data are used in the publication of the Effective Federal Funds Rate (EFFR) and Overnight Bank Funding Rate (OBFR) and in analysis of current money market conditions.

Proposed revisions: The Board proposes to add a data item to specify the day-count convention used for all interest rates reported on the FR 2420 reporting form. The Board also proposes revisions to the FR 2420 instructions to allow for more timely collection of data, improve monitoring of the transition away from the London Interbank Offered Rate (LIBOR), strengthen the reference rate production process, and ensure the integrity of reported data. The proposed revisions support the

¹ A selected borrowing from a non-exempt entity is an unsecured borrowing (an unsecured primary obligation undertaken by the reporting institution as a means of obtaining funds) in U.S. dollars from a counterparty that is a non-exempt entity as derived from Regulation D, section 204.2(a)(vii).

Board's monetary policy and supervisory mandates by providing greater insight into funding market conditions in periods where conditions change rapidly, potentially affecting policy measures taken by the Federal Reserve. The proposed revisions to FR 2420 would be effective with the January 1, 2022, as of date.

Reporting Form Revisions

The Board proposes to add a data item to specify the day-count convention used for all interest rates reported on FR 2420. The Federal Reserve has identified limited instances of reporting institutions using multiple day-count conventions in calculating reported interest rates, specifically found in the reporting of Part C interest rates. The proposed revision would improve the accuracy of reported data, benefiting the Federal Reserve's monitoring of funding market conditions and strengthening the production of the EFFR and OBFR. The proposed data item would provide the following day-count conventions as options: Actual/360, actual/365, 30/360, 30/365, actual/actual, and other.

Instruction Revisions

Additional Reference Rate Options for Floating-Rate Time Deposits and CDs (Part C)

The Board proposes to include additional reference rates to which floating-rate time deposits and CDs are tied. The additional rates include the Secured Overnight Financing Rate (SOFR), other SOFR-based rates, and OBFR, all of which are published daily by the Federal Reserve Bank of New York (FRBNY). Other SOFR-based rates include the SOFR Index and the SOFR Averages over 30, 90, and 180 days. This revision would improve the ability of the Federal Reserve to monitor the progress of the transition from LIBOR to SOFR with respect to floating-rate money market instruments.2

Earlier Deadline for Submission of Time Deposit and CD Data (General Instructions)

The Board proposes to change the deadline for submission of time deposit and CD data in Part C to 2 p.m. ET one business day (T+1) after the report date, rather than two business days (T+2) after the report date. This proposed change would provide more timely data and improve the Federal Reserve's monitoring of funding market

conditions. The change would be particularly beneficial on occasions when market conditions change quickly, such as when a deterioration in time deposit and CD markets may produce spillovers to other markets.

Earlier Deadline for Submission of Federal Funds Purchased, Eurodollar, and Selected Deposits Data (General Instructions)

The Board proposes to change the deadline for submission of Federal Funds Purchased, Eurodollars, and Selected Deposits data in Parts A, B, and D to 7 p.m. ET the same day (T+0) as the transaction date, rather than 7 a.m. ET one business day (T+1) after the transaction date. The proposed earlier reporting deadline would allow for more opportunity for data review and validation, reducing operational risk associated with the publication of the EFFR and OBFR.

Clarifications To Prevent Errors (Parts C and D)

The Board proposes other minor additions to the FR 2420 instructions to prevent confusion and errors on the part of reporting institutions. Guidance would be added for certain reciprocal deposits, including insured deposit cash sweeps and Certificate of Deposit Account Registry Service deposits (Part C). Additional guidance would be included on the correct reporting of brokered deposits (Part C) and certain securities lending transactions (Part D).

Legal authorization and confidentiality: The FR 2420 is authorized by section 11 of the Federal Reserve Act (FRA) and section 7 of the International Banking Act of 1978 (IBA). Section 11 of the FRA authorizes the Board to require reports from depository institutions as it may deem necessary and authorizes the Board to prescribe reports of liabilities and assets from insured depository institutions to enable the Board to discharge its responsibility to monitor and control monetary and credit aggregates (12 U.S.C. 248(a)). Section 7 of the IBA provides that federal branches and agencies of foreign banks are subject to section 11 of the FRA as if they were state member banks (12 U.S.C. 3105(c)). The obligation to respond to the FR 2420 is mandatory.

The FRBNY uses aggregate data from the FR 2420 to publish the EFFR, OBFR, and associated statistics daily. The information provided by individual respondents to the FR 2420 is nonpublic commercial or financial information, which is both customarily and actually treated as private by the respondents. Responses to the FR 2420 are therefore accorded confidential treatment

pursuant to exemption 4 of the Freedom of Information Act (5 U.S.C. 552(b)(4)).

Consultation outside the agency: A group of large FR 2420 respondents (less than 10) were consulted in November 2020 regarding the feasibility of reporting timestamps for FR 2420 transactions, shifting reporting deadlines, and the day-count conventions used when reporting interest rates on FR 2420 transactions. Outreach results suggest that timestamps for transactions are not recorded in a consistent fashion across respondents, and thus the current proposals do not call for the reporting of timestamps. Outreach also suggests that most respondents currently report Parts A, B, and D of the FR 2420 report on a T+0 basis, and no respondents consulted suggested that a T+0 reporting deadline for Parts A, B, and D was not feasible. Most respondents consulted noted that they should be able to report Part C transactions on a T+1 basis. Feedback also showed that most transactions are reported using the actual/360 day-count convention for interest rates, but other day-count conventions are used for some reported transactions.

Board of Governors of the Federal Reserve System, April 29, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board. [FR Doc. 2021–09424 Filed 5–4–21; 8:45 am] BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Grants to States for Access and Visitation, OMB #0970–0204

AGENCY: Division of Program Innovation, Office of Child Support Enforcement, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Division of Program Innovation (DPI), Office of Child Support Enforcement (OCSE), Administration for Children and Families (ACF) is requesting a 3-year extension of the Access and Visitation Survey: Annual Report (OMB #0970–0204, expiration 10/31/2021). There are no changes requested to the form.

DATES: Comments due within 30 days of publication. OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the

² The Alternative Reference Rates Committee is a group of private-market participants convened by the Board and the FRBNY to help ensure a successful transition from U.S. dollar LIBOR to a more robust reference rate, its recommended alternative, the SOFR.

Federal Register. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this

notice to www.reginfo.gov/public/do/ PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

SUPPLEMENTARY INFORMATION:

Description: The grantee and/or subgrantee submits the spreadsheet and survey yearly. Information is used by OCSE as the primary means for adhering to the statutory (Sec. 469B. [42 U.S.C. 669b]) and regulatory (45 CFR part 303) requirements for recipients of "Grants to States for Access and Visitation."

Respondents: State Child Access and Visitation Programs and state and/or local service providers.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Online Portal Survey by States and Jurisdictions	54 296	1 1	16 16	864 4,736

Estimated Total Annual Burden

Authority: Sec.469B [42 U.S.C.669b]; 45 CFR part 303.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021-09452 Filed 5-4-21; 8:45 am]

BILLING CODE 4184-41-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; P41 NCBIB Review F–SEP 2.

Date: June 21–23, 2021.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Dennis Hlasta, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Blvd., Bethesda, MD 20892, (301) 451–4794, dennis.hlasta@mail.nih.gov.

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; P41 NCBIB Review F–SEP 1.

Date: June 30, 2021.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Plaza, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Dennis Hlasta, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Blvd., Bethesda, MD 20892, (301) 451–4794, dennis.hlasta@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, HHS)

Dated: April 30, 2021.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–09491 Filed 5–4–21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Generic Clearance To Collect Stakeholder Feedback on the Research Domain Criteria (RDoC) Initiative, (NIMH)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Andrew Hooper, Ph.D., NIMH Project Clearance Liaison, Science Policy and Evaluation Branch, Office of Science Policy, Planning and Communications, NIMH, Neuroscience Center, 6001 Executive Boulevard, MSC 9667, Bethesda, Maryland 20892, call (301) 480-8433, or email your request, including your mailing address, to nimhprapubliccomments@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information,

including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimizes the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Generic Clearance to Collect Stakeholder Feedback on the Research Domain Criteria (RDoC) Initiative, 0925–0756, EXTENSION, exp., date 07/31/2021, National Institute of Mental Health (NIMH), National Institutes of Health (NIH).

Need and Use of Information Collection: This request serves as notice that the National Institute of Mental Health (NIMH) plans to collect

stakeholder feedback to assess the strengths and weaknesses of the Research Domain Criteria (RDoC) initiative. NIMH launched RDoC in 2009 to implement Strategy 1.4 of the 2008 NIMH Strategic Plan: "Develop new ways of classifying disorders based on dimensions of observable behaviors and brain functions." Rather than beginning with a syndrome and then working "down" to clarify mechanisms, the aim of RDoC is to guide research that begins with disruptions in neurobiological and behavioral mechanisms, and then works across systems to clarify connections among such disruptions and clinical symptoms. NIMH has developed social media platforms and tools for the RDoC initiative, including a dedicated RDoC twitter account (https://twitter.com/ nimh_rdoc), the RDoC website, which also houses the RDoC matrix (https:// www.nimh.nih.gov/research-priorities/

rdoc/index.shtml), and several educational and training resources (including webinars) to educate the field and interface with scientists who may have questions about RDoC (https:// www.nimh.nih.gov/research-priorities/ rdoc/rdoc-educational-and-trainingresources.shtml). The evaluation approach will be conducted using surveys centered around current content (i.e., website, twitter, and webinars), as well as open ended surveys that will cover the scientific content of RDoC. The information collected will be used by NIMH staff to determine success of the RDoC initiative, develop future directions and endeavors, and to help guide programmatic priorities for RDoC and the Institute.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 490.

ESTIMATED ANNUALIZED BURDEN HOURS

Instrument type	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Workshops Interviews Surveys Focus Groups Evaluation Forms	50 10 100 10 100	1 1 1 1	8 30/60 30/60 1 15/60	400 5 50 10 25
Total	270	270		490

Dated: April 14, 2021.

Andrew A. Hooper,

Project Clearance Liaison, National Institute of Mental Health, National Institutes of Health.

[FR Doc. 2021–09486 Filed 5–4–21; 8:45 am] BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose

confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; P41 NCBIB Review D—SEP

Date: June 29–July 1, 2021.

Time: 09:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Democracy II, 707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: John K. Hayes, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Blvd., Suite 959, Bethesda, MD 20892, (301) 451–3398, hayesj@mail.nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.866, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, HHS) Dated: April 30, 2021.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-09492 Filed 5-4-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material,

and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; R13 Conference Grant Applications.

Date: June 24, 2021.

Time: 10:00 a.m. to 11:30 a.m. Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jian Yang, Ph.D., Scientific Review Officer, Review Branch, Division of Extramural Activities, NIDDK, National Institutes of Health, Room 7011, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7799, yangj@extra.niddk.nih.gov,

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: April 30, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-09490 Filed 5-4-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS-R2-ES-2020-0133; FXES11130200000-212-FF02ENEH00]

Endangered and Threatened Wildlife and Plants; Initiation of 5-Year Status Reviews of 23 Species in the Southwest

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of initiation of reviews; request for information.

SUMMARY: We, the U.S. Fish and Wildlife Service, are conducting 5-year status reviews under the Endangered Species Act of 23 animal and plant species. A 5-year status review is based on the best scientific and commercial data available at the time of the review; therefore, we are requesting submission of any such information that has become available since the last review for the species.

DATES: To ensure consideration, we are requesting submission of new information no later than June 4, 2021. However, we will continue to accept new information about any listed species at any time.

ADDRESSES: For how to request or submit information, see Request for Information and How Do I Ask Questions or Provide Information? in the **SUPPLEMENTARY INFORMATION** section. FOR FURTHER INFORMATION CONTACT: For general information, please contact Angela Anders, via phone at 505–248– 7953 or via email at Angela_Anders@ fws.gov (email). For information on a particular species, contact the appropriate person or office listed in the table in the SUPPLEMENTARY INFORMATION section. Individuals who are hearing impaired or speech impaired may call the Federal Relay Service at 800-877-8339 for TTY assistance.

SUPPLEMENTARY INFORMATION:

Why do we conduct a 5-year review?

Under the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 et seq.), we maintain Lists of Endangered and Threatened Wildlife and Plants (which we collectively refer to as the List) in the Code of Federal Regulations (CFR) at 50 CFR 17.11 (for animals) and 17.12 (for plants). Section 4(c)(2)(A) of the ESA requires us to review each listed species' status at least

once every 5 years. Our regulations at 50 CFR 424.21 require that we publish a notice in the **Federal Register** announcing those species under active review. For additional information about 5-year reviews, refer to our factsheet at http://www.fws.gov/endangered/what-we-do/recovery-overview.html.

What information do we consider in our review?

A 5-year review considers all new information available at the time of the review. In conducting these reviews, we consider the best scientific and commercial data that have become available since the listing determination or most recent status review, such as:

- (A) Species biology, including but not limited to population trends, distribution, abundance, demographics, and genetics;
- (B) Habitat conditions, including but not limited to amount, distribution, and suitability;
- (C) Conservation measures that have been implemented that benefit the species;
- (D) Threat status and trends in relation to the five listing factors (as defined in section 4(a)(1) of the ESA); and
- (E) Other new information, data, or corrections, including but not limited to taxonomic or nomenclatural changes, identification of erroneous information contained in the List, and improved analytical methods.

Any new information will be considered during the 5-year review and will also be useful in evaluating the ongoing recovery programs for the species.

Which species are under review?

The species in the following table are under active 5-year status review.

Common name	Scientific name	Listing status	Current range	Final listing rule (Federal Register citation and publication date)	Contact person, phone, email	Contact person's U.S. mail address
			ANIMAL	s		
Trout, Apache	Oncorhynchus apache.	Threatened	Arizona (USA)	40 FR 29863, 7/16/1975	Jeff Humphrey, Field Supervisor, 602–242– 0210 (phone) or Jeff_Humphrey@ fws.gov (email).	U.S. Fish and Wildlife Service, Arizona Eco- logical Services Of- fice, 9828 North 31st Avenue, #C3, Phoe- nix, AZ 85051–2518.
Crane, whooping	Grus americana	Endangered	Kansas, Montana, Ne- braska, North Dakota, Oklahoma, South Da- kota, Texas, Wis- consin (USA), and Canada.	32 FR 4001, 3/11/1967	Peter Fasbender, As- sistant Regional Di- rector—Ecological Services, 505–248– 6671 (office phone) or Peter_Fasbender@ fws.gov (email)	U.S. Fish and Wildlife Service, Southwest Regional Office, P.O. Box 1306, Albu- querque, NM, 87103.

Common name	Scientific name	Listing status	Current range	Final listing rule (Federal Register citation and publication date)	Contact person, phone, email	Contact person's U.S. mail address
		Experimental population, non-essential.	Alabama, Arkansas, Colorado, Florida, Georgia, Idaho, Illi- nois, Indiana, Iowa, Kentucky, Louisiana, Michigan, Minnesota, Missouri, North Caro- lina, New Mexico, Ohio, South Carolina, Tennessee, Utah, Vir- ginia, Wisconsin, West Virginia.	58 FR 5561, 1/22/0993; 62 FR 38932, 7/21/ 1997; 66 FR 33903, 6/26/2001; 76 FR 6066 2/3/2011.		
Prairie-chicken, Attwater's greater.	Tympanuchus cupido attwateri.	Endangered	Texas (USĀ)	32 FR 4001, 3/11/1967	John Magera, Refuge Manager, 979–234– 3021 (office phone) or John_Magera@ fws.gov (email).	Attwater Prairie Chicke National Wildlife Ref- uge, P.O. Box 519, Eagle Lake, Texas 77434.
Amphipod, Peck's Cave. Beetle [no com- mon name].	Stygobromus (=Stygonectes) pecki. Rhadine infernalis	Endangered Endangered	Texas (USA) Texas (USA)	62 FR 66295, 12/18/ 1997. 65 FR 81419 12/26/ 2000.	Adam Zerrenner, Field Supervisor, 512–490– 0057 (office phone), 512–577–6594 (direct line) or Adam_ Zerrenner@fws.gov (email).	U.S. Fish and Wildlife Service, Austin Eco- logical Services Field Office, 10711 Burnet Road, Suite 200, Aus tin, TX 78758.
Beetle [no com- mon name]. Beetle, Comal	Rhadine exilis	Endangered	Texas (USA)	65 FR 81419, 12/26/ 2000. 62 FR 66295, 12/18/	(email).	
Springs dryopid.	Stygoparnus comalensis.	Endangered	Texas (USA)	1997.		
Beetle, Comal Springs riffle. Pupfish, Coman-	Heterelmis comalensis. Cyprinodon	Endangered Endangered	Texas (USA)	62 FR 66295, 12/18/ 1997. 32 FR 4001, 3/11/1967.		
che Springs. Pupfish, Leon	elegans. Cyprinodon	Endangered	Texas (USA)	45 FR 54678, 8/15/1980.		
Springs. Salamander,	bovinus. Eurycea naufragia	Threatened	Texas (USA)	79 FR 20107, 4/11/2014.		
Georgetown. Salamander, Jollyville Pla-	Eurycea tonkawae	Threatened	Texas (USA)	78 FR 51278, 8/20/2013.		
teau. Salamander, Sa-	Eurycea	Threatened	Texas (USA)	79 FR 20107, 4/11/2014.		
lado. Salamander, San	chisholmensis. Eurycea nana	Threatened	Texas (USA)	45 FR 47355, 7/14/1980.		
Marcos. Spider, Govern- ment Canyon Bat Cave.	Neoleptoneta microps.	Endangered	Texas (USA)	65 FR 81418, 12/26/ 2000.		
Warbler (=wood), golden- cheeked.	Dendroica chrysoparia.	Endangered	Texas (USA), El Salvador, Guatemala, Honduras, Mexico, and Nicaragua.	55 FR 53153, 12/27/ 1990.		
Chub, Chihuahua	Gila nigrescens	Threatened	New Mexico (USA), and Mexico.	48 FR 46053, 10/11/ 1983.	Shawn Sartorious, Field Supervisor, 505–761– 4781 or Shawn_ Sartorious@fws.gov (email).	U.S. Fish and Wildlife Service, 2105 Osuna Rd. NE, Albuquerque NM 87113-1001.
Isopod, Socorro	Thermosphaeroma thermophilus.	Endangered	New Mexico (USA)	43 FR 12690, 3/27/1978.	(email).	
			PLANTS	S		
Wild-buckwheat, Gypsum. Cactus, Knowlton's.	Eriogonum gypsophilum. Pediocactus knowltonii.	Threatened Endangered	New Mexico (USA) Colorado and New Mexico (USA).	46 FR 49639, 1/19/1981 44 FR 62244, 10/29/ 1979.	Shawn Sartorious, Field Supervisor, 505–761– 4781 or Shawn_ Sartorious@fws.gov (email).	U.S. Fish and Wildlife Service, 2105 Osuna Rd. NE, Albuquerque NM 87113-1001.
Ladies-tresses, Canelo Hills. Cactus, Nichol's Turk's head.	Spiranthes delitescens. Echinocactus horizonthalonius var. nicholii.	Endangered Endangered	Arizona (USA)Arizona (USA)	62 FR 665, 1/6/1997 44 FR 61927, 10/26/ 1979.	Jeff Humphrey, Field Supervisor, 602–242– 0210 (phone) or Jeff_ Humphrey@fws.gov (email).	U.S. Fish and Wildlife Service, Arizona Eco logical Services Of- fice, 9828 North 31st Avenue, #C3, Phoe- nix, AZ 85051–2517.
Ragwort, San Francisco Peaks.	Packera franciscana.	Threatened	Arizona (USA)	44 FR 61927, 10/26/ 1979.		111A, AZ 00001-Z017.

Request for Information

To ensure that a 5-year review is complete and based on the best available scientific and commercial information, we request new information from all sources. See What Information Do We Consider in Our Review? for specific criteria. If you submit information, please support it with documentation such as maps, bibliographic references, methods used to gather and analyze the data, and/or copies of any pertinent publications, reports, or letters by knowledgeable sources.

How do I ask questions or provide information?

If you wish to provide information for any species listed above, please submit your comments and materials to the appropriate contact in the table above. You may also direct questions to those contacts. Individuals who are hearing impaired or speech impaired may call the Federal Relay Service at 800–877–8339 for TTY assistance.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Completed and Active Reviews

A list of all completed and currently active 5-year reviews can be found at https://ecos.fws.gov/ecp/report/species-five-year-review.

Authority

This document is published under the authority of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Amy L. Lueders,

Regional Director, Southwest Region, U.S. Fish and Wildlife Service.

[FR Doc. 2021–09379 Filed 5–4–21; 8:45 am]

BILLING CODE 4333-15-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS-HQ-MB-2017-0092; 91200-FF09M20300-189-FXMB123109EAGLE]

Updated Collision Risk Model Priors for Estimating Eagle Fatalities at Wind Energy Facilities

AGENCY: Fish and Wildlife Service,

Interior.

ACTION: Notice of availability.

summary: This notice announces our adoption of updated species-specific eagle exposure and collision probabilities used to generate fatality estimates for consideration in issuing eagle incidental take permits to windenergy facilities under the Bald and Golden Eagle Protection Act. This action will improve our ability to carry out our statutory responsibility to ensure conservation of bald eagles and golden eagles when issuing those permits.

DATES: May 6, 2021.

ADDRESSES: Information related to this notice, including the public comments received in response to the previous **Federal Register** notices, is available at the Federal eRulemaking Portal: http://www.regulations.gov in Docket No. FWS-HO-MB-2017-0092.

FOR FURTHER INFORMATION CONTACT:

Brian Millsap, at 505–559–3963 (telephone), or brian_a_millsap@fws.gov (email). Individuals who are hearing impaired or speech impaired may call the Federal Relay Service at 800–877–8337 for TTY assistance.

SUPPLEMENTARY INFORMATION:

Background

The Bald and Golden Eagle Protection Act (16 U.S.C. 668-668d; "Act") prohibits take of bald eagles and golden eagles except pursuant to Federal regulations. The Act authorizes the Secretary of the Interior to issue regulations to permit the "taking" of eagles for various purposes, provided the taking is compatible with the preservation of eagles. Under regulations in part 22 of title 50 of the Code of Federal Regulations, we, the U.S. Fish and Wildlife Service (hereafter, "the Service"), issue permits to authorize take of eagles that is incidental to an activity (50 CFR 22.26).

In carrying out our responsibility to issue these types of permits for windenergy facilities, we use a collision-risk model (CRM) to predict the number of bald and golden eagles that may be taken at facilities (USFWS 2013; New et al. 2015). The CRM allows the Service

to produce conservative initial take estimates for new wind energy facilities, as well as to produce more precise updated estimates for operating facilities that have collected fatality monitoring data. The take estimates provided by the CRM allow the Service to ensure authorized eagle take numbers are within the eagle management unit take limits, and provide the data necessary to assess effects of take permits on local area eagle populations, both required actions under our Programmatic Environmental Impact Statement for eagle take permits (USFWS 2016a). The CRM incorporates prior information (priors) on eagle exposure and eagle collision probability, and these priors are updated as new information becomes available as part of the adaptive management process associated with eagle take permitting (USFWS 2016b).

In 2017 the Service undertook a review of newly available information and generated updated priors for the CRM. The Service announced the updated priors and availability of a report summarizing the analysis in a June 21, 2018, Federal Register notice (83 FR 28858) that solicited public comment on the proposed priors and how the Service should use the updated bald eagle priors in the CRM. The report is available at: https://www.fws.gov/ migratorybirds/pdf/management/ crmpriorsreport2018.pdf or as described above in ADDRESSES (at www.regulations.gov in Docket No. FWS-HQ-MB-2017-0092). At the request of wind-industry representatives, the Service reopened the comment period for another 30 days on November 13, 2018 (83 FR 56365).

Alternatives Considered and Summary of Responses

In our notice of availability, we presented updated priors for golden eagle exposure and golden eagle collision probability. We also developed and presented for the first time priors for bald eagle exposure and collision probability. These updated and new priors incorporate substantial new information, and their adoption thus constitutes an improvement in the scientific information used by the Service to estimate the effects of our take permits on eagle populations.

The alternatives for both eagle species that we considered and presented for public comment are as follows:

Alternative 1—Use the updated species-specific priors, and use the 80th quantile of the CRM fatality estimates as the initial permitted take number for permits, as is the current practice.

Alternative 2—Use the updated species-specific priors, and because bald eagle populations are increasing and additional take is sustainable (U.S. Fish and Wildlife Service 2016a,c), accept a more risk-tolerant CRM approach for the initial permitted take number for bald eagles.

Alternative 3—Given the limitations in data available to inform the bald eagle priors, initiate an expertelicitation process to further refine the bald eagle priors.

Of the 58 comments received during the two comment periods, we received substantive comments from several entities, including States, environmental organizations, and wind-energy organizations or companies. Many of the comments stated that the Service's CRM either overestimated or underestimated eagle fatalities, or stated that another method for estimating exposures and collisions should be adopted. Because the CRM has been the subject of three prior peer reviews and three rounds of public comment (February 18, 2011; May 2, 2013; May 6, 2016 [U.S. Fish and Wildlife Service 2011, 2013, 2016]), including being considered in detail as part of the 2016 revisions to the regulations pertaining to incidental take of eagles and eagle nests (81 FR 91494, December 16, 2016), we regarded these comments as outside the scope of this notice and we did not consider them

Most of the comments were in support of Alternative 1, use of the 80th quantile of the species-specific fatality distributions. However, many comments from the wind industry opposed Alternative 1 and asserted that approach was not based on best available science and results in unduly burdensome higher costs for eagle take that is unlikely to occur.

Industry largely objected to Alternative 2 because the underlying priors are still based on data that does not represent all locations in the United States. One energy coalition suggested that Alternative 2 should not be used because a confidence interval should not be prematurely selected until the Service has validated the model. This validation process should include public input to ensure that those impacted by the take estimates have an opportunity to evaluate and opine on the impacts of any confidence interval selected. A major trade association commented that Alternative 2 using the 50th or 60th quantile of the fatality distribution for bald eagles as the permitted take number would be preferable to the current use of the 80th quantile.

Industry rejected Alternative 3 on the grounds that available data and reports on eagle and wind interaction exist that could be used to inform a reasonable risk assessment approach without the need for eliciting scientific and technical judgments from experts. However, of the State fish and wildlife agencies that commented, most supported Alternative 3 because a further refined national bald eagle prior using expert elicitation would help to inform the uncertainty in the exposure and collision probability for bald eagles given their variable densities across the landscape.

Service Decision

The Service is adopting Alternative 2 as the best approach given currently available data and status of eagle populations. We will use the 80th quantile of the fatality distribution as the initial permitted take number for golden eagles and the 60th quantile of the fatality distribution as the initial permitted take number for bald eagles. We regard this approach as a suitable balance between the more secure status of bald eagles and the uncertainty in their take estimates that is consistent with our 2016 Programmatic **Environmental Impact Statement** (USFWS 2016a).

With regard to initiating an expert elicitation process, we agree with many States that gathering additional information from either experts or industry has the potential to further refine the bald eagle priors. For this reason, we may choose to engage in an expert elicitation process in the future. In the meantime, the best method to gain the information needed to develop a more accurate assessment is through fatality monitoring of permitted projects. The fatality-estimation process using the CRM is an exercise in adaptive management, and as more data are collected the Service will continue to revise and update the priors over time. Should it become apparent that a different risk balance is appropriate based on additional data, we will address that scenario in conjunction with a future update of the CRM. In order to streamline the adaptive management process and ensure rapid adoption of new scientific information going forward, in the future the Service will update and implement the updated priors for both eagle species as soon as sufficient new information becomes available to warrant an update. We will notify the public of future updates by posting them on the Service's Eagle Management web page (https:// www.fws.gov/birds/management/

managed-species/eaglemanagement.php) or the equivalent.

Upon publication of this notice, we will use the following data and risk tolerances for initial fatality predictions at wind energy facilities: The updated species-specific exposure and collision priors for both eagle species; the 80th quantile of the fatality distribution as the permitted take number for golden eagles; and the 60th quantile of the fatality distribution as the permitted take number for bald eagles. We will use the updated priors for all eagle incidental take permits issued to wind facilities, including those issued under the Endangered Species Act (16 U.S.C. 1531 et seq.) when eagles are covered in a habitat conservation plan as a nonlisted species. (See 50 CFR 22.11(a).)

Literature Cited

U.S. Fish and Wildlife Service. 2011. Migratory Birds; Draft Eagle Conservation Plan Guidance. 76:9529–9530.

U.S. Fish and Wildlife Service. 2013. Migratory Birds; Eagle Conservation Plan Guidance: Module 1—Land-Based Wind Energy, Version 2. **Federal Register** 78:25758.

U.S. Fish and Wildlife Service. 2016a. Programmatic Environmental Impact Statement for the Eagle Rule Revision. Division of Migratory Bird Management, U.S. Fish and Wildlife Service, Washington, DC USA. https://www.fws.gov/migratorybirds/pdf/management/FINAL-PEIS-Permits-to-Incidentally-Take-Eagles.pdf.

U.S. Fish and Wildlife Service. 2016b. Eagle Permits; Revisions to Regulations for Eagle Incidental Take and Take of Eagle Nests. **Federal Register** 242:91494–91553.

U.S. Fish and Wildlife Service. 2016c. Bald and golden eagles: Population demographics and estimation of sustainable take in the United States, 2016 update. Status Reports, Division of Migratory Bird Management, U.S. Fish and Wildlife Service, Washington, DC USA. https://www.fws.gov/migratorybirds/pdf/management/EagleRuleRevisions-StatusReport.pdf.

Martha Williams,

Principal Deputy Director, Exercising the Delegated Authority of the Director, U.S. Fish and Wildlife Service.

[FR Doc. 2021–09362 Filed 5–4–21; 8:45 am]

BILLING CODE 4333-15-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLHQ310000.L13100000.PP0000; OMB Control No. 1004-0179]

Agency Information Collection Activities; Helium Contracts

AGENCY: Bureau of Land Management,

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Bureau of Land Management (BLM) proposes to renew an information collection.

DATES: Interested persons are invited to submit comments on or before July 6, 2021.

ADDRESSES: Send your written comments on this information collection request (ICR) by mail to Darrin King, Information Collection Clearance Officer, U.S. Department of the Interior, Bureau of Land Management, Attention PRA Office, 440 W 200 S #500, Salt Lake City, UT 84101; or by email to BLM_HQ_PRA_ Comments@blm.gov. Please reference Office of Management and Budget (OMB) Control Number 1004-0179 in the subject line of your comments. Please note that due to COVID-19, the electronic submission of comments is recommended.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Jennifer Spencer by email at *j35spenc@blm.gov*, or by telephone at 307–775–6261. Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance. You may also view the ICR at http://www.reginfo.gov/public/do/PRAMain.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA, 44 U.S.C. 3501 et seq.) and 5 CFR 1320.8(d)(1), all information collections require approval under the PRA. The BLM 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: This control number authorizes the BLM to collect information that enables in-kind sales of helium in accordance with the Helium Stewardship Act (50 U.S.C. 167-167q) and 43 CFR part 3195. This request of for OMB to renew this OMB control number for an additional three years. There are no program, form, or other policy changes proposed with this renewal request. The BLM is requesting, however, that the burden for this OMB control number be adjusted from 240 to 244 total annual burden hours. The change in burden results from changes to the number of respondents for each information collection (form number) approved under this OMB control number.

Title of Collection: Helium Contracts (43 CFR part 3195).

OMB Control Number: 1004–0179. Form Numbers: 3195–1; 3195–2; 3195–3; and 3195–4.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Private helium merchants that sell a major helium requirement (i.e., an amount of refined helium greater than 200,000 standard cubic feet of refined gaseous helium or 7,510 liters of liquid helium) to a Federal agency or to private helium purchasers for use in Federal Government contracts.

Total Estimated Number of Annual Respondents: 40.

Total Estimated Number of Annual Responses: 61.

Estimated Completion Time per Response: 4 hours.

Total Estimated Number of Annual Burden Hours: 244.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: Quarterly for the Refined Helium Deliveries Detail (Form 3195–4); Annually for the Calculation of Excess Refining Capacity (Form 3195–1) and Refiners' Annual Tolling Report (Form 3195–2); and On occasion for the Refiners' Tolling Occurrence Report (Form 3195–3).

Total Estimated Annual Nonhour Burden Cost: None.

An agency may not conduct or sponsor and, notwithstanding any other provision of law, 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.*).

Darrin A. King,

Information Collection Clearance Officer. [FR Doc. 2021–09495 Filed 5–4–21; 8:45 am] BILLING CODE 4310–84–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLHQ310000.L13100000.PP0000; OMB Control No. 1004–0034]

Agency Information Collection Activities; Oil and Gas, or Geothermal Resources: Transfers and Assignments

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Bureau of Land Management (BLM) proposes to renew an information collection.

DATES: Interested persons are invited to submit comments on or before June 4, 2021.

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: To request additional information about this ICR, contact Jennifer Spencer by

email at j35spenc@blm.gov, or by telephone at 307–775–6261. Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance. You may also view the ICR at http://www.reginfo.gov/public/do/PRAMain.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA, 44 U.S.C. 3501 et seq.) and 5 CFR 1320.8(d)(1), we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on December 21, 2020 (85 FR 83102). 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: This collection of information enables the BLM to process assignments of record title interest and transfers of operating rights in a lease for oil and gas or geothermal resources. Each assignment or transfer is a contract between private parties but, by law, must be approved by the Secretary. The BLM uses information about assignments and transfers to prevent unlawful extraction of mineral resources, to ensure prompt payment of rentals and royalties for the rights obtained under a Federal lease, and to ensure that leases are not encumbered with agreements that cause the minerals to be uneconomical to produce, resulting in lost revenues to the Federal Government. The information also enables the BLM to ensure the assignee or transferee is in compliance with the bonding requirements, when necessary, before approval of the transfer or assignment. Form 3000-003 is used to transfer record title interest (i.e., primary ownership of a lease or the lessee's interest). Form 3003–003a is used to transfer operating rights interest (i.e., also referred to as working interest or a sublease). This request is to extend for an additional three years OMB's approval for the collections of information under this OMB control number.

There are no changes to the information collections (Forms 3003-003 and 3003-003a) under OMB control number 1004–0034. The only program change to the information collections is due to an increase in cost-recovery fees from \$95 to \$100 per filing. The estimated annual responses have been adjusted downward by 8,808, from 17,626 to 8,818 responses. These adjustments have decreased the hour burden by 4,404, from 8,814 to 4,410 hours. Similarly, the non-hour cost burdens have been adjusted downward by \$792,670, from \$1,674,470 to \$881,800. This downward adjustment in costs is offset by a \$44,090 increase due to an increase in cost recovery fees. The cost recovery fees were increased pursuant to a BLM final rule titled, Minerals Management: Adjustment of Cost Recovery Fees, published in the Federal Register on October 9, 2020 (85 FR 64056). The itemized changes in burdens are outlined in the information collection request that has been submitted to OMB and is available at http://www.reginfo.gov/public/do/ PRAMain.

Title of Collection: Oil and Gas, or Geothermal Resources: Transfers and Assignments (43 CFR Subparts 3106, 3135, and 3216).

OMB Control Number: 1004–0034. *Form Numbers:* 3000–003; 3000–003a.

Type of Review: Extension with revision of a currently approved collection.

Respondents/Affected Public: Assignors and assignees of record title interest in a lease for oil and gas or geothermal resources; and transferors and transferees of operating rights (sublease) in a lease for oil and gas or geothermal resources.

Total Estimated Number of Annual Respondents: 8,818.

Total Estimated Number of Annual Responses: 8,818.

Estimated Completion Time per Response: 30 minutes.

Total Estimated Number of Annual Burden Hours: 4,410.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.
Total Estimated Annual Nonhour
Burden Cost: \$881,800.

An agency may not conduct or sponsor and, notwithstanding any other provision of law, 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.*).

Darrin King,

Information Collection Clearance Officer. [FR Doc. 2021–09496 Filed 5–4–21; 8:45 am] BILLING CODE 4310–84–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701-TA-523 and 731-TA-1259 (Review)]

Boltless Steel Shelving Units Prepackaged for Sale From China

Determinations

On the basis of the record ¹ developed in the subject five-year reviews, the United States International Trade Commission ("Commission") determines, pursuant to the Tariff Act of 1930 ("the Act"), that revocation of the antidumping and countervailing duty orders on boltless steel shelving units prepackaged for sale from China would be likely to lead to continuation or recurrence of material injury to an

¹The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

industry in the United States within a reasonably foreseeable time.

Background

The Commission instituted these reviews on September 1, 2020 (85 FR 54404) and determined on December 7, 2020 that it would conduct expedited reviews (86 FR 18295, April 8, 2021).

The Commission made these determinations pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)). It completed and filed its determinations in these reviews on April 29, 2021. The views of the Commission are contained in USITC Publication 5190 (April 2021), entitled Boltless Steel Shelving Units Prepackaged for Sale from China: Investigation Nos. 701–TA–523 and 731–TA–1259 (Review).

By order of the Commission. Issued: April 29, 2021.

Lisa Barton.

Secretary to the Commission. $[{\rm FR\ Doc.\ 2021-09429\ Filed\ 5-4-21;\ 8:45\ am}]$

BILLING CODE 7020-02-P

DEPARTMENT OF JUSTICE

Antitrust Division

United States v. Stone Canyon Industries Holdings LLC, et al.; Proposed Final Judgment and Competitive Impact Statement

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h), that a proposed Final Judgment, Stipulation, and Competitive Impact Statement have been filed with the United States District Court for the District of Columbia in United States of America v. Stone Canyon Industries Holdings LLC, Civil Action No. 21-cv-01067. On April 19, 2021, the United States filed a Complaint alleging that the acquisition of Morton Salt, Inc. by SCIH Salt Holdings Inc. ("SCIH") would violate Section 7 of the Clayton Act, 15 U.S.C. 18. The proposed Final Judgment, filed at the same time as the Complaint, requires SCIH to divest its US Salt LLC subsidiary.

Copies of the Complaint, proposed Final Judgment, and Competitive Impact Statement are available for inspection on the Antitrust Division's website at http://www.justice.gov/atr and at the Office of the Clerk of the United States District Court for the District of Columbia. Copies of these materials may be obtained from the Antitrust Division upon request and payment of the copying fee set by Department of Justice regulations.

Public comment is invited within 60 days of the date of this notice. Such comments, including the name of the submitter, and responses thereto, will be posted on the Antitrust Division's website, filed with the Court, and, under certain circumstances, published in the Federal Register. Comments should be submitted in English and directed to Katrina Rouse, Chief, Defense, Industrials, and Aerospace Section, Antitrust Division, Department of Justice, 450 Fifth Street NW, Suite 8700, Washington, DC 20530.

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA, U.S. Department of Justice, Antitrust Division, 450 Fifth Street N.W., Suite 8700, Washington, DC 20530. Plaintiff, v. STONE CANYON INDUSTRIES HOLDINGS LLC, 1875 Century Park East, Suite 320, Los Angeles, CA 90067, SCIH SALT HOLDINGS INC., 10995 Lowell Avenue, Suite 500, Overland Park, KS 66210, K+S AKTIENGESELLSCHAFT Bertha-von-Suttner-Str. 7, 34131 Kassel, Hesse, Germany, and MORTON SALT, INC., 444 West Lake Street, Suite 300, Chicago, IL 60606, Defendants.

Civil Action No.: 1:21-cv-01067-TJK Judge Timothy J. Kelly

Complaint

The United States of America ("United States"), acting under the direction of the Attorney General of the United States, brings this civil antitrust action against Defendants Stone Canyon Industries Holdings LLC ("Stone Canyon"), SCIH Salt Holdings Inc. ("SCIH"), K+S Aktiengesellschaft ("K+S AG"), and Morton Salt, Inc. ("Morton") to enjoin SCIH's proposed acquisition of assets including Morton from K+S AG. The United States complains and alleges as follows:

I. Nature of the Action

1. Pursuant to a Transaction Agreement dated October 5, 2020, SCIH intends to acquire assets including Morton from K+S AG for approximately \$3.2 billion. As a result of the acquisition, SCIH would control both Morton and US Salt, which are the largest suppliers of certain evaporated salt products in the United States.

2. Together, Morton and US Salt would have a monopoly in the United States and Canada for pharmaceutical-grade salt, the purest grade of evaporated salt, which is used to make life-saving treatments and products for patients in need of dialysis fluid, intravenous saline solution, or other medical products.

- 3. Additionally, Morton and US Salt are two of only three companies that supply U.S. households with "round-can" table salt, a type of evaporated salt that is sold in 26-ounce round containers with a metal spout and used to flavor food.
- 4. Morton and US Salt are also two of only three major suppliers in the northeastern United States of bulk evaporated salt, which is used by food processors and chemical manufacturers to make pre-packaged food and everyday cleaning products.
- 5. Today, customers benefit from competition between Morton and US Salt in the form of lower prices, higher quality products, and/or improved service. The proposed transaction would eliminate this competition, driving the opposite result: Higher prices, lower quality products, and poorer service for customers of pharmaceutical-grade salt in the United States and Canada, for customers of round-can table salt in the United States, and for customers of bulk evaporated salt in the northeastern United States.
- 6. Accordingly, SCIH's acquisition of Morton would violate Section 7 of the Clayton Act, 15 U.S.C. 18, and should be enjoined.

II. The Parties and the Transaction

- 7. K+S AG is a chemical company headquartered in Kassel, Germany. In 2020, K+S AG reported revenues of approximately \$4.4 billion. K+S AG's Operating Unit Salt Americas business includes Morton as well as K+S Windsor Salt, which sells salt products in Canada, and Sociedad Punta de Lobos, which sells salt products in Chile.
- 8. Morton is a K+S AG subsidiary with approximately \$1 billion in revenue in 2020. Morton is the largest supplier of pharmaceutical-grade salt in the United States and Canada, the largest supplier of round-can table salt in the United States, and one of only three suppliers of bulk evaporated salt in the northeastern United States.
- 9. Stone Canyon is an industrial holding company incorporated in Delaware and headquartered in Los Angeles, California. Stone Canyon acquired Kissner Group Holdings LP, which it later renamed SCIH, in April 2020.
- 10. SCIH is a subsidiary of Stone Canyon and is headquartered in Overland Park, Kansas. In 2020, SCIH had revenues of approximately \$1 billion. SCIH is a leading supplier of salt products, including evaporated salt.

11. US Salt, a subsidiary of SCIH with approximately \$95 million in revenues

in 2020, is the nation's second-largest supplier of pharmaceutical-grade salt in the United States and Canada, the second-largest supplier of round-can table salt in the United States, and one of only three suppliers of bulk evaporated salt in the northeastern United States.

12. Pursuant to a Transaction Agreement dated October 5, 2020, SCIH agreed to acquire K+S AG's Operating Unit Salt Americas business, including Morton, for approximately \$3.2 billion.

III. Jurisdiction and Venue

- 13. The United States brings this action under Section 15 of the Clayton Act, 15 U.S.C. 25, to prevent and restrain Defendants from violating Section 7 of the Clayton Act, 15 U.S.C. 18.
- 14. Defendants' activities substantially affect interstate commerce. Defendants sell pharmaceutical-grade salt and round-can table salt throughout the United States and bulk evaporated salt throughout the northeastern United States. This Court has subject matter jurisdiction over this matter pursuant to Section 15 of the Clayton Act, 15 U.S.C. 25, and 28 U.S.C. 1331, 1337(a), and 1345.
- 15. Defendants have consented to venue and personal jurisdiction in this judicial district. Venue is proper under Section 12 of the Clayton Act, 15 U.S.C. 22, and 28 U.S.C. 1391(b) and (c)(2), for Stone Canyon, SCIH, and Morton, and venue is proper for K+S AG, a German corporation, under 28 U.S.C. 1391(c)(3).

IV. Relevant Markets

A. Relevant Product Markets

- 16. Morton and SCIH's US Salt subsidiary both produce and sell evaporated salt. Evaporated salt is a type of sodium chloride produced through "vacuum evaporation." In the vacuum evaporation process, water is pumped into a salt deposit where the salt dissolves, and the resulting brine is forced into an evaporator on the surface where it is boiled in a series of pans until only the salt remains. Evaporated salt is nearly 100% sodium chloride and contains almost no other trace minerals. Because of the evaporation process, individual grains of evaporated salt are also more consistent and regularly shaped than other forms of salt.
- 17. Evaporated salt is distinct from salt created through other production methods, such as rock salt and solar salt. Rock salt is mined and then crushed into smaller sizes before being transported to the surface. Rock salt is less expensive to produce than evaporated salt, but it is also coarser,

irregularly shaped, and contains other minerals and impurities. As a result, rock salt is used for applications that have less demanding quality requirements such as de-icing roads. Solar salt is created when salt water is captured in shallow ponds where the sun evaporates most of the water. It can only be produced in warm climates where the evaporation rate exceeds the precipitation rate. Solar salt is less pure and not as uniform in shape as evaporated salt, but it is purer than rock salt. Solar salt is used for applications such as water softening.

18. Evaporated salt typically is used in applications that require the highest quality of salt, such as human consumption. There are different types of evaporated salt that have different characteristics, end uses, and customers. Three types of evaporated salt produced by Defendants constitute relevant product markets—pharmaceutical-grade salt, round-can table salt, and bulk evaporated salt.

i. Pharmaceutical-Grade Salt

19. Pharmaceutical-grade salt is the grade of salt with the highest percentage of sodium chloride and thus is the purest grade of evaporated salt. Pharmaceutical-grade salt is used in the pharmaceutical industry as a building block for a number of life-saving treatments and products, including dialysis fluid, intravenous saline solution, and other medical products. Pharmaceutical-grade salt must be evaporated from salt deposits of extremely high purity and then undergo post-production processing to ensure that it contains virtually no trace minerals or other impurities.

20. Because of these stringent standards, the mining and production process for pharmaceutical-grade salt must be extensively monitored and documented to ensure purity and consistency across production batches. This documentation must then be provided to customers as a validation of the quality and purity of the pharmaceutical-grade salt.

21. Rock salt and solar salt do not meet the purity requirements for pharmaceutical-grade salt. Other grades of evaporated salt—for example, salt used in food processing—also cannot serve as a substitute for pharmaceutical-grade salt. Pharmaceutical-grade salt pharmaceutical-grade salt. This ensures that it does not contain trace minerals that would impact the efficacy of pharmaceutical products made using pharmaceutical-grade salt. Pharmaceutical-grade salt.

contain additives such as anti-caking agents that are added during the processing of other types of evaporated salt. Because of these requirements, pharmaceutical-grade salt is more difficult to produce than other forms of evaporated salt.

22. In the event of a small but significant increase in price by a hypothetical monopolist of pharmaceutical-grade salt, substitution away from pharmaceutical-grade salt would be insufficient to render the price increase unprofitable. Pharmaceutical-grade salt is therefore a line of commerce, or relevant product market, for purposes of analyzing the effects of the acquisition under Section 7 of the Clayton Act, 15 U.S.C. 18.

ii. Round-Can Table Salt

Table salt is evaporated salt that is processed for human consumption. It is regulated by the Food and Drug Administration ("FDA") and must meet high purity standards. Table salt also has a highly consistent size across granules and contains agents to prevent clumping and evaporation. Without additional processing—which raises price considerably—rock salt and solar salt cannot meet the same purity requirements or achieve the same consistent granule size as table salt. Pharmaceutical-grade salt meets the purity requirements for table salt but does not contain the necessary agents to prevent clumping and evaporation. As such, rock salt, solar salt, and pharmaceutical-grade salt are not substitutes for table salt.

24. In the United States, the packaging format strongly preferred by consumers for table salt is the round can, which is a 26-ounce cardboard cylinder with a paper label and a metal spout. The round-can's size, shape, material, and metal spout make it an easy receptacle to use one-handed without spilling while cooking or refilling a salt shaker, which is a product characteristic that is highly valued by consumers. Reflecting consumer preference, retailers like grocery stores dedicate shelf space specifically to round-can packaging. As a result, approximately 95% of the table salt sold to consumers in the United States is sold in a round can.

25. Table salt packaged in other containers, such as boxes or bags, is not a reasonable substitute for round-can table salt. Boxes without a metal spout and bags are more difficult to use and store and may spill once opened. Larger packages of table salt also are not reasonable substitutes for round-can table salt, as they contain significantly more salt than an individual can practically use.

26. In the event of a small but significant increase in price by a hypothetical monopolist of round-can table salt, substitution away from round-can table salt would be insufficient to render the price increase unprofitable. Round-can table salt is therefore a line of commerce, or relevant product market, for purposes of analyzing the effects of the acquisition under Section 7 of the Clayton Act, 15 U.S.C. 18.

iii. Bulk Evaporated Salt

- 27. Bulk evaporated salt is salt that is of sufficient purity to be used for human consumption that is sold in bulk form. Bulk evaporated salt is used to manufacture chemicals necessary to create essential everyday cleaning products such as disinfectants, soap, and bleach. Bulk evaporated salt is also an essential ingredient in nearly all processed pre-packaged foods, such as sauces, chips and other snacks, and frozen meals. Because bulk evaporated salt is incorporated into products endconsumers ingest or touch, it is regulated by the FDA and must meet stringent purity requirements.
- 28. Customers for bulk evaporated salt include chemical companies and large pre-packaged food manufacturers as well as smaller customers, such as bakeries, that use salt as an essential ingredient in their food products. To accommodate these customers, many of whom purchase thousands of tons of salt per year, evaporated salt is sold in bulk, by the truckload or in containers ranging from 50-pound bags to 2,000-pound "super-sacks."
- 29. Bulk evaporated salt is distinct from evaporated salt used for other applications. Compared to other types of evaporated salt, it has unique end-uses, customers, and packaging. While pharmaceutical-grade salt and roundcan table salt are of sufficient purity, they are priced too high and packaged in quantities that are too small to serve as substitutes for bulk evaporated salt. Bulk evaporated salt also is distinct from rock salt and solar salt, which have lower purity levels and non-uniform textures that make them unsuitable for chemical and food-production end uses. None of these types of salt can serve as a substitute to bulk evaporated salt.
- 30. In the event of a small but significant increase in price by a hypothetical monopolist of bulk evaporated salt, substitution away from bulk evaporated salt would be insufficient to render the price increase unprofitable. Bulk evaporated salt is therefore a line of commerce, or relevant product market, for purposes of analyzing the effects of the acquisition

under Section 7 of the Clayton Act, 15 U.S.C. 18.

B. Relevant Geographic Markets

i. Pharmaceutical-Grade Salt

- 31. Pharmaceutical-grade salt is manufactured in only a few locations in the United States. From these locations, pharmaceutical-grade salt is shipped to customers throughout the United States and Canada.
- 32. While pharmaceutical-grade salt is shipped throughout the United States and Canada, shipping it from overseas is prohibitively expensive. This is because pharmaceutical-grade salt may not contain anti-caking agents. Without anti-caking agents, pharmaceutical-grade salt has a short shelf-life and may be damaged by the time and rigors of ocean-shipping. These limitations make ocean-shipping cost-prohibitive.
- 33. A hypothetical monopolist of pharmaceutical-grade salt in the United States and Canada could profitably impose a small but significant nontransitory increase in price for pharmaceutical-grade salt without losing sufficient sales to render the price increase unprofitable. Accordingly, the relevant geographic market for the purposes of analyzing the effects of the acquisition on pharmaceutical-grade salt under Section 7 of the Clayton Act, 15 U.S.C. 18, is the United States and Canada.

ii. Round-Can Table Salt

- 34. Competition among round-can table salt suppliers occurs at a national level. Retailers, many of which are grocery store chains, mass merchandisers, or convenience stores with large national footprints, purchase round-can table salt for all of their locations at once, and suppliers ship round-can table salt from coast to coast.
- 35. Round-can table salt is not imported from outside the United States. In addition to being heavy—and therefore expensive to transport—table salt in other countries is typically sold in bags or cardboard boxes. As such, foreign suppliers of table salt typically lack the production facilities to produce round cans for the United States market.
- 36. A hypothetical monopolist of round-can table salt in the United States could profitably impose a small but significant non-transitory increase in price for round-can table salt without losing sufficient sales to render the price increase unprofitable. Accordingly, the relevant geographic market for the purposes of analyzing the effects of the acquisition on round-can table salt under Section 7 of the Clayton Act, 15 U.S.C. 18, is the United States.

iii. Bulk Evaporated Salt

- 37. Bulk evaporated salt is a product that can be produced at a relatively low cost, but it is heavy and therefore expensive to transport. As a result, customers purchase from nearby suppliers to minimize shipping costs that can be high relative to the value of the bulk evaporated salt being purchased.
- 38. Both Morton and US Salt—along with only one other competitoroperate bulk evaporated salt production facilities in upstate New York. All three companies use these facilities to service customers in the northeastern United States, including Connecticut, Delaware, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont. Customers in the northeastern United States can economically procure bulk evaporated salt from only these three locations. Other more distant bulk evaporated salt facilities cannot compete successfully on a regular basis for customers in the northeastern United States because the suppliers are too far away, making transportation costs too great.
- 39. A hypothetical monopolist of bulk evaporated salt in the northeastern United States could profitably impose a small but significant non-transitory increase in price for bulk evaporated salt without losing sufficient sales to render the price increase unprofitable. Accordingly, the relevant geographic market for the purposes of analyzing the effects of the acquisition on bulk evaporated salt under Section 7 of the Clayton Act, 15 U.S.C. 18, is the northeastern United States.

V. Anticompetitive Effects

- 40. The proposed transaction would lessen competition and harm customers for pharmaceutical-grade salt in the United States and Canada, round-can table salt in the United States, and bulk evaporated salt in the northeastern United States by eliminating the substantial head-to-head competition that currently exists between Morton and US Salt. Customers in each of these markets would pay higher prices and receive lower quality and service as a result of the acquisition.
- A. Pharmaceutical-Grade Salt in the United States and Canada
- 41. Morton and US Salt are the only two suppliers of pharmaceutical-grade salt in the United States and Canada, with Morton currently having a market share of around 77% and US Salt a share of around 23%. The acquisition would thus give the combined firm a monopoly in the sale of pharmaceutical-

grade salt in the United States and Canada, leaving pharmaceutical companies and other customers without a competitive alternative for this critical ingredient in dialysis fluid, intravenous saline solution, and other medical products.

42. Morton and US Salt compete to sell pharmaceutical-grade salt on the basis of quality and surety of supply. This competition has resulted in higher quality, lower prices, and better customer service. The combination of Morton and US Salt would eliminate this competition and its future benefits to customers, including pharmaceutical companies. Post-acquisition, the combined Morton and US Salt likely would have the incentive and ability to increase prices and offer less favorable contractual terms.

43. The proposed acquisition, therefore, likely would substantially lessen competition in the production of pharmaceutical-grade salt in the United States and Canada in violation of Section 7 of the Clayton Act, 15 U.S.C.

B. Round-Can Table Salt in the United States

44. Morton and US Salt are two of the largest table salt suppliers in the United States and are two of only three suppliers of round-can table salt in the United States. Morton is the largest supplier of branded round-can table salt in the United States. US Salt is the largest supplier of private-label round-can table salt—which is made by US Salt but sold under the brands of retailers and other third-parties—in the United States. US Salt is also the second-largest supplier of branded round-can table salt, with around six percent of sales.

45. Today, US Salt's private-label and branded round-can table salt products compete directly with Morton's branded round-can table salt. Together, the combined firm would control at least 90% of the round-can table salt market in the United States.

46. The combination of Morton and US Salt would eliminate the head-to-head competition between Morton and US Salt and leave customers in the United States with only two alternatives for round-can table salt in the United States. Post-acquisition, the combined firm likely would have the incentive and ability to increase prices and offer less favorable contractual terms.

47. Morton and US Salt compete for sales of round-can table salt on the basis of quality, price, and contractual terms such as delivery times. This competition has resulted in higher quality, lower prices, and more reliable delivery. The

combination of Morton and US Salt would eliminate this competition and its future benefits to customers, including grocery chains, big box stores, and discount stores.

48. The proposed acquisition, therefore, likely would substantially lessen competition in the production of round-can table salt in the United States in violation of Section 7 of the Clayton Act, 15 U.S.C. 18.

C. Bulk Evaporated Salt in the Northeastern United States

49. Three bulk evaporated salt suppliers—Morton, US Salt, and one additional competitor, each with production facilities in upstate New York—compete for bulk evaporated salt customers in the northeastern United States. The combination of Morton and US Salt would eliminate the head-to-head competition between the parties and result in only two remaining competitors in the region.

50. Bulk evaporated salt customers in the northeastern United States, including food processors and chemical manufacturers, have been able to secure lower prices and improved quality and service—such as more reliable delivery—by threatening to switch between Morton and US Salt. The elimination of this head-to-head competition would allow a combined Morton and US Salt to exercise market power to unilaterally increase prices and reduce the quality and service for bulk evaporated salt customers in the northeastern United States.

51. The proposed acquisition, therefore, likely would substantially lessen competition in the production of bulk evaporated salt in the northeastern United States in violation of Section 7 of the Clayton Act, 15 U.S.C. 18.

VI. Entry

A. Difficulty of Entry Into Pharmaceutical-Grade Salt in the United States and Canada

52. Entry of new competitors into pharmaceutical-grade salt in the United States would be difficult and time-consuming and is unlikely to prevent the harm to competition that is likely to result if the proposed transaction is consummated.

53. A potential pharmaceutical-grade salt entrant would need to acquire suitable land that includes a salt deposit of sufficient purity, obtain the permits necessary to construct an evaporation and processing facility, possess or obtain appropriate financing for a significant capital expenditure, and then design, construct, and qualify the facility. This process would likely take

several years, at a minimum. No new evaporated salt facility has been constructed in the United States in over 20 years.

54. Even if an entrant was able to construct an evaporated salt production facility, before selling a single grain of pharmaceutical-grade salt, it would need to install and test additional equipment needed to meet the exacting purity requirements for pharmaceuticalgrade salt. Reputational barriers make entry even more difficult, as customers would be reluctant to switch to an unproven supplier that could not guarantee access to high-quality pharmaceutical-grade salt. Thus, entry would not be timely, likely, or sufficient to mitigate the anticompetitive effects from SCIH's proposed acquisition of Morton.

B. Difficulty of Entry Into Round-Can Table Salt in the United States

55. Entry of new competitors into round-can table salt in the United States would be difficult and time-consuming and is unlikely to prevent the anticompetitive effects that are likely to result if the proposed transaction is consummated.

56. Even though table salt has lower purity requirements than pharmaceutical-grade salt, a round-can table salt entrant would still need to take all of the steps to construct a facility that a pharmaceutical-grade salt entrant would, including locating an appropriate salt deposit, and investing significant time and money to build the facility.

57. In addition, an entrant in round-can table salt would have to secure a round-can packaging line. The packaging process for round-can table salt, created decades ago, is based on technology from that era and has proven to be difficult to replicate in a price-competitive manner. As a result, potential entrants with access to suitable salt deposits have tried, and failed, to develop round-can packaging technology in the last five years.

58. Entry through the construction of a new round-can table salt facility therefore will not be timely, likely, or sufficient to mitigate the anticompetitive effects of SCIH's proposed acquisition of Morton.

C. Difficulty of Entry Into Bulk Evaporated Salt in the Northeastern United States

59. Entry of new competitors into bulk evaporated salt in the northeastern United States would be difficult and time-consuming and is unlikely to prevent the harm to competition that is likely to result if the proposed transaction is consummated.

60. Just as with pharmaceutical-grade salt or round-can table salt, a new entrant in bulk evaporated salt would need to invest significant time and money to acquire land and construct an evaporated salt processing facility. Entry into bulk evaporated salt in the northeastern United States is particularly difficult because this area has limited salt deposits, which are necessary serve the market.

61. Entry through the construction of a new bulk evaporated salt production facility will therefore not be timely, likely, or sufficient to mitigate the anticompetitive effects from SCIH's proposed acquisition of Morton.

VII. Violations Alleged

62. SCIH's proposed acquisition of Morton is likely to substantially lessen competition in the production and sale of evaporated salt products, including pharmaceutical-grade salt in the United States and Canada, round-can table salt in the United States, and bulk evaporated salt in the northeastern United States, in violation of Section 7 of the Clayton Act, 15 U.S.C. 18.

63. The acquisition will likely have the following anticompetitive effects, among others, in the relevant markets:

a. Actual and potential competition between Morton and US Salt will be eliminated:

b. competition generally will be substantially lessened; and

c. prices will likely increase and quality and the level of service will likely decrease.

VIII. Request for Relief

64. The United States requests that this Court:

a. Adjudge and decree SCIH's acquisition of Morton to be unlawful and in violation of Section 7 of the Clayton Act, 15 U.S.C. 18;

b. preliminarily and permanently enjoin Defendants and all persons acting on their behalf from consummating the proposed acquisition by SCIH of Morton or from entering into or carrying out any other contract, agreement, plan, or understanding, the effect of which would be to combine Morton with US Salt:

c. award the United States the costs for this action; and

d. grant the United States such other relief as the Court deems just and proper.

Dated: April 19, 2021 Respectfully submitted, COUNSEL FOR PLAINTIFF UNITED STATES:

RICHARD POWERS

Acting Assistant Attorney General Antitrust Division

KATHLEEN S. O'NEILL

Senior Director of Investigation and Litigation, Antitrust Division

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UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA, Plaintiff, v. STONE CANYON INDUSTRIES HOLDINGS LLC; SCIH SALT HOLDINGS INC; MORTON SALT, INC.; and K+S AKTIENGESELLSCHAFT, Defendants.

Civil Action No.: 1:21-cv-01067-TJK Judge Timothy J. Kelly

Proposed Final Judgment

Whereas, Plaintiff, United States of America, filed its Complaint on April 19, 2021;

And whereas, the United States and Defendants, Stone Canyon Industries Holdings LLC ("Stone Canyon"); SCIH Salt Holdings Inc. ("SCIH"); Morton Salt, Inc. ("Morton"); and K+S Aktiengesellschaft (K+S AG"), have consented to entry of this Final Judgment without the taking of testimony, without trial or adjudication of any issue of fact or law, and without this Final Judgment constituting any evidence against or admission by any party relating to any issue of fact or law;

And whereas, Defendants agree to make a divestiture to remedy the loss of competition alleged in the Complaint;

And whereas, Defendants represent that the divestiture and other relief required by this Final Judgment can and will be made and that Defendants will not later raise a claim of hardship or difficulty as grounds for asking the Court to modify any provision of this Final Judgment;

Now therefore, it is ordered, adjudged, and decreed:

I. Jurisdiction

The Court has jurisdiction over the subject matter of and each of the parties to this action. The Complaint states a claim upon which relief may be granted against Defendants under Section 7 of the Clayton Act, as amended (15 U.S.C. 18).

II. Definitions

As used in this Final Judgment:

A. "Stone Canyon" means Defendant Stone Canyon Industries Holdings LLC, a Delaware limited corporation with its headquarters in Los Angeles, California, its successors and assigns, and its subsidiaries, divisions, groups, affiliates, including SCIH, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

B. "SCIH" means Defendant SCIH Salt Holdings Inc., an affiliate of Stone Canyon and a Delaware corporation with its headquarters in Overland Park, Kansas, its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents and employees.

C. "US Salt" means US Salt LLC, a Delaware limited liability company with its headquarters in Overland Park, Kansas, its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees. US Salt is an indirect, wholly-owned subsidiary of SCIH.

D. "K+S AG" means Defendant K+S Aktiengesellschaft, a German company with its headquarters in Hesse, Germany, its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

E. "Morton" means Defendant Morton Salt, Inc., a Delaware corporation with its headquarters in Chicago, Illinois, its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

F. "Acquirer" means the entity to which Defendants divest the Divestiture Assets.

G. "Divestiture Assets" means all of Defendants' rights, titles, and interests in US Salt, including:

- 1. The refinery and associated acreage located at 3580 Salt Point Road, Watkins Glen, NY 14891;
- 2. the leased warehouse located at 224 N Main Street, Horseheads, NY 14845;
- 3. all other real property, including fee simple interests and real property leasehold interests and renewal rights thereto, improvements to real property, and options to purchase any adjoining or other property, together with all buildings, facilities, and other structures;
- 4. all tangible personal property, including fixed assets, machinery and manufacturing equipment, tools, vehicles, inventory, materials, office equipment and furniture, computer hardware, and supplies;
- all contracts, contractual rights, and customer relationships, and all other agreements, commitments, and understandings, including supply agreements, teaming agreements, and leases, and all outstanding offers or solicitations to enter into a similar arrangement;

6. all licenses, permits, certifications, approvals, consents, registrations, waivers, and authorizations issued or granted by any governmental organization, and all pending applications or renewals;

7. all records and data, including (a) customer lists, accounts, sales, and credits records, (b) production, repair, maintenance, and performance records, (c) manuals and technical information Defendants provide to their own employees, customers, suppliers, agents, or licensees, (d) records and research data concerning historic and current research and development activities, and (e) drawings, blueprints, and designs;

8. all intellectual property owned, licensed, or sublicensed, either as licensor or licensee, including (a) patents, patent applications, and inventions and discoveries that may be patentable, (b) registered and unregistered copyrights and copyright applications, and (c) registered and unregistered trademarks, trade dress, service marks, trade names, and trademark applications; and

all other intangible property, including (a) commercial names and d/ b/a names, (b) technical information, (c) computer software and related documentation, know-how, trade secrets, design protocols, specifications for materials, specifications for parts, specifications for devices, safety procedures (e.g., for the handling of materials and substances), quality assurance and control procedures, and (d) rights in internet websites and internet domain names.

Provided, however, that the assets specified in Paragraphs (G)(1)-(9) above do not include (a) any trademarks, trade names, commercial names, doing business as ("d/b/a") names, service marks, or service names containing the name "Kissner" or (b) the SCIH enterprise licenses for Adobe Acrobat, Atera, Microsoft Office 365, Mitel, Team Viewer, Ultipro, and Webroot.

H. "Divestiture Date" means the date on which the Divestiture Assets are divested to Acquirer pursuant to this Final Judgment.

I. "Including" means including but not limited to.

J. "Relevant Personnel" means all full-time, part-time, or contract employees involved in the production or sale of evaporated salt, wherever located, for (1) US Salt, or (2) SCIH. Provided, however, that Relevant Personnel does not include (a) employees of SCIH engaged in human resources, legal, information technology, or other general or administrative support functions; or (b) any SCIH employee with the title Senior Vice President or higher.

K. "Transaction" means the proposed acquisition of Morton by SCIH.

III. Applicability

A. This Final Judgment applies to Stone Canvon, SCIH, Morton, and K+S AG, as defined above, and all other persons in active concert or participation with any Defendant who receive actual notice of this Final Judgment.

B. If, prior to complying with Section IV and Section V of this Final Judgment, Defendants sell or otherwise dispose of all or substantially all of their assets or of business units that include the Divestiture Assets, Defendants must require any purchaser to be bound by the provisions of this Final Judgment. Defendants need not obtain such an agreement from Acquirer.

IV. Divestiture

A. Defendants are ordered and directed, within 120 calendar days after the Court's entry of the Asset Preservation and Hold Separate Stipulation and Order in this matter, to divest the Divestiture Assets in a manner consistent with this Final Judgment to an Acquirer acceptable to the United States, in its sole discretion. The United States, in its sole discretion, may agree to one or more extensions of this time period not to exceed 60 calendar days in total and will notify the Court of any extensions.

B. Defendants must use best efforts to divest the Divestiture Assets as expeditiously as possible and may not

take any action to impede the permitting, operation, or divestiture of the Divestiture Assets. Defendants must take no action that would jeopardize the divestiture ordered by the Court.

C. Unless the United States otherwise consents in writing, divestiture pursuant to this Final Judgment must include the entire Divestiture Assets and must be accomplished in such a way as to satisfy the United States, in its sole discretion, that the Divestiture Assets can and will be used by Acquirer as part of a viable, ongoing business in the production and sale of evaporated salt products and that the divestiture to Acquirer will remedy the competitive harm alleged in the Complaint.

D. The divestiture must be made to an Acquirer that, in the United States' sole judgment, has the intent and capability, including the necessary managerial, operational, technical, and financial capability, to compete effectively in the production and sale of evaporated salt

products.

E. The divestiture must be accomplished in a manner that satisfies the United States, in its sole discretion, that none of the terms of any agreement between Acquirer and Defendants gives Defendants the ability unreasonably to raise Acquirer's costs, lower Acquirer's efficiency, or otherwise interfere in the ability of the Acquirer to compete effectively in the production and sale of

evaporated salt products.

F. In accomplishing the divestiture ordered by this Final Judgment, Defendants promptly must make known, by usual and customary means, the availability of the Divestiture Assets. Defendants must inform any person making an inquiry relating to a possible purchase of the Divestiture Assets that the Divestiture Assets are being divested in accordance with this Final Judgment and must provide that person with a copy of this Final Judgment. Defendants must offer to furnish to all prospective Acquirers, subject to customary confidentiality assurances, all information and documents relating to the Divestiture Assets that are customarily provided in a due-diligence process; provided, however, that Defendants need not provide information or documents subject to the attorney-client privilege or workproduct doctrine. Defendants must make all information and documents available to the United States at the same time that the information and documents are made available to any other person.

G. Defendants must provide prospective Acquirers with (1) access to make inspections of the Divestiture Assets; (2) access to all environmental,

zoning, and other permitting documents and information relating to the Divestiture Assets; and (3) access to all financial, operational, or other documents and information relating to the Divestiture Assets that customarily would be provided as part of a duediligence process. Defendants also must disclose all encumbrances on any part of the Divestiture Assets, including on intangible property.

H. Defendants must cooperate with and assist Acquirer in identifying and, at the option of Acquirer, hiring all Relevant Personnel, including:

- 1. Within 10 business days following the filing of the Complaint in this matter, Defendants must identify all Relevant Personnel to Acquirer and the United States, including by providing organization charts covering all Relevant Personnel.
- 2. Within 10 business days following receipt of a request by Acquirer or the United States, Defendants must provide to Acquirer and the United States additional information relating to Relevant Personnel, including name, job title, reporting relationships, past experience, responsibilities, training and educational histories, relevant certifications, and job performance evaluations. Defendants also must provide to Acquirer and the United States current and accrued compensation and benefits, including most recent bonuses paid, aggregate annual compensation, current target or guaranteed bonus any retention agreement or incentives, and any other payments due, compensation or benefit accrued, or promises made to the Relevant Personnel. If Defendants are barred by any applicable law from providing any of this information, Defendants must provide, within 10 business days following receipt of the request, the requested information to the full extent permitted by law and also must provide a written explanation of Defendants' inability to provide the remaining information, including specifically identifying the provisions of the applicable laws.
- 3. At the request of Acquirer, Defendants must promptly make Relevant Personnel available for private interviews with Acquirer during normal business hours at a mutually agreeable location.
- 4. Defendants must not interfere with any effort by Acquirer to employ any Relevant Personnel. Interference includes offering to increase the compensation or improve the benefits of Relevant Personnel unless: (a) The offer is part of a company-wide increase in compensation or improvement in benefits that was announced prior to

October 5, 2020; or (b) the offer is approved by the United States in its sole discretion. Defendants' obligations under this Paragraph will expire six months after the Divestiture Date.

- 5. For Relevant Personnel who elect employment with Acquirer within six months of the Divestiture Date, Defendants must waive all non-compete and non-disclosure agreements, vest all unvested pension and other equity rights that those Relevant Personnel have fully or partially accrued, provide any pay pro-rata, provide all other compensation and benefits that those Relevant Personnel have fully or partially accrued, and provide all other benefits that those Relevant Personnel otherwise would have been provided had the Relevant Personnel continued employment with Defendants, including any retention bonuses or payments. Defendants may maintain reasonable restrictions on disclosure by Relevant Personnel of Defendants' proprietary non-public information that is unrelated to the production and sale of evaporated salt products and not otherwise required to be disclosed by this Final Judgment.
- 6. For a period of 12 months from the Divestiture Date, Defendants may not solicit to rehire Relevant Personnel who were hired by Acquirer within six months of the Divestiture Date unless (a) an individual is terminated or laid off by Acquirer or (b) Acquirer agrees in writing that Defendants may solicit to re-hire that individual. Nothing in this Paragraph prohibits Defendants from advertising employment openings using general solicitations or advertisements and rehiring Relevant Personnel who apply for an employment opening through a general solicitation or advertisement.
- I. Defendants must warrant to Acquirer that (1) the Divestiture Assets will be operational and without material defect on the date of their transfer to Acquirer; (2) there are no material defects in the environmental, zoning, or other permits relating to the operation of the Divestiture Assets; and (3) Defendants have disclosed all encumbrances on any part of the Divestiture Assets, including on intangible property. Following the sale of the Divestiture Assets, Defendants must not undertake, directly or indirectly, challenges to the environmental, zoning, or other permits relating to the operation of the Divestiture Assets.
- J. Defendants must assign, subcontract, or otherwise transfer all contracts, agreements, and relationships (or portions of such contracts, agreements, and relationships) included in the Divestiture Assets, including all

supply and sales contracts, to Acquirer; provided, however, that for any contract or agreement that requires the consent of another party to assign, subcontract, or otherwise transfer, Defendants must use best efforts to accomplish the assignment, subcontracting, or transfer. Defendants must not interfere with any negotiations between Acquirer and a contracting party.

K. Defendants must use best efforts to assist Acquirer to obtain all necessary licenses, registrations, and permits to operate the Divestiture Assets. Until Acquirer obtains the necessary licenses, registrations, and permits, Defendants must provide Acquirer with the benefit of Defendants' licenses, registrations, and permits to the full extent

permissible by law.

L. At the option of Acquirer, and subject to approval by the United States in its sole discretion, on or before the Divestiture Date, Defendants must enter into a contract to provide transition services for back office, human resource, and information technology services and support for US Salt for a period of up to 12 months on terms and conditions reasonably related to market conditions for the provision of the transition services. Any amendment to or modification of any provision of a contract for transition services is subject to approval by the United States, in its sole discretion. The United States, in its sole discretion, may approve one or more extensions of this contract for transition services, for a total of up to an additional six months. If Acquirer seeks an extension of the term of any contract for transition services, Defendants must notify the United States in writing at least three months prior to the date the contract expires. Acquirer may terminate a contract for transition services, or any portion of a contract for transition services, without cost or penalty at any time upon 30 days' written notice. The employee(s) of Defendants tasked with providing transition services must not share any competitively sensitive information of Acquirer with any other employee of Defendants.

M. If any term of an agreement between Defendants and Acquirer, including an agreement to effectuate the divestiture required by this Final Judgment, varies from a term of this Final Judgment then, to the extent that Defendants cannot fully comply with both, this Final Judgment determines Defendants' obligations.

V. Appointment of Divestiture Trustee

A. If Defendants have not divested the Divestiture Assets within the period specified in Paragraph IV.A, Defendants must immediately notify the United States of that fact in writing. Upon application of the United States, which Defendants may not oppose, the Court will appoint a divestiture trustee selected by the United States and approved by the Court to effect the divestiture of the Divestiture Assets.

B. After the appointment of a divestiture trustee by the Court, only the divestiture trustee will have the right to sell the Divestiture Assets. The divestiture trustee will have the power and authority to accomplish the divestiture to an Acquirer acceptable to the United States, in its sole discretion, at a price and on terms obtainable through reasonable effort by the divestiture trustee, subject to the provisions of Sections IV, V, and VI of this Final Judgment, and will have other powers as the Court deems appropriate. The divestiture trustee must sell the Divestiture Assets as quickly as possible.

C. Defendants may not object to a sale by the divestiture trustee on any ground other than malfeasance by the divestiture trustee. Objections by Defendants must be conveyed in writing to the United States and the divestiture trustee within 10 calendar days after the divestiture trustee has provided the notice of proposed divestiture required by Section VI.

D. The divestiture trustee will serve at the cost and expense of Defendants pursuant to a written agreement, on terms and conditions, including confidentiality requirements and conflict-of-interest certifications, that are approved by the United States, in its sole discretion.

E. The divestiture trustee may hire at the cost and expense of Defendants any agents or consultants, including investment bankers, attorneys, and accountants, that are reasonably necessary in the divestiture trustee's judgment to assist with the divestiture trustee's duties. These agents or consultants will be accountable solely to the divestiture trustee and will serve on terms and conditions, including terms and conditions governing confidentiality requirements and conflict-of-interest certifications, approved by the United States in its sole discretion.

F. The compensation of the divestiture trustee and agents or consultants hired by the divestiture trustee must be reasonable in light of the value of the Divestiture Assets and based on a fee arrangement that provides the divestiture trustee with incentives based on the price and terms of the divestiture and the speed with which it is accomplished. If the

divestiture trustee and Defendants are unable to reach agreement on the divestiture trustee's compensation or other terms and conditions of engagement within 14 calendar days of the appointment of the divestiture trustee by the Court, the United States, in its sole discretion, may take appropriate action, including by making a recommendation to the Court. Within three business days of hiring an agent or consultant, the divestiture trustee must provide written notice of the hiring and rate of compensation to Defendants and the United States.

G. The divestiture trustee must account for all monies derived from the sale of the assets sold by the divestiture trustee and all costs and expenses incurred. Within 30 calendar days of the date of the sale of the assets sold by the divestiture trustee, the divestiture trustee must submit that accounting to the Court for approval. After approval by the Court of the divestiture trustee's accounting, including fees for unpaid services and those of agents or consultants hired by the divestiture trustee, all remaining money must be paid to Stone Canyon or SCIH and the trust will then be terminated.

H. Defendants must use best efforts to assist the divestiture trustee to accomplish the required divestiture. Subject to reasonable protection for trade secrets, other confidential research, development, or commercial information, or any applicable privileges, Defendants must provide the divestiture trustee and agents or consultants retained by the divestiture trustee with full and complete access to all personnel, books, records, and facilities of the Divestiture Assets. Defendants also must provide or develop financial and other information relevant to the Divestiture Assets that the divestiture trustee may reasonably request. Defendants must not take any action to interfere with or to impede the divestiture trustee's accomplishment of the divestiture.

I. The divestiture trustee must maintain complete records of all efforts made to sell the Divestiture Assets, including by filing monthly reports with the United States setting forth the divestiture trustee's efforts to accomplish the divestiture ordered by this Final Judgment. The reports must include the name, address, and telephone number of each person who, during the preceding month, made an offer to acquire, expressed an interest in acquiring, entered into negotiations to acquire, or was contacted or made an inquiry about acquiring any interest in the Divestiture Assets and must describe in detail each contact.

I. If the divestiture trustee has not accomplished the divestiture ordered by this Final Judgment within six months of appointment, the divestiture trustee must promptly provide the United States with a report setting forth: (1) The divestiture trustee's efforts to accomplish the required divestiture; (2) the reasons, in the divestiture trustee's judgment, why the required divestiture has not been accomplished; and (3) the divestiture trustee's recommendations for completing the divestiture. Following receipt of that report, the United States may make additional recommendations to the Court. The Court thereafter may enter such orders as it deems appropriate to carry out the purpose of this Final Judgment, which may include extending the trust and the term of the divestiture trustee's appointment by a period requested by the United States.

K. The divestiture trustee will serve until divestiture of all Divestiture Assets is completed or for a term otherwise ordered by the Court.

L. If the United States determines that the divestiture trustee is not acting diligently or in a reasonably costeffective manner, the United States may recommend that the Court appoint a substitute divestiture trustee.

VI. Notice of Proposed Divestiture

A. Within two business days following execution of a definitive agreement to divest the Divestiture Assets, Defendants or the divestiture trustee, whichever is then responsible for effecting the divestiture, must notify the United States of the proposed divestiture. If the divestiture trustee is responsible for completing the divestiture, the divestiture trustee also must notify Defendants. The notice must set forth the details of the proposed divestiture and list the name, address, and telephone number of each person not previously identified who offered or expressed an interest in or desire to acquire any ownership interest in the Divestiture Assets.

B. Within 15 calendar days of receipt by the United States of the notice required by Paragraph VI.A, the United States may request from Defendants, the proposed Acquirer, other third parties, or the divestiture trustee additional information concerning the proposed divestiture, the proposed Acquirer, and other prospective Acquirers. Defendants and the divestiture trustee must furnish the additional information requested within 15 calendar days of the receipt of the request, unless the United States provides written agreement to a different period.

C. Within 45 calendar days after receipt of the notice required by Paragraph VI.A or within 20 calendar days after the United States has been provided the additional information requested pursuant to Paragraph VI.B. whichever is later, the United States will provide written notice to Defendants and any divestiture trustee that states whether the United States, in its sole discretion, objects to the proposed Acquirer or any other aspect of the proposed divestiture. Without written notice that the United States does not object, a divestiture may not be consummated. If the United States provides written notice that it does not object, the divestiture may be consummated, subject only to Defendants' limited right to object to the sale under Paragraph V.C of this Final Judgment. Upon objection by Defendants pursuant to Paragraph V.C, a divestiture by the divestiture trustee may not be consummated unless approved by the Court.

D. No information or documents obtained pursuant to this Section VI may be divulged by the United States to any person other than an authorized representative of the executive branch of the United States except in the course of legal proceedings to which the United States is a party, including grand-jury proceedings, for the purpose of evaluating a proposed Acquirer or securing compliance with this Final Judgment, or as otherwise required by

law.

E. In the event of a request by a third party for disclosure of information under the Freedom of Information Act, 5 U.S.C. 552, the United States Department of Justice's Antitrust Division will act in accordance with that statute, and the Department of Justice regulations at 28 CFR part 16, including the provision on confidential commercial information, at 28 CFR 16.7. Persons submitting information to the Antitrust Division should designate the confidential commercial information portions of all applicable documents and information under 28 CFR 16.7. Designations of confidentiality expire ten years after submission, "unless the submitter requests and provides justification for a longer designation period." See 28 CFR 16.7(b).

F. If at the time a person furnishes information or documents to the United States pursuant to this Section VI, that person represents and identifies in writing information or documents for which a claim of protection may be asserted under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure, and marks each pertinent page of such material, "Subject to claim of protection

under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure," the United States must give that person ten calendar days' notice before divulging the material in any legal proceeding (other than a grand-jury proceeding).

VII. Financing

Defendants may not finance all or any part of Acquirer's purchase of all or part of the Divestiture Assets.

VIII. Asset Preservation and Hold Separate

Defendants must take all steps necessary to comply with the Asset Preservation and Hold Separate Stipulation and Order entered by the Court.

IX. Affidavits

A. Within 20 calendar days of the filing of the Complaint in this matter, and every 30 calendar days thereafter until the divestiture required by this Final Judgment has been completed, each Defendant must deliver to the United States an affidavit signed by each Defendant's Chief Financial Officer and General Counsel, describing in reasonable detail the fact and manner of that Defendant's compliance with this Final Judgment. The United States, in its sole discretion, may approve different signatories for the affidavits.

B. Each affidavit must include: (1) The name, address, and telephone number of each person who, during the preceding 30 calendar days, made an offer to acquire, expressed an interest in acquiring, entered into negotiations to acquire, or was contacted or made an inquiry about acquiring, an interest in the Divestiture Assets, and describe in detail each contact with such persons during that period; (2) a description of the efforts Defendants have taken to solicit buyers for and complete the sale of the Divestiture Assets and to provide required information to prospective Acquirers; and (3) a description of any limitations placed by Defendants on information provided to prospective Acquirers. Objection by the United States to information provided by Defendants to prospective Acquirers must be made within 14 calendar days of receipt of the affidavit, except that the United States may object at any time if the information set forth in the affidavit is not true or complete.

C. Defendants must keep all records of any efforts made to divest the Divestiture Assets until one year after the Divestiture Date.

D. Within 20 calendar days of the filing of the Complaint in this matter, each Defendant must deliver to the United States an affidavit signed by each Defendant's Chief Financial Officer and General Counsel, describing in reasonable detail all actions that Defendants have taken and all steps that Defendants have implemented on an ongoing basis to comply with Section VIII of this Final Judgment. The United States, in its sole discretion, may approve different signatories for the affidavits.

E. If a Defendant makes any changes to the actions and steps described in affidavits provided pursuant to Paragraph IX.D, the Defendant must, within 15 calendar days after any change is implemented, deliver to the United States an affidavit describing those changes.

F. Defendants must keep all records of any efforts made to comply with Section VIII until one year after the divestiture has been completed.

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X. Compliance Inspection

A. For the purpose of determining or securing compliance with this Final Judgment or of related orders such as the Asset Preservation and Hold Separate Stipulation and Order, or of determining whether this Final Judgment should be modified or vacated, upon written request of an authorized representative of the Assistant Attorney General for the Antitrust Division, and reasonable notice to Defendants, Defendants must permit, from time to time and subject to legally recognized privileges, authorized representatives, including agents retained by the United States:

1. To have access during Defendants' office hours to inspect and copy, or at the option of the United States, to require Defendants to provide electronic copies of all books, ledgers, accounts, records, data, and documents in the possession, custody, or control of Defendants, relating to any matters contained in this Final Judgment; and

2. to interview, either informally or on the record, Defendants' officers, employees, or agents, who may have their individual counsel present, relating to any matters contained in this Final Judgment. The interviews must be subject to the reasonable convenience of the interviewee and without restraint or interference by Defendants.

B. Upon the written request of an authorized representative of the Assistant Attorney General for the Antitrust Division, Defendants must submit written reports or respond to written interrogatories, under oath if requested, relating to any matters contained in this Final Judgment.

C. No information or documents obtained by the United States pursuant to this Section X may be divulged by the United States to any person other than an authorized representative of the executive branch of the United States except in the course of legal proceedings to which the United States is a party, including grand jury proceedings, for the purpose of securing compliance with this Final Judgment, or as otherwise required by law.

D. In the event of a request by a third party for disclosure of information under the Freedom of Information Act, 5 U.S.C. 552, the Antitrust Division will act in accordance with that statute, and the Department of Justice regulations at 28 CFR part 16, including the provision on confidential commercial information, at 28 CFR 16.7. Defendants submitting information to the Antitrust Division should designate the confidential commercial information portions of all applicable documents and information under 28 CFR 16.7. Designations of confidentiality expire ten years after submission, "unless the submitter requests and provides justification for a longer designation period." See 28 CFR $16.\bar{7}(b)$.

E. If at the time that Defendants furnish information or documents to the United States pursuant to this Section X, Defendants represent and identify in writing information or documents for which a claim of protection may be asserted under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure, and Defendants mark each pertinent page of such material, "Subject to claim of protection under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure," the United States must give Defendants 10 calendar days' notice before divulging the material in any legal proceeding (other than a grand jury proceeding).

XI. Firewalls

A. For a period of two years following the filing of this Proposed Final Judgment, Stone Canyon and SCIH must implement and maintain procedures to prevent any employees of Stone Canyon and SCIH from sharing competitively sensitive information relating to US Salt with personnel with responsibilities relating to Morton's production or sale of evaporated salt products.

B. Stone Canyon and SCIH, within 30 calendar days of the Court's entry of the Asset Preservation and Hold Separate Stipulation and Order, must submit to the United States a document setting forth in detail the procedures implemented to effect compliance with this Section XI. Upon receipt of the document, the United States will inform Stone Canyon and SCIH within 10 business days whether, in its sole discretion, the United States approves or rejects Stone Canyon and SCIH's

compliance plan. Within 10 business days of receiving a notice of rejection, Stone Canyon and SCIH must submit a revised compliance plan. The United States may request that the Court determine whether Stone Canyon and SCIH's proposed compliance plan fulfills the requirements of Paragraph XI.A.

XII. Limitations on Reacquisition

Defendants may not reacquire any part of or any interest in the Divestiture Assets during the term of this Final Judgment.

XIII. Retention of Jurisdiction

The Court retains jurisdiction to enable any party to this Final Judgment to apply to the Court at any time for further orders and directions as may be necessary or appropriate to carry out or construe this Final Judgment, to modify any of its provisions, to enforce compliance, and to punish violations of its provisions.

XIV. Enforcement of Final Judgment

A. The United States retains and reserves all rights to enforce the provisions of this Final Judgment, including the right to seek an order of contempt from the Court. Defendants agree that in a civil contempt action, a motion to show cause, or a similar action brought by the United States relating to an alleged violation of this Final Judgment, the United States may establish a violation of this Final Judgment and the appropriateness of a remedy therefor by a preponderance of the evidence, and Defendants waive any argument that a different standard of proof should apply.

B. This Final Judgment should be interpreted to give full effect to the procompetitive purposes of the antitrust laws and to restore the competition the United States alleged was harmed by the challenged conduct. Defendants agree that they may be held in contempt of, and that the Court may enforce, any provision of this Final Judgment that, as interpreted by the Court in light of these procompetitive principles and applying ordinary tools of interpretation, is stated specifically and in reasonable detail, whether or not it is clear and unambiguous on its face. In any such interpretation, the terms of this Final Judgment should not be construed against either party as the drafter.

C. In an enforcement proceeding in which the Court finds that Defendants have violated this Final Judgment, the United States may apply to the Court for a one-time extension of this Final Judgment, together with other relief that may be appropriate. In connection with

a successful effort by the United States to enforce this Final Judgment against a Defendant, whether litigated or resolved before litigation, that Defendant agrees to reimburse the United States for the fees and expenses of its attorneys, as well as all other costs including experts' fees, incurred in connection with that effort to enforce the Final Judgment, including in the investigation of the potential violation.

D. For a period of four years following the expiration of this Final Judgment, if the United States has evidence that a Defendant violated this Final Judgment before it expired, the United States may file an action against that Defendant in this Court requesting that the Court order: (1) Defendant to comply with the terms of this Final Judgment for an additional term of at least four years following the filing of the enforcement action; (2) all appropriate contempt remedies; (3) additional relief needed to ensure the Defendant complies with the terms of this Final Judgment; and (4) fees or expenses as called for by this Section XIV.

XV. Expiration of Final Judgment

Unless the Court grants an extension, this Final Judgment will expire 10 years from the date of its entry, except that after five years from the date of its entry, this Final Judgment may be terminated upon notice by the United States to the Court and Defendants that the divestiture has been completed and continuation of this Final Judgment no longer is necessary or in the public interest.

XVI. Public Interest Determination

Entry of this Final Judgment is in the public interest. The parties have complied with the requirements of the Antitrust Procedures and Penalties Act, 15 U.S.C. 16, including by making available to the public copies of this Final Judgment, and the Competitive Impact Statement, public comments thereon, and any response to comments by the United States. Based upon the record before the Court, which includes the Competitive Impact Statement and, if applicable, any comments and response to comments filed with the Court, entry of this Final Judgment is in the public interest.

Date:

[Court approval subject to procedures of Antitrust Procedures and Penalties Act, 15 U.S.C. 16]

United States District Judge

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA, Plaintiff, v. STONE CANYON INDUSTRIES HOLDINGS LLC; SCIH SALT HOLDINGS INC; MORTON SALT, INC.; and K+S AKTIENGESELLSCHAFT, Defendants. Civil Action No.: 1:21-cv-01067-TJK Judge Timothy J. Kelly

Competitive Impact Statement

In accordance with the Antitrust Procedures and Penalties Act, 15 U.S.C. 16 (the "APPA" or "Tunney Act"), the United States of America files this Competitive Impact Statement related to the proposed Final Judgment filed in this civil antitrust proceeding.

I. Nature and Purpose of the Proceeding

On October 5, 2020, Stone Canyon Industry Holdings LLC ("Stone Canyon") and its portfolio company SCIH Salt Holdings Inc. ("SCIH") agreed to acquire the K+S Aktiengesellschaft ("K+S AG") Operating Unit Salt Americas business, a bundle of several subsidiaries including Morton Salt, Inc. ("Morton"). The United States filed a civil antitrust Complaint on April 19, 2021, seeking to enjoin the proposed acquisition. The Complaint alleges that the likely effect of this acquisition would be to substantially lessen competition in the production and sale of evaporated salt products, including pharmaceutical-grade salt in the United States and Canada, "round-can" table salt in the United States, and bulk evaporated salt in the northeastern United States, in violation of Section 7 of the Clayton Act, 15 U.S.C. 18.

At the same time the Complaint was filed, the United States filed a proposed Final Judgment and an Asset Preservation and Hold Separate Stipulation and Order ("Stipulation and Order"), which are designed to remedy the loss of competition alleged in the Complaint.

Under the proposed Final Judgment, which is explained more fully below, Defendants are required to divest SCIH's subsidiary, US Salt LLC ("US Salt").

Under the terms of the Stipulation and Order, Defendants must take certain steps to ensure that US Salt is operated as a competitively independent, economically viable, and ongoing business concern, which must remain independent and uninfluenced by Defendants, and that competition is maintained during the pendency of the required divestiture. On April 22, 2021, the Court entered the Stipulation and Order

The United States and Defendants have stipulated that the proposed Final Judgment may be entered after compliance with the APPA. Entry of the proposed Final Judgment will terminate this action, except that the Court will retain jurisdiction to construe, modify, or enforce the provisions of the proposed Final Judgment and to punish violations thereof.

II. Description of Events Giving Rise to the Alleged Violation

A. The Defendants and the Proposed Transaction

Stone Canyon is an industrial holding company incorporated in Delaware and headquartered in Los Angeles, California. Stone Canyon acquired Kissner Group Holdings LP, which it later renamed SCIH, in April 2020.

SCIH is a subsidiary of Stone Canyon and is headquartered in Overland Park, Kansas. In 2020, SCIH had revenues of approximately \$1 billion. SCIH is a leading supplier of salt products, including evaporated salt products.

K+S AG is a chemical company headquartered in Kassel, Germany. In 2020, K+S AG reported revenues of approximately \$4.4 billion. K+S AG's Operating Unit Salt Americas business includes Morton as well as K+S Windsor Salt, which sells salt products in Canada, and Sociedad Punta de Lobos, which sells salt products in Chile

Morton is a K+S AG subsidiary with approximately \$1 billion in revenue in 2020. Morton is the largest supplier of pharmaceutical-grade salt in the United States and Canada, the largest supplier of "round-can" table salt in the United States, and one of only three suppliers of bulk evaporated salt in the northeastern United States.

Pursuant to a Transaction Agreement dated October 5, 2020, SCIH agreed to acquire K+S AG's Operating Unit Salt Americas business, including Morton, for approximately \$3.2 billion.

B. Relevant Product Markets

Morton and SCIH's US Salt subsidiary both produce and sell evaporated salt. Evaporated salt is a type of sodium chloride produced through "vacuum evaporation." In the vacuum evaporation process, water is pumped into a salt deposit where the salt dissolves, and the resulting brine is forced into an evaporator on the surface where it is boiled in a series of pans until only the salt remains. Evaporated salt is nearly 100% sodium chloride and contains almost no other trace minerals. Because of the evaporation process, individual grains of evaporated salt are also more consistent and regularly shaped than other forms of salt.

Evaporated salt is distinct from salt created through other production

methods, such as rock salt and solar salt. Rock salt is mined and then crushed into smaller sizes before being transported to the surface. Rock salt is less expensive to produce than evaporated salt, but it is also coarser, irregularly shaped, and contains other minerals and impurities. As a result, rock salt is used for applications that have less demanding quality requirements such as de-icing roads. Solar salt is created when salt water is captured in shallow ponds where the sun evaporates most of the water. It can only be produced in warm climates where the evaporation rate exceeds the precipitation rate. Solar salt is less pure and not as uniform in shape as evaporated salt, but it is purer than rock salt. Solar salt is used for applications such as water softening.

Evaporated salt typically is used in applications that require the highest quality of salt, such as human consumption. There are different types of evaporated salt that have different characteristics, end uses, and customers. As alleged in the Complaint, three types of evaporated salt produced by Defendants constitute relevant product markets—pharmaceutical-grade salt, round-can table salt, and bulk evaporated salt.

i. Pharmaceutical-Grade Salt

Pharmaceutical-grade salt is the grade of salt with the highest percentage of sodium chloride and thus is the purest grade of evaporated salt. Pharmaceutical-grade salt is used in the pharmaceutical industry as a building block for a number of life-saving treatments and products, including dialysis fluid, intravenous saline solution, and other medical products. Pharmaceutical-grade salt must be evaporated from salt deposits of extremely high purity and then undergo post-production processing to ensure that it contains virtually no trace minerals or other impurities.

Because of these stringent standards, the mining and production process for pharmaceutical-grade salt must be extensively monitored and documented to ensure purity and consistency across production batches. This documentation must then be provided to customers as a validation of the quality and purity of the pharmaceutical-grade salt.

Rock salt and solar salt do not meet the purity requirements for pharmaceutical-grade salt. Other grades of evaporated salt—for example, salt used in food processing—also cannot serve as a substitute for pharmaceuticalgrade salt. Pharmaceutical-grade salt must contain a higher percentage of sodium chloride than other types of evaporated salt. This ensures that it does not contain trace minerals that would impact the efficacy of pharmaceutical products made using pharmaceutical-grade salt. Pharmaceutical-grade salt also cannot contain additives such as anti-caking agents that are added during the processing of other types of evaporated salt. Because of these requirements, pharmaceutical-grade salt is more difficult to produce than other forms of evaporated salt.

The Complaint alleges that, in the event of a small but significant increase in price by a hypothetical monopolist of pharmaceutical-grade salt, substitution away from pharmaceutical-grade salt would be insufficient to render the price increase unprofitable. Pharmaceuticalgrade salt is therefore a line of commerce, or relevant product market, for purposes of analyzing the effects of the acquisition under Section 7 of the Clayton Act, 15 U.S.C. 18.

ii. Round-Can Table Salt

Table salt is evaporated salt that is processed for human consumption. It is regulated by the Food and Drug Administration ("FDA") and must meet high purity standards. Table salt also has a highly consistent size across granules and contains agents to prevent clumping and evaporation. Without additional processing—which raises price considerably—rock salt and solar salt cannot meet the same purity requirements or achieve the same consistent granule size as table salt. Pharmaceutical-grade salt meets the purity requirements for table salt but does not contain the necessary agents to prevent clumping and evaporation. As such, rock salt, solar salt, and pharmaceutical-grade salt are not substitutes for table salt.

In the United States, the packaging format strongly preferred by consumers for table salt is the round can, which is a 26-ounce cardboard cylinder with a paper label and a metal spout. The round-can's size, shape, material, and metal spout make it an easy receptacle to use one-handed without spilling while cooking or refilling a salt shaker, which is a product characteristic that is highly valued by consumers. Reflecting consumer preference, retailers like grocery stores dedicate shelf space specifically to round-can packaging. As a result, approximately 95% of the table salt sold to consumers in the United States is sold in a round can.

Table salt packaged in other containers, such as boxes or bags, is not a reasonable substitute for round-can table salt. Boxes without a metal spout and bags are more difficult to use and

store and may spill once opened. Larger packages of table salt also are not reasonable substitutes for round-can table salt, as they contain significantly more salt than an individual can practically use.

The Complaint alleges that, in the event of a small but significant increase in price by a hypothetical monopolist of round-can table salt, substitution away from round-can table salt would be insufficient to render the price increase unprofitable. Round-can table salt is therefore a line of commerce, or relevant product market, for purposes of analyzing the effects of the acquisition under Section 7 of the Clayton Act, 15 U.S.C. 18.

iii. Bulk Evaporated Salt

Bulk evaporated salt is salt that is of sufficient purity to be used for human consumption that is sold in bulk form. Bulk evaporated salt is used to manufacture chemicals necessary to create essential everyday cleaning products such as disinfectants, soap, and bleach. Bulk evaporated salt is also an essential ingredient in nearly all processed pre-packaged foods, such as sauces, chips and other snacks, and frozen meals. Because bulk evaporated salt is incorporated into products endconsumers ingest or touch, it is regulated by the FDA and must meet stringent purity requirements.

Customers for bulk evaporated salt include chemical companies and large pre-packaged food manufacturers as well as smaller customers, such as bakeries, that use salt as an essential ingredient in their food products. To accommodate these customers, many of whom purchase thousands of tons of salt per year, evaporated salt is sold in bulk, by the truckload or in containers ranging from 50-pound bags to 2,000-

pound "super-sacks."

Bulk evaporated salt is distinct from evaporated salt used for other applications. Compared to other types of evaporated salt, it has unique end-uses, customers, and packaging. While pharmaceutical-grade salt and roundcan table salt are of sufficient purity, they are priced too high and packaged in quantities that are too small to serve as substitutes for bulk evaporated salt. Bulk evaporated salt also is distinct from rock salt and solar salt, which have lower purity levels and non-uniform textures that make them unsuitable for chemical and food-production end uses. None of these types of salt can serve as a substitute to bulk evaporated salt.

The Complaint alleges that, in the event of a small but significant increase in price by a hypothetical monopolist of bulk evaporated salt, substitution away

from bulk evaporated salt would be insufficient to render the price increase unprofitable. Bulk evaporated salt is therefore a line of commerce, or relevant product market, for purposes of analyzing the effects of the acquisition under Section 7 of the Clayton Act.

C. Relevant Geographic Markets

i. Pharmaceutical-Grade Salt

Pharmaceutical-grade salt is manufactured in only a few locations in the United States. From these locations, pharmaceutical-grade salt is shipped to customers throughout the United States and Canada.

While pharmaceutical-grade salt is shipped throughout the United States and Canada, shipping it from overseas is prohibitively expensive. This is because pharmaceutical-grade salt may not contain anti-caking agents. Without anti-caking agents, pharmaceuticalgrade salt has a short shelf-life and may be damaged by the time and rigors of ocean-shipping. These limitations make ocean-shipping cost-prohibitive.

The Complaint alleges that a hypothetical monopolist of pharmaceutical-grade salt in the United States and Canada could profitably impose a small but significant nontransitory increase in price for pharmaceutical-grade salt without losing sufficient sales to render the price increase unprofitable. Accordingly, the Complaint alleges that the relevant geographic market for the purposes of analyzing the effects of the acquisition on pharmaceutical-grade salt under Section 7 of the Clayton Act, 15 U.S.C. 18 is the United States and Canada.

ii. Round-Can Table Salt

Competition among round-can table salt suppliers occurs at a national level. Retailers, many of which are grocery store chains, mass merchandisers, or convenience stores with large national footprints, purchase round-can table salt for all of their locations at once, and suppliers ship round-can table salt from coast to coast.

Round-can table salt is not imported from outside the United States. In addition to being heavy—and therefore expensive to transport—table salt in other countries is typically sold in bags or cardboard boxes. As such, foreign suppliers of table salt typically lack the production facilities to produce round cans for the United States market.

The Complaint alleges that a hypothetical monopolist of round-can table salt in the United States could profitably impose a small but significant non-transitory increase in price for round-can table salt without losing

sufficient sales to render the price increase unprofitable. Accordingly, the Complaint alleges that the relevant geographic market for the purposes of analyzing the effects of the acquisition on round-can table salt under Section 7 of the Clayton Act, 15 U.S.C. 18 is the United States.

iii. Bulk Evaporated Salt

Bulk evaporated salt is a product that can be produced at a relatively low cost, but it is heavy and therefore expensive to transport. As a result, customers purchase from nearby suppliers to minimize shipping costs that can be high relative to the value of the bulk evaporated salt being purchased.

Both Morton and US Salt—along with only one other competitor—operate bulk evaporated salt production facilities in upstate New York. All three companies use these facilities to service customers in the northeastern United States, including Connecticut, Delaware, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont. Customers in the northeastern United States can economically procure bulk evaporated salt from only these three locations. Other more distant bulk evaporated salt facilities cannot compete successfully on a regular basis for customers in the northeastern United States because the suppliers are too far away, making transportation costs too great.

The Complaint alleges that a hypothetical monopolist of bulk evaporated salt in the northeastern United States could profitably impose a small but significant non-transitory increase in price for bulk evaporated salt without losing sufficient sales to render the price increase unprofitable. Accordingly, the Complaint alleges that the relevant geographic market for the purposes of analyzing the effects of the acquisition on bulk evaporated salt under Section 7 of the Clayton Act, 15 U.S.C. 18 is the northeastern United States.

D. Anticompetitive Effects of the Proposed Transaction

The Complaint alleges that the proposed transaction would lessen competition and harm customers for pharmaceutical-grade salt in the United States and Canada, round-can table salt in the United States, and bulk evaporated salt in the northeastern United States by eliminating the substantial head-to-head competition that currently exists between Morton and US Salt. The Complaint further alleges that customers in each of these markets would pay higher prices and

receive lower quality and service as a result of the acquisition.

i. Pharmaceutical-Grade Salt in the United States and Canada

As described in the Complaint, Morton and US Salt are the only two suppliers of pharmaceutical-grade salt in the United States and Canada, with Morton currently having a market share of around 77% and US Salt a share of around 23%. The acquisition would thus give the combined firm a monopoly in the sale of pharmaceutical-grade salt in the United States and Canada, leaving pharmaceutical companies and other customers without a competitive alternative for this critical ingredient in dialysis fluid, intravenous saline solution, and other medical products.

The Complaint alleges that Morton and US Salt compete to sell pharmaceutical-grade salt on the basis of quality and surety of supply. This competition has resulted in higher quality, lower prices, and better customer service. The combination of Morton and US Salt would eliminate this competition and its future benefits to customers, including pharmaceutical companies. Post-acquisition, the combined Morton and US Salt likely would have the incentive and ability to increase prices and offer less favorable contractual terms.

As alleged in the Complaint, the proposed acquisition, therefore, likely would substantially lessen competition in the production of pharmaceutical-grade salt in the United States and Canada in violation of Section 7 of the Clayton Act, 15 U.S.C. 18.

ii. Round-Can Table Salt in the United States

As described in the Complaint, Morton and US Salt are two of the largest table salt suppliers in the United States and are two of only three suppliers of round-can table salt in the United States. Morton is the largest supplier of branded round-can table salt in the United States. US Salt is the largest supplier of private-label roundcan table salt—which is made by US Salt but sold under the brands of retailers and other third-parties—in the United States. US Salt is also the second-largest supplier of branded round-can table salt, with around six percent of sales.

The Complaint alleges that, today, US Salt's private-label and branded round-can table salt products compete directly with Morton's branded round-can table salt. Together, the combined firm would control at least 90% of the round-can table salt market in the United States.

The Complaint further alleges that the combination of Morton and US Salt would eliminate the head-to-head competition between Morton and US Salt and leave customers in the United States with only two alternatives for round-can table salt in the United States. Post-acquisition, the combined firm likely would have the incentive and ability to increase prices and offer less favorable contractual terms.

The Complaint also alleges that Morton and US Salt compete for sales of round-can table salt on the basis of quality, price, and contractual terms such as delivery times. This competition has resulted in higher quality, lower prices, and more reliable delivery. The combination of Morton and US Salt would eliminate this competition and its future benefits to customers, including grocery chains, big box stores, and discount stores.

As alleged in the Complaint, the proposed acquisition, therefore, likely would substantially lessen competition in the production of round-can table salt in the United States in violation of Section 7 of the Clayton Act, 15 U.S.C. 18.

iii. Bulk Evaporated Salt in the Northeastern United States

As described in the Complaint, three bulk evaporated salt suppliers—Morton, US Salt, and one additional competitor, each with production facilities in upstate New York—compete for bulk evaporated salt customers in the northeastern United States. The combination of Morton and US Salt would eliminate the head-to-head competition between the parties and result in only two remaining competitors in the region.

The Complaint alleges that bulk evaporated salt customers in the northeastern United States, including food processors and chemical manufacturers, have been able to secure lower prices and improved quality and service—such as more reliable delivery—by threatening to switch between Morton and US Salt. The elimination of this head-to-head competition would allow a combined Morton and US Salt to exercise market power to unilaterally increase prices and reduce the quality and service for bulk evaporated salt customers in the northeastern United States.

As alleged in the Complaint, the proposed acquisition, therefore, likely would substantially lessen competition in the production of bulk evaporated salt in the northeastern United States in violation of Section 7 of the Clayton Act, 15 U.S.C. 18.

E. Difficulty of Entry

 i. Difficulty of Entry Into Pharmaceutical-Grade Salt in the United States and Canada

As alleged in the Complaint, entry of new competitors into pharmaceuticalgrade salt in the United States would be difficult and time-consuming and is unlikely to prevent the harm to competition that is likely to result if the proposed transaction is consummated.

The Complaint alleges that potential pharmaceutical-grade salt entrant would need to acquire suitable land that includes a salt deposit of sufficient purity, obtain the permits necessary to construct an evaporation and processing facility, possess or obtain appropriate financing for a significant capital expenditure, and then design, construct, and qualify the facility. This process would likely take several years, at a minimum. No new evaporated salt facility has been constructed in the United States in over 20 years.

The Complaint alleges that, even if an entrant were able to construct an evaporated salt production facility, before selling a single grain of pharmaceutical-grade salt, it would need to install and test additional equipment needed to meet the exacting purity requirements for pharmaceuticalgrade salt. Reputational barriers make entry even more difficult, as customers would be reluctant to switch to an unproven supplier that could not guarantee access to high-quality pharmaceutical-grade salt. Thus, as alleged in the Complaint, entry would not be timely, likely, or sufficient to mitigate the anticompetitive effects from SCIH's proposed acquisition of Morton.

ii. Difficulty of Entry Into Round-Can Table Salt in the United States

As alleged in the Complaint, entry of new competitors into round-can table salt in the United States would be difficult and time-consuming and is unlikely to prevent the anticompetitive effects that are likely to result if the proposed transaction is consummated.

The Complaint alleged that, even though table salt has lower purity requirements than pharmaceutical-grade salt, a round-can table salt entrant would still need to take all of the steps to construct a facility that a pharmaceutical-grade salt entrant would, including locating an appropriate salt deposit, and investing significant time and money to build the facility.

The Complaint alleges that, in addition, an entrant in round-can table salt would have to secure a round-can packaging line. The packaging process for round-can table salt, created decades ago, is based on technology from that era and has proven to be difficult to replicate in a price-competitive manner. As a result, potential entrants with access to suitable salt deposits have tried, and failed, to develop round-can packaging technology in the last five years.

Thus, as alleged in the Complaint, entry through the construction of a new round-can table salt facility therefore will not be timely, likely, or sufficient to mitigate the anticompetitive effects of SCIH's proposed acquisition of Morton.

iii. Difficulty of Entry Into Bulk Evaporated Salt in the Northeastern United States

As alleged in the Complaint, entry of new competitors into bulk evaporated salt in the northeastern United States would be difficult and time-consuming and is unlikely to prevent the harm to competition that is likely to result if the proposed transaction is consummated.

The Complaint alleges that, just as with pharmaceutical-grade salt or round-can table salt, a new entrant in bulk evaporated salt would need to invest significant time and money to acquire land and construct an evaporated salt processing facility. The Complaint further alleges that entry into bulk evaporated salt in the northeastern United States is particularly difficult because this area has limited salt deposits, which are necessary serve the market.

As alleged in the Complaint, entry through the construction of a new bulk evaporated salt production facility will therefore not be timely, likely, or sufficient to mitigate the anticompetitive effects from SCIH's proposed acquisition of Morton.

III. Explanation of the Proposed Final Judgment

The proposed Final Judgment requires Stone Canyon and its subsidiary, SCIH, to divest their entire evaporated salt business, US Salt, to proceed with their proposed acquisition of Morton. This divestiture allows a third-party buyer to step in as the owner of US Salt and use all of those assets to compete for the production and sale of pharmaceuticalgrade salt in the United States and Canada, round-can table salt in the United States, and bulk evaporated salt in the northeastern United States. The proposed divestiture will thus establish an independent and economically viable competitor that will ensure competition in these markets going forward.

Paragraph IV(A) of the proposed Final Judgment requires Defendants, within

120 calendar days after the entry of the Stipulation and Order by the Court, to divest the Divestiture Assets to an Acquirer acceptable to the United States, in its sole discretion. The assets must be divested in such a way as to satisfy the United States, in its sole discretion, that the Divestiture Assets can and will be used by the Acquirer as part of a viable, ongoing business in the production and sale of evaporated salt products so that the Acquirer can compete effectively in the market for pharmaceutical-grade salt in the United States and Canada, round-can table salt in the United States, and bulk evaporated salt in the northeastern United States. Defendants must use best efforts to accomplish the divestiture of the Divestiture Assets quickly and must take no action to jeopardize the divestiture.

The Divestiture Assets include all of Defendants' rights, titles, and interests in US Salt, including two US Salt facilities (a refinery located in Watkins Glen, NY and a warehouse located in Horseheads, NY).

The proposed Final Judgment contains provisions intended to facilitate efforts by the Acquirer to hire certain employees. Specifically, Paragraph IV(H) of the proposed Final Judgment requires Defendants to provide the Acquirer and the United States with organization charts and information relating to these employees and to make them available for interviews. It also provides that Defendants must not interfere with any efforts by the Acquirer to hire these employees. In addition, for employees who elect employment with the Acquirer, Defendants must waive all non-compete and non-disclosure agreements, vest all unvested pension and other equity rights, provide any pay pro-rata, provide all other compensation and benefits that those employees have fully or partially accrued, and provide all other benefits that those employees otherwise would have been provided had those employees continued employment with Defendants, including any retention bonuses or payments.

Paragraph IV(H) further provides that Defendants may not solicit to hire any employees who elect employment with the Acquirer within a certain time after the divestiture is completed, unless an individual is terminated or laid off by the Acquirer or the Acquirer agrees in writing that Defendants may solicit or hire that individual. The nonsolicitation period runs for 12 months from the date of the divestiture. Paragraph IV(H) does not prohibit Defendants from advertising employment openings using general

solicitations or advertisements and rehiring employees who apply for a position through a general solicitation or advertisement.

Paragraph IV(J) of the proposed Final Judgment will facilitate the transfer of customers and other contractual relationships from Defendants to the Acquirer. Defendants must transfer all contracts, agreements, and relationships to the Acquirer and must use best efforts to assign, subcontract, or otherwise transfer contracts or agreements that require the consent of another party before assignment, subcontracting, or other transfer.

The proposed Final Judgment contains provisions to ensure that the Acquirer will be able to operate US Salt and serve customers immediately upon completion of the divestiture. For example, Paragraph IV(L) of the proposed Final Judgment requires Defendants, at the Acquirer's option, to enter into a transition services agreement for back office, human resource, and information technology services and support for US Salt for a period of up to 12 months. The Acquirer may terminate the transition services agreement, or any portion of it, without cost or penalty at any time upon 30 days' written notice. Paragraph IV(L) further provides that the United States, in its sole discretion, may approve one or more extensions of the transition services agreement for a total of up to an additional six months and that any amendments to or modifications of any provisions of a transition services agreement between Defendants and Acquirer are subject to approval by the United States, in its sole discretion. Paragraph IV(L) also provides that employees of Defendants tasked with providing any transition services must not share any competitively sensitive information of the Acquirer with any other employee of Defendants.

Paragraph IV(K) requires Defendants to use best efforts to assist the Acquirer to obtain all necessary licenses, registrations, and permits to operate US Salt. Defendants must provide Acquirer with the benefit of Defendants' licenses, registrations, and permits until Acquirer obtains the necessary licenses, registrations, and permits,

Certain executives and employees of Stone Canyon and/or SCIH, who will remain with Stone Canyon and/or SCIH after the divestiture, have had access to competitively sensitive information about US Salt's business operations. In order to prevent Stone Canyon and SCIH from using that information, Paragraph XI(A) requires Stone Canyon and SCIH to implement a firewall. Specifically, Stone Canyon and SCIH

must implement and maintain reasonable procedures to prevent the sharing of competitively sensitive information relating to US Salt with Defendants' personnel with responsibilities relating to Morton's production or sale of evaporated salt products. Such a firewall will prevent competitively sensitive information about US Salt—to which Stone Canyon will have had access prior to the divestiture—from being used to influence business decisions relating to Morton's production or sale of evaporated salt products or otherwise used to subvert competition. The implementation of these procedures for a two-year period will ensure that the information cannot be used while it is still competitively sensitive. After two vears, any information will be sufficiently out of date to no longer pose a risk and the firewall can be eliminated. Under Paragraph XI(B), Stone Canyon and SCIH must, within 30 days of the entry of the Stipulation and Order, submit a document setting forth in detail the procedures Defendants have implemented to effect compliance with Section XI. The United States will determine, in its sole discretion, whether to approve or reject Stone Canyon and SCIH's proposed compliance plan.

If Defendants do not accomplish the divestiture within the period prescribed in Paragraph IV(A) of the proposed Final Judgment, Section V of the proposed Final Judgment provides that the Court will appoint a divestiture trustee selected by the United States to effect the divestiture. If a divestiture trustee is appointed, the proposed Final Judgment provides that Defendants must pay all costs and expenses of the trustee. The divestiture trustee's compensation must be structured so as to provide an incentive for the trustee based on the price and terms obtained and the speed with which the divestiture is accomplished. After the divestiture trustee's appointment becomes effective, the trustee must provide monthly reports to the United States setting forth his or her efforts to accomplish the divestiture. If the divestiture has not been accomplished within six months of the divestiture trustee's appointment, the United States may make recommendations to the Court, which will enter such orders as appropriate, in order to carry out the purpose of the proposed Final Judgment, including by extending the trust or the term of the divestiture trustee's appointment by a period requested by the United States.

The proposed Final Judgment also contains provisions designed to promote

compliance with and make enforcement of the Final Judgment as effective as possible. Paragraph XIV(A) provides that the United States retains and reserves all rights to enforce the Final Judgment, including the right to seek an order of contempt from the Court. Under the terms of this paragraph, Defendants have agreed that in any civil contempt action, any motion to show cause, or any similar action brought by the United States regarding an alleged violation of the Final Judgment, the United States may establish the violation and the appropriateness of any remedy by a preponderance of the evidence and that Defendants have waived any argument that a different standard of proof should apply. This provision aligns the standard for compliance with the Final Judgment with the standard of proof that applies to the underlying offense that the Final Judgment addresses.

Paragraph XIV(B) provides additional clarification regarding the interpretation of the provisions of the proposed Final Judgment. The proposed Final Judgment is intended to remedy the loss of competition the United States alleges would otherwise be harmed by the transaction. Defendants agree that they will abide by the proposed Final Judgment and that they may be held in contempt of the Court for failing to comply with any provision of the proposed Final Judgment that is stated specifically and in reasonable detail, as interpreted in light of this

procompetitive purpose.
Paragraph XIV(C) provides that if the Court finds in an enforcement proceeding that a Defendant has violated the Final Judgment, the United States may apply to the Court for a onetime extension of the Final Judgment, together with such other relief as may be appropriate. In addition, to compensate American taxpayers for any costs associated with investigating and enforcing violations of the Final Judgment, Paragraph XIV(C) provides that, in any successful effort by the United States to enforce the Final Judgment against a Defendant, whether litigated or resolved before litigation, the Defendant must reimburse the United States for attorneys' fees, experts' fees, and other costs incurred in connection with any effort to enforce the Final Judgment, including the investigation of the potential violation.

Paragraph XIV(D) states that the United States may file an action against a Defendant for violating the Final Judgment for up to four years after the Final Judgment has expired or been terminated. This provision is meant to address circumstances such as when evidence that a violation of the Final

Judgment occurred during the term of the Final Judgment is not discovered until after the Final Judgment has expired or been terminated or when there is not sufficient time for the United States to complete an investigation of an alleged violation until after the Final Judgment has expired or been terminated. This provision, therefore, makes clear that, for four years after the Final Judgment has expired or been terminated, the United States may still challenge a violation that occurred during the term of the Final Judgment.

Finally, Section XV of the proposed Final Judgment provides that the Final Judgment will expire 10 years from the date of its entry, except that after five years from the date of its entry, the Final Judgment may be terminated upon notice by the United States to the Court and Defendants that the divestiture has been completed and that continuation of the Final Judgment is no longer necessary or in the public interest.

IV. Remedies Available to Potential Private Plaintiffs

Section 4 of the Clayton Act, 15 U.S.C. 15, provides that any person who has been injured as a result of conduct prohibited by the antitrust laws may bring suit in federal court to recover three times the damages the person has suffered, as well as costs and reasonable attorneys' fees. Entry of the proposed Final Judgment neither impairs nor assists the bringing of any private antitrust damage action. Under the provisions of Section 5(a) of the Clayton Act, 15 U.S.C. 16(a), the proposed Final Judgment has no prima facie effect in any subsequent private lawsuit that may be brought against Defendants.

V. Procedures Available for Modification of the Proposed Final Judgment

The United States and Defendants have stipulated that the proposed Final Judgment may be entered by the Court after compliance with the provisions of the APPA, provided that the United States has not withdrawn its consent. The APPA conditions entry upon the Court's determination that the proposed Final Judgment is in the public interest.

The APPA provides a period of at least 60 days preceding the effective date of the proposed Final Judgment within which any person may submit to the United States written comments regarding the proposed Final Judgment. Any person who wishes to comment should do so within 60 days of the date of publication of this Competitive Impact Statement in the **Federal Register**, or the last date of publication

in a newspaper of the summary of this Competitive Impact Statement, whichever is later. All comments received during this period will be considered by the U.S. Department of Justice, which remains free to withdraw its consent to the proposed Final Judgment at any time before the Court's entry of the Final Judgment. The comments and the response of the United States will be filed with the Court. In addition, the comments and the United States' responses will be published in the Federal Register unless the Court agrees that the United States instead may publish them on the U.S. Department of Justice, Antitrust Division's internet website.

Written comments should be submitted in English to: Katrina Rouse, Chief, Defense, Industrials, and Aerospace Section, Antitrust Division, U.S. Department of Justice, 450 Fifth Street NW, Suite 8700, Washington, DC 20530.

The proposed Final Judgment provides that the Court retains jurisdiction over this action, and the parties may apply to the Court for any order necessary or appropriate for the modification, interpretation, or enforcement of the Final Judgment.

VI. Alternatives to the Proposed Final Judgment

As an alternative to the proposed Final Judgment, the United States considered a full trial on the merits against Defendants. The United States could have continued the litigation and sought preliminary and permanent injunctions against Stone Canyon and SCIH's acquisition of Morton. The United States is satisfied, however, that the relief required by the proposed Final Judgment will remedy the anticompetitive effects alleged in the Complaint, preserving competition for the production and sale of evaporated salt products in the markets alleged in the Complaint: Pharmaceutical-grade salt in the United States and Canada, round-can table salt in the United States, and bulk evaporated salt in the northeastern United States. Thus, the proposed Final Judgment achieves all or substantially all of the relief the United States would have obtained through litigation but avoids the time, expense, and uncertainty of a full trial on the merits.

VII. Standard of Review Under the APPA for the Proposed Final Judgment

Under the Clayton Act and APPA, proposed Final Judgments or "consent decrees" in antitrust cases brought by the United States are subject to a 60-day comment period, after which the Court

shall determine whether entry of the proposed Final Judgment "is in the public interest." 15 U.S.C. 16(e)(1). In making that determination, the Court, in accordance with the statute as amended in 2004, is required to consider:

(A) The competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration of relief sought, anticipated effects of alternative remedies actually considered, whether its terms are ambiguous, and any other competitive considerations bearing upon the adequacy of such judgment that the court deems necessary to a determination of whether the consent judgment is in the public interest; and

(B) the impact of entry of such judgment upon competition in the relevant market or markets, upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. 16(e)(1)(A) & (B). In considering these statutory factors, the Court's inquiry is necessarily a limited one as the government is entitled to "broad discretion to settle with the defendant within the reaches of the public interest." United States v. Microsoft Corp., 56 F.3d 1448, 1461 (D.C. Cir. 1995); United States v. U.S. Airways Grp., Inc., 38 F. Supp. 3d 69, 75 (D.D.C. 2014) (explaining that the ''court's inquiry is limited'' in Tunney Act settlements); United States v. InBev N.V./S.A., No. 08-1965 (JR), 2009 U.S. Dist. LEXIS 84787, at *3 (D.D.C. Aug. 11, 2009) (noting that a court's review of a proposed Final Judgment is limited and only inquires "into whether the government's determination that the proposed remedies will cure the antitrust violations alleged in the complaint was reasonable, and whether the mechanism to enforce the final judgment are clear and manageable").

As the U.S. Court of Appeals for the District of Columbia Circuit has held, under the APPA a court considers, among other things, the relationship between the remedy secured and the specific allegations in the government's complaint, whether the proposed Final Judgment is sufficiently clear, whether its enforcement mechanisms are sufficient, and whether it may positively harm third parties. See Microsoft, 56 F.3d at 1458-62. With respect to the adequacy of the relief secured by the proposed Final Judgment, a court may not "make de novo determination of facts and issues." United States v. W. Elec. Co., 993 F.2d 1572, 1577 (D.C. Cir. 1993) (quotation marks omitted); see also Microsoft, 56 F.3d at 1460-62; United States v. Alcoa, Inc., 152 F.

Supp. 2d 37, 40 (D.D.C. 2001); United States v. Enova Corp., 107 F. Supp. 2d 10, 16 (D.D.C. 2000); InBev, 2009 U.S. Dist. LEXIS 84787, at *3. Instead, "[t]he balancing of competing social and political interests affected by a proposed antitrust consent decree must be left, in the first instance, to the discretion of the Attorney General." W. Elec. Co., 993 F.2d at 1577 (quotation marks omitted). "The court should bear in mind the flexibility of the public interest inquiry: the court's function is not to determine whether the resulting array of rights and liabilities is one that will best serve society, but only to confirm that the resulting settlement is within the reaches of the public interest.' Microsoft, 56 F.3d at 1460 (quotation marks omitted); see also United States v. Deutsche Telekom AG, No. 19-2232 (TJK), 2020 WL 1873555, at *7 (D.D.C. Apr. 14, 2020). More demanding requirements would "have enormous practical consequences for the government's ability to negotiate future settlements," contrary to congressional intent. Microsoft, 56 F.3d at 1456. "The Tunney Act was not intended to create a disincentive to the use of the consent decree." Id.

The United States' predictions about the efficacy of the remedy are to be afforded deference by the Court. See, e.g., Microsoft, 56 F.3d at 1461 (recognizing courts should give "due respect to the Justice Department's . . view of the nature of its case"); United States v. Iron Mountain, Inc., 217 F. Supp. 3d 146, 152-53 (D.D.C. 2016) ("In evaluating objections to settlement agreements under the Tunney Act, a court must be mindful that [t]he government need not prove that the settlements will perfectly remedy the alleged antitrust harms[;] it need only provide a factual basis for concluding that the settlements are reasonably adequate remedies for the alleged harms." (internal citations omitted)); United States v. Republic Servs., Inc., 723 F. Supp. 2d 157, 160 (D.D.C. 2010) (noting "the deferential review to which the government's proposed remedy is accorded"); United States v. Archer-Daniels-Midland Co., 272 F. Supp. 2d 1, 6 (D.D.C. 2003) ("A district court must accord due respect to the government's prediction as to the effect of proposed remedies, its perception of the market structure, and its view of the nature of the case."). The ultimate question is whether "the remedies [obtained by the Final Judgment are so inconsonant with the allegations charged as to fall outside of the 'reaches of the public interest.'" Microsoft, 56 F.3d at 1461 (quoting W. Elec. Co., 900 F.2d at 309).

Moreover, the Court's role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its complaint, and does not authorize the Court to "construct [its] own hypothetical case and then evaluate the decree against that case." Microsoft, 56 F.3d at 1459; see also U.S. Airways, 38 F. Supp. 3d at 75 (noting that the court must simply determine whether there is a factual foundation for the government's decisions such that its conclusions regarding the proposed settlements are reasonable); InBev, 2009 U.S. Dist. LEXIS 84787, at *20 ("[T]he 'public interest' is not to be measured by comparing the violations alleged in the complaint against those the court believes could have, or even should have, been alleged"). Because the "court's authority to review the decree depends entirely on the government's exercising its prosecutorial discretion by bringing a case in the first place," it follows that "the court is only authorized to review the decree itself," and not to "effectively redraft the complaint" to inquire into other matters that the United States did not pursue. Microsoft, 56 F.3d at 1459-60.

In its 2004 amendments to the APPA, Congress made clear its intent to preserve the practical benefits of using judgments proposed by the United States in antitrust enforcement, Public Law 108-237 § 221, and added the unambiguous instruction that "[n]othing in this section shall be construed to require the court to conduct an evidentiary hearing or to require the court to permit anyone to intervene." 15 U.S.C. 16(e)(2); see also U.S. Airways, 38 F. Supp. 3d at 76 (indicating that a court is not required to hold an evidentiary hearing or to permit intervenors as part of its review under the Tunney Act). This language explicitly wrote into the statute what Congress intended when it first enacted the Tunney Act in 1974. As Senator Tunney explained: "[t]he court is nowhere compelled to go to trial or to engage in extended proceedings which might have the effect of vitiating the benefits of prompt and less costly settlement through the consent decree process." 119 Cong. Rec. 24,598 (1973) (statement of Sen. Tunney). "A court can make its public interest determination based on the competitive impact statement and response to public comments alone." U.S. Airways, 38 F. Supp. 3d at 76 (citing Enova Corp., 107 F. Supp. 2d at 17).

VIII. Determinative Documents

There are no determinative materials or documents within the meaning of the

APPA that were considered by the United States in formulating the proposed Final Judgment.

Dated: April 29, 2021 Respectfully submitted,

FOR PLAINTIFF UNITED STATES OF AMERICA:

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[FR Doc. 2021–09504 Filed 5–4–21; 8:45 am]

BILLING CODE 4410-11-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration [Docket No. 19–32]

Melanie Baker, N.P.; Decision and Order

On June 21, 2019, a former Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause and Immediate Suspension of Registration (hereinafter collectively, OSC) to Melanie Baker, N.P. (hereinafter, Respondent). Administrative Law Judge Exhibit (hereinafter, ALJX) 1 (Order to Show Cause), at 1. The OSC informed Respondent of the immediate suspension of her Certificate of Registration No. MV3148257 (hereinafter, registration) pursuant to 21 U.S.C. 824(d), because her continued registration constituted an imminent danger to the public health and safety. Id. The OSC also proposed the revocation of Respondent's registration and denial of any pending applications for renewal or modification pursuant to 21 U.S.C. 824(a)(4), "because [her] continued registration is inconsistent with the public interest. . . ." Id. (citing 21 U.S.C. 823(f)).

I. Procedural History

The OSC alleged that "[f]rom at least February 2017 to May 2019, [Respondent] issued numerous prescriptions for Schedule IIN through Schedule IV controlled substances to five patients in violation of federal and state law." OSC, at 3. The OSC alleged violations of 21 CFR 1306.04(a), Louisiana Statute Annotated § 40:978, and Louisiana Administrative Code tit. 46, Pt. LIII, § 2745(B)(1), and Pt. XLVII,

§ 4513(D). Id. at 2. The OSC stated that the prescriptions Respondent issued to the five patients in this case "were issued outside the usual course of professional practice and not for a legitimate medical purpose." Id. at 3. The OSC included the expert's opinion that Respondent "regularly prescribed highly addictive and intoxicating combinations of controlled substances to [her] patients." Id. The OSC also alleged that Respondent "consistently failed to: (1) Perform adequate psychiatric and cognitive evaluations; (2) make appropriate diagnoses based on sufficient clinical evidence, and document [those] diagnoses in [her] medical records; (3) document a legitimate medical purpose for the controlled substances that [Respondent] prescribed; (4) monitor [her] patients' medication compliance; and (5) respond to red flags of drug abuse and diversion." Id. The OSC then went on to outline specific allegations of deficiencies for each of the five patients at issue in this case. Id. at 3-10.

The OSC notified Respondent of the right to either request a hearing on the allegations or submit a written statement in lieu of exercising the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. Id. at 11

(citing 21 CFR 1301.43).

By letter dated July 22, 2019, Respondent timely requested a hearing and proceeded pro se.1 ALJX 2 (Request for Hearing), at 1; Tr. 11. The matter was placed on the docket of the Office of Administrative Law Judges and was assigned to Administrative Law Judge Mark M. Dowd (hereinafter, ALJ). On July 23, 2019, the ALJ established a schedule for the filing of prehearing statements. ALJX 3 (Order for Prehearing Statements), at 1–2. The Government filed its prehearing statement on July 30, 2019. ALJX 4 (Government's Prehearing Statement), at 1. Respondent filed her Prehearing Statement on August 6, 2019. See ALJX 5 (Respondent's Prehearing Statement), at 1. On August 8, 2019, the ALJ issued a Prehearing Ruling that, among other things, set out twenty-five agreed upon stipulations and established schedules for the filing of additional prehearing documents and for the hearing. ALJX 6 (Prehearing Ruling). Respondent filed a supplemental prehearing statement on August 13, 2019. ALJX 7 (Respondent's Supplemental Prehearing).

The hearing in this matter took place in New Orleans, Louisiana, and spanned two days. See generally Transcript of

Proceedings in the Matter of Melanie Baker, N.P. (hereinafter, Tr.). Both parties filed posthearing briefs. See Government's Proposed Findings of Fact and Conclusions of Law (hereinafter, Govt Posthearing), and Respondent's Posthearing Brief (hereinafter, Resp Posthearing). On November 8, 2019, the ALJ issued his Recommended Rulings, Findings of Fact, Conclusions of Law and Decision (hereinafter, RD). According to the ALJ, neither party filed exceptions to the RD and the deadline for doing so has passed. See Transmittal Letter from the ALJ, dated December 4, 2019. I have reviewed and agree with the procedural rulings of the ALJ during the administration of the hearing.²

Having considered the record in its entirety, I find that Respondent issued controlled substance prescriptions to five individuals beneath the applicable standard of care and outside of the usual course of the professional practice in Louisiana in violation of federal law, and I find that Respondent committed violations of state law. I agree with the ALI that revocation is the appropriate sanction. RD, at 120. I make the following findings of fact.

II. Findings of Fact

A. DEA Registration

The parties stipulated that Respondent is registered with DEA as a practitioner able to handle controlled substances in schedules IIN through V under DEA Certificate of Registration No. MV3148257, at 4480 General DeGaulle Drive, Suite 107, Executive Square, New Orleans, Louisiana 70131. RD, at 44; ALJX 6, Appendix A, at 1; and ALJX 4, Attachment A (Controlled Substance Registration Certificate). This registration expired on July 31, 2020.3 See ALJX 4, Attachment A.

B. Government's Case

The Government's documentary evidence consisted primarily of patient files and prescription records for five

individuals prescribed controlled substances by Respondent between February 2017 and May 2019. See Government Exhibits (hereinafter, GX) 1-10. The Government's evidence also contained a copy of the Louisiana Prescription Drug Monitoring Results for Respondent from May 23, 2017, to May 23, 2019. See GX 11 (Louisiana Prescription Drug Monitoring Results). Finally, the Government included the Curriculum Vitae for its expert witness Dr. Chambers. See GX 12 (Curriculum Vitae of Dr. Chambers). The Government called two witnesses to testify at the hearing: A DEA Diversion Investigator (hereinafter, DI) and the Government's expert Dr. Chambers.

DI testified regarding her professional background and training, Tr. 27-28, and about her investigation-related actions in this matter.4 Tr. 28-48; RD, at 17-18. She testified that in June 2018, DEA discovered questionable prescriptions issued by Respondent while investigating two pharmacies located in New Orleans. Tr. 28. DEA identified several "red flags" in the prescriptions issued by Respondent, including "patients that were living at the same address, patients that were coming from long distances, patients that were being prescribed high strengths of amphetamines and other dangerous combinations." Id. In July 2018, DI queried the Louisiana Prescription Monitoring Program for Respondent's prescriptions and discovered the same red flags. Id. at 29. DI also testified that she received statistics from the Louisiana Board of Pharmacy indicating that Respondent was the number one prescriber of controlled substance dosage units among mid-level practitioners in the state.⁵ *Id.* at 29–30.

DI further testified that DEA visited pharmacies where prescriptions issued by Respondent were filled to obtain copies of the prescriptions. Id. at 32. DEA also served an administrative subpoena for thirty of Respondent's patient files, which were received in August 2018. *Id.* at 30–31. Finally, DI testified that DEA sent eleven of the patient files to an expert witness, Dr. Andrew Chambers, to review. Id. at 31, 73-74. Having read and analyzed all of the record evidence, I agree with the ALJ that DI's testimony was "credible and should be afforded considerable weight." RD, at 77.

¹I find that the Government's service of the OSC was adequate.

² My agreement includes the ALJ's decision to proceed with the scheduled hearing when Respondent's identified witnesses were unavailable. RD, at 14-15. Respondent identified additional witnesses in her Prehearing Statement, but they were not present to testify at the hearing. RD, at 14; Tr. 11–14. Respondent said she was "prepared to proceed" to the hearing without the witnesses because one of the witnesses could not "speak to the reasons [Respondent] made clinical decisions," and Respondent was "unable to reach" the other witnesses. Tr. 13. I agree with the ALI's decision to proceed with the hearing. See RD, at 14; Tr. 13-15.

 $^{^{3}}$ The fact that a respondent allows her registration to expire during the pendency of an OSC does not impact my jurisdiction or prerogative under the Controlled Substances Act (hereinafter, CSA) to adjudicate the OSC to finality. Jeffrey D. Olsen, M.D., 84 FR 68,474 (2019).

⁴ DI's testimony explained that that Respondent used to go by the name Melanie Varnado. Tr. 37. I find that Melanie Baker and Melanie Varnado are used interchangeably in the record to describe the same person.

⁵ DI defined a "mid-level practitioner" as "nurse practitioners, physician assistants, [prescribers] that are not actual medical doctors." Id.

Dr. Chambers testified regarding his professional and educational background. Tr. 49-60; RD, at 56-57, 79-80. Dr. Chambers testified that he was a licensed physician and he was a board-certified addiction psychiatrist. GX 12, at 8; Tr. 49-50; RD, at 56. He testified that he maintained a clinical practice, which he had operated since the year 2000, and that approximately 50% of his work was clinical. Tr. 52; RD, at 56, 80. He further testified that he was a teacher, and from his resume it appears that he teaches at various institutions including as a tenured Associate Professor of Psychiatry and director of the addiction psychiatry specialty at the Indiana University School of Medicine. Tr. 53-54; GX 12, at 1; RD, at 56. Dr. Chambers testified that he has had the opportunity to teach nurses and to supervise nurse practitioners including providing oversight of their prescribing decisions. Tr. 53-54; RD, at 56. I agree with the ALJ's finding that "Dr. Chambers possesse[d] an impressive amount of study, experience, and expertise in th[e] relatively narrow field of addiction psychiatry." RD, at 82.

Although Dr. Chambers is licensed in Indiana, he testified that he was familiar with the standard of care for prescribing controlled substances in Louisiana and had reviewed relevant sections of the Louisiana code. Tr. 60; RD, at 80. I agree with the ALJ that Dr. Chambers "demonstrated a formidable knowledge relating to the Louisiana standard of care involving the prescribing of controlled substances, and the requisite professional practices." RD, at 82. Ultimately, Dr. Chambers "was offered and qualified as an expert in the field of addiction psychiatry and on the standard of care for prescribing controlled substances for psychiatric care in Louisiana." Id. at 79-80. I find that Dr. Chambers was properly qualified as an expert witness.6

The ALJ conducted a thorough assessment of Dr. Chambers' credibility, with which I agree. *Id.* at 79–82. I further agree with the ALJ's finding that "Dr. Chambers provided consistent, reliable and fully developed testimony in this matter." *Id.* at 82. I additionally note that Respondent presented no expert testimony that conflicted with Dr. Chamber's opinions. *Id.*; see also, infra n.7.

C. Respondent's Case

The Respondent's documentary evidence consisted of Respondent's Curriculum Vitae, Initial Psychiatric **Evaluation and Medication Management** forms implemented in Respondent's practice, starting in October 2018, following a quality review from an insurance company, and the practice's discharge policy. Respondent's Exhibits (hereinafter, RX), 1-4; Tr. 325-29. Respondent also provided eight scholarly articles in defense of her treatment practices.7 RX 5; RD, at 81. Respondent's testimony on her own behalf was limited to offering and authenticating her five exhibits.8 Tr. 324-30. The ALJ found, and I agree, that Respondent's limited testimony was "internally consistent and consistent with the remaining record." RD, at 77. Respondent's testimony on this limited scope was also uncontested. Id.

Despite being instructed during the hearing that she could not present her case for the first time in closing, Respondent attempted to introduce a number of evidentiary "facts" in her posthearing brief 9 that she presumably believed to be mitigating or to explain the rationale behind her prescribing. RD, at 77; Tr. 341; Resp Posthearing. Some of these "facts" had little-to-no relevance to this case,10 and other 'facts'' were blanket statements that Respondent's actions were correct and/ or were supported by scientific evidence. Resp Posthearing, at 5-8. None of these supposed "facts" were given under oath and none were subject to cross-examination; therefore, I agree with the ALJ that they were "not part of the evidentiary record." RD, at 77. Even if Respondent's "facts" had been appropriately submitted through testimonial evidence, they would likely not have outweighed the credible testimony of the Government's expert.¹¹ Moreover, many of these "facts" could not be given significant weight because they were not documented in the patient files, as the Government's expert credibly testified was required to satisfy the standard of care. See infra II.E.

D. Respondent's Practice

As there was no substantive testimony from Respondent or anyone affiliated with Respondent's practice, R.V. Psychiatric Services, L.L.C., it was difficult to determine the structure of the practice from the evidence at hand. It is clear, however, that all of the medical records prior to the year 2013 appear to be created by R.V.¹² Beginning in 2013 for K.W., 2014 for M.G., 2015 for F.P., and 2016 for M.H., 13 both R.V. and Respondent appear to be seeing and/or prescribing for the individuals identified in this case. See GX 3; GX 5; GX 7; GX 9; Tr. 116. At all times relevant to this case, namely February 2017 to May 2019, Respondent appears to be the only provider from R.V. Psychiatric Services, L.L.C., prescribing controlled substances to the five individuals identified in this case.14

E. The Standard of Care in the State of Louisiana

In accordance with Dr. Chambers' credible and uncontroverted testimony and the record as a whole, I find that the standard of care for prescribing controlled substances in Louisiana requires the following: (1) An appropriate assessment and evaluation to make a diagnosis; (2) sound rationale for prescribing controlled substances related to that diagnosis; (3) ongoing monitoring to ensure that the desired outcome is achieved and undesirable side effects are not experienced; and (4) appropriate documentation. Tr. 69–70,

⁶ Dr. Chambers has previously been qualified as an expert in DEA proceedings and his testimony was found credible. See, e.g., Bernard Wilberforce Shelton, M.D., 83 FR 14,028, 14,036 (2018); Lon F. Alexander, 82 FR 49,704 (2017).

⁷ The ALJ found, and I agree, that "Dr. Chambers thoroughly and credibly discounted the articles' prominence, repute, and application to the issues before us." RD, at 81; see also Tr. 280–307. Ultimately the ALJ concluded, and I agree, that "the articles provided no defense to the Respondent's charged practices" and that "Dr. Chambers' live testimony and opinions greatly outweigh the journal articles submitted by the Respondent." RD, at 81 and n.21.

⁸ See supra n.2.

⁹ Many of these same "facts" were also referenced in Respondent's opening statement, prehearing brief, and/or cross-examination questions. *See* RD, at 77; ALJX 5; ALJX 7; Tr. 20–24, 243–79.

¹⁰ For example, Respondent included statements that all of the prescription medications at issue were approved by insurance providers. *See, e.g.,* Tr. 24.

¹¹Respondent attempted to challenge Dr. Chamber's expertise by providing examples of what she believes reflects Dr. Chambers' unfamiliarity with the manner in which prescriptions must be

written in Louisiana. Resp Posthearing, at 3 (arguing that Dr. Chambers "was unfamiliar with the state board of pharmacy requirement to write certain prescriptions a certain way"). The standard of care violations alleged in this case are related to Respondent's issuance of prescriptions without a legitimate medical purpose; the manner in which the prescriptions were written is not at issue in this case. *Infra* II.E.

¹² In making this decision, I am not attributing to Respondent any actions or inactions of R.V. Respondent was judged herein solely on her actions or inactions during the period of time at issue in this case. Where I have discussed actions or inactions by R.V. or by Respondent outside of the period of time at issue in this case, it is only to provide context to understand the allegations against Respondent. See also RD, at 92 n. 24.

¹³F.A. does not appear to have been seen by R.V. since she began treatment at the practice in 2017. GX 1.

¹⁴ There are some notations in the medical records during the time period at issue in this case that do not appear to be written by either Respondent or R.V.; however, the Respondent ultimately signs and therefor adopts those notations as her own. *See supra* II.E.; Tr. 225–27.

72; RD, at 57–58. Throughout his testimony, Dr. Chambers expanded on the standard of care, explaining in detail what a prescriber must do to satisfy each of these four requirements.

First, Dr. Chambers explained what a prescriber must do to satisfy the standard of care's requirement that there be an appropriate assessment and evaluation to make a diagnosis. To satisfy this requirement, a prescriber should conduct "a clinical interview that would cover psychiatric history, addiction history, social history, and demographics, in order to develop a hypothesis as to the correct diagnosis." Tr. 71. To make a psychiatric diagnosis, "the standard of care is that the physician would evaluate for signs and symptoms that are consistent with that diagnosis and actually write them in the chart." Id. at 213. Further, "[i]t is actually not sufficient to simply state the diagnosis and not have evidence to support that diagnosis." Id. Dr. Chambers explained that a prescriber should also do objective measures testing because "the nature of addictive disease is such that the self-report is often not as reliable as you might find in other areas of health care. . . ." Id. at 71. Dr. Chambers testified that urine drug screening and evaluation of the prescription drug monitoring program database are two ways to conduct an objective assessment. Id. at 71–72

Dr. Chambers also explained that a provider must conduct an appropriate assessment or evaluation to inform the diagnosis even when that provider is sharing in care or taking over care of a patient from a prior prescriber. Id. at 116-17. "There is a responsibility of the second practitioner to look at the information from the prior prescriber, but to also come to their own conclusion and build a treatment plan that would incorporate [the prior] information but also incorporate their own examination, . . . you owe it to the patient to double-check the prior prescriber." Id. at 117. If a new provider "[does not] make any changes" and" continues to do exactly what [the previous provider] did," then the new provider "own[s] that person's decision." *Id.* at 224–25.

Dr. Chambers' opinion that the standard of care in Louisiana requires an appropriate assessment and evaluation to make a diagnosis is reflected in Louisiana law. La. Admin. Code tit. 46, Pt. XLVII, § 4513(D)(2)(b)(xi) (2019) 15 states that

"no APRN[16] shall prescribe any controlled substance or other drug having addiction-forming or addiction sustaining liability without a good faith prior examination. . . ."

Second, Dr. Chambers explained what constitutes sound rationale for prescribing controlled substances related to a specific diagnosis. Throughout his testimony, he described sound rationale as having a "clear, strong basis." Tr. 194. He explained that the standard of care required that new controlled substance prescriptions be justified in the medical records. Id. at 193. He also explained that "clinical decision-making about controlled substances especially is a multi-variable decision" that has to be made within the 'whole context" of an individual patient. Id. at 111.

Dr. Chambers' opinion that the standard of care in Louisiana requires sound rationale for prescribing controlled substances is further supported by Louisiana law. La. Admin. Code tit. 46, Pt. XLVII, § 4513(D)(2)(b)(xi) states that "no APRN shall prescribe any controlled substance or other drug having addiction-forming or addiction sustaining liability without a good faith . . . medical indication."

Third, Dr. Chambers explained what ongoing monitoring the standard of care required to ensure that the desired outcome of treatment is achieved and that negative side effects are avoided. With regard to monitoring, Dr. Chambers explained that an initial evaluation is comprehensive, and that at each subsequent visit a physician should "continuously [gather] new data to, A, confirm [you are] not running into trouble with your [prescribed medications, but B, are they working, or can you get rid of them, because maybe [the patient got] better." Tr. 118. One "side effect" Dr. Chambers opined that practitioners should look for is diversion. Id. at 246, 272-73. Dr. Chambers testified that he considers "the potential for diversion" to be an "unfortunate side effect," and that diversion is "more common if [a practitioner is] not also monitoring [the

patient] or dosing them correctly." 17 Id. at 246. By "monitoring," Dr. Chambers "mean[s] urine drug screens, [and/or] prescription drug monitoring program database inquir[ies]." Id. at 317. Dr. Chambers also explained that addiction is a negative side effect that a prescriber should monitor for signs of. 18 Id. at 70, 115, 137. Dr. Chambers opined that "[a]ny time you make a diagnosis, or if you have sufficient evidence that a person has addiction, it [is] absolutely a standard of care to drug-test them . . [r]andomly and frequently." Id. at 137. According to Dr. Chambers, a prescriber "cannot rely on a patient with mental illness and addiction [to] self-report . . . [i]t needs confirmation with drugtesting." Id. at 149. Appropriate monitoring also requires investigation and documentation of issues that arise, such as reasons for a missed appointment, potential withdrawal if the patient was without medication, and reports of hospitalization. Id. at 275, 279.

Fourth, Dr. Chambers explained what appropriate documentation was required to be in compliance with the standard of care. He explained that the record must document a comprehensive evaluation including a mental status or psychiatric exam, and the history including the psychiatric history, substance abuse history, and social history. Id. at 72. Appropriate documentation requires the practitioner to "[build] a narrative that describes real people and events," including what the patient is doing that causes concern, in order to establish "that there really is a cognitive problem." *Id.* at 257. The record must also document objective measures testing, such as urine drug screening or inquiries of the prescription drug monitor database. Id. at 72, 257. Moreover, for documentation to be appropriate, anyone who sees a patient must sign their notes in the medical record. Id. at 201-02, 225. A practitioner signing a note written by another practitioner "owns it" despite the ambiguity over "who actually made

[the] decision[s]." Id. at 227.

¹⁵This citation is to La. Admin. Code tit. 46, Pt. XLVII, § 4513 effective February 20, 2018, through September 19, 2019. There is no substantive changes to the portions of § 4513 that are relevant

to this case between the prior version of this law, effective April 2016 to February 19, 2018, and the cited version of the law.

¹⁶ APRN stands for Advance Practice Registered Nurse which means, amongst other things, that the nurse has "acquired advanced clinical knowledge and skills [to prepare her] to provide direct care to patients" including the "assessment, diagnosis, and management of patient problems, which includes the use and prescription of pharmacologic and non-pharmacologic interventions." La. Admin. Code tit. 46, Pt. XLVII, § 4505 (2018) (amended on February 20, 2018, with no substantive changes to the cited text). Respondent is an APRN. RX 1 (Respondent's Curriculum Vitae), at 1.

¹⁷ Dr. Chambers further testified that with regard to diversion of controlled substances, a practitioner has "to really make sure [the dosage is] not too high." Tr. 317.

¹⁸ Dr. Chambers explained that monitoring is especially important in a psychiatric practice because people with several varieties of mental illness present in this case have a higher rate of becoming addicted including addiction to prescribed controlled substances. Tr. 70, 77–78. Dr. Chambers explained "that the circuits in the brain that are impacted by the mental illness cause the individual to have a much more rapid acceleration into the disease process of drug addiction, because the circuits in the brain where mental illness happens and addiction happens are interlinked." *Id.* at 78.

Dr. Chambers also explained that the standard of care requires that a prescriber act on data obtained from urine drug screening or the prescription drug monitoring program: "you [cannot] just gather that and put it in the chart." *Id.* at 73.

Dr. Chambers' opinion that the standard of care in Louisiana requires appropriate documentation is additionally supported by Louisiana law. La. Admin. Code tit. 46, Pt. XLVII, § 4513(D)(4) (2019) states that "[a]n APRN who prescribed a controlled substance shall maintain a complete record of the examination, evaluation and treatment of the patient which must include documentation of the diagnosis and reason for prescribing controlled substances." ¹⁹

F. Patients

1. Facts Relevant to All Patients

During his testimony, Dr. Chambers outlined some of the dangers of prescribing various classes of controlled substances ²⁰ both singularly and collectively. With regard to stimulants

or uppers, Dr. Chambers explained that they are addictive, are susceptible to diversion, and one form of stimulants, amphetamine, can be readily converted to methamphetamines in a home lab. Id. at 78-80. Additionally, Dr. Chambers noted that recently in the United States there was an increase in prescribing amphetamines to adults and an increase in overdoses caused by stimulants. Id. at 81. Prescribing amphetamines to adults to treat ADD, as Dr. Chambers explained, is "controversial and problematic." Id. at 81. According to Dr. Chambers, "[m]ost cases of legitimate ADD and ADHD are diagnosed between [the] age of six and 13, kind of schoolaged children. When you get outside of that age zone, you have to worry about a . . . differential diagnosis, where there could be a whole lot of other things going on, and actually [they are] not ADD." Id. at 88-89.

Regarding sedatives, benzodiazepines or downers, Dr. Chambers described the biggest danger as addiction. Id. at 82. When prescribed chronically, patients "can rapidly develop tolerance and dependence on a benzodiazepine" and "when that tolerance occurs, . . . the brain . . . acquire[s] a form of psychopathology that mimics the problem that the drug was originally intended to treat." *Id.* at 82. Additionally, Dr. Chambers testified that "benzodiazepines are central nervous system depressants, so they suppress cognitive and motor function over time." Id. at 83. Dr. Chambers explained, that in patients with certain mental illnesses these drugs can cause disinhibited behavior, which tends to increase impulsiveness in patients, and they shorten the patients' lifespan. Id. at 84. Additionally, when benzodiazepines are combined with additional downers or other drugs, they become quite dangerous, which can cause an overdose death. Id. at 79, 84-85, 213. Dr. Chambers further testified that the prescribing of benzodiazepines and addictive medications to preteens and teenagers is especially problematic, because in those years, "the brain is especially vulnerable to addiction." Id. at 195; see also id. at 120.

Dr. Chambers testified extensively about the dangers of prescribing both an upper and a downer to the same individual, and stated that "[there is] no legitimate medical indication for that" combination. *Id.* at 132; *see also id.* at 146, 198, 215, 231. Instead, according to Dr. Chambers, the combination of "uppers and downers, has long been understood to be a pattern of illicit substance use." *Id.* at 146. And the combination "can create a bipolar pattern of symptoms in someone who

[does not] even have bipolar, but if they do have bipolar it could make it worse."

Dr. Chambers also provided generally applicable testimony about controlled substance prescribing pitfalls for common mental health diagnoses. Regarding ADD diagnoses, Dr. Chambers explained that "virtually all [of] the major mental illnesses—schizophrenia, bipolar disorder, major depression, PTSD, some of the personality disorders—they all generate cognitive symptoms that look like ADD." Tr. 131. He further explained that in a psychiatric practice, "someone who really [does not] know how to diagnose mental illness could readily diagnose every person that walks in the door with ADD, and if they just follow the FDA guideline, [vou are] now delivering amphetamines to everybody who walks in your door with any mental illness." Id. Similarly, "insomnia [is] built into [a] depression" diagnosis. *Id.* at 209.

2. Prescribing for F.A.

Between February 2018 and February 2019, Respondent issued twenty-three controlled substance prescriptions to F.A. for mixed amphetamine salts. GX 2 (Prescriptions Issued to F.A.); RD, at 88. Dr. Chambers testified that each of these twenty-three prescriptions was issued outside the usual course of professional practice and without a legitimate medical purpose. Tr. 102–03; RD, at 88.

In support of his opinion, Dr. Chambers testified that Respondent did not perform an appropriate assessment to diagnose the three-year-old patient with ADD. Tr. 88-92, 97; RD, at 89. Dr. Chambers explained that "normal children [that young] have behaviors that can look like ADD." Tr. 89. Accordingly, Dr. Chambers explained, to diagnose a three-year-old with ADD, a practitioner must gather "more than one independent source of information." Id. at 90; see also RD, at 89. Put another way, Dr. Chambers explained that the standard of care for this particular patient required "a collection of lines of evidence." Tr. 93; see also RD, at 89. Per Dr. Chambers, the evidence can come from parents, teachers, or even through objective testing in the form of "cognitive batteries." Tr. 91; see also RD, at 89. Dr. Chambers criticized the information Respondent collected to support the diagnosis, which consisted of a report from a day care center and reports from the parents. GX 1 (Patient File for F.A.), at 12; Tr. 90–95. With regard to the day care report, Dr. Chambers criticized that it documented behavior occurring more than a year prior to the diagnosis. Tr. 91. He further explained that preschool

 $^{^{19}}$ The law further clarifies, "[t]he name, dose, strength, quantity of the controlled substance and the date that the controlled substance was prescribed must also be documented in the record." Id

 $^{^{\}rm 20}\,\rm I$ find the following facts related to the controlled substances at issue in this case. (1) The parties stipulated that amphetamine is a Schedule II controlled substance, and that Adderall is a brand name drug containing amphetamine salts. ALJX 7, at 13. According to Dr. Chambers, amphetamines are stimulants, and stimulants are sometimes referred to as uppers. Tr. 81, 132, 264. (2) The parties stipulated that lisdexamfetamine is a Schedule II controlled substance, and that Vyvanse is a brand name drug containing lisdexamfetamine. ALIX 7, at 13, According to Dr. Chambers. lisdexamfetamine is a stimulant that is "very similar" to and "essentially has the same effects" as Adderall. Tr. 186. (3) The parties stipulated that codeine is a Schedule III controlled substance. According to Dr. Chambers, codeine is an opiate and can be found in acetaminophen with codeine. Id. at 205. (4) The parties stipulated that alprazolam is a Schedule IV controlled substance. ALJX 7, at 13. According to Dr. Chambers, alprazolam is a short-acting benzodiazepine and it is marketed under the brand name Xanax. Tr. 151: see also GX 8, at 7–8. According to Dr. Chambers, benzodiazepines, or "benzos" for short, are sedatives and are sometimes referred to as downers. Tr. 206, 264. (5) The parties stipulated that clonazepam is a Schedule IV controlled substance. ALJX 7, at 13. According to Dr. Chambers, clonazepam is a benzodiazepine. Tr. 205. Klonopin is a brand name drug containing clonazepam. Compare GX 9, at 23-24 with GX 9, at 5; GX 10, at 3. (6) The parties stipulated that lorazepam is a Schedule IV controlled substance. ALJX 7, at 13. Lorazepam is marketed under the brand name Ativan. See GX 6, at 1-2. According to Dr. Chambers, Ativan is a benzodiazepine, and is "even more potent and powerful than the Ambien." Tr. 128-29. (7) The parties stipulated that zolpidem is a Schedule IV controlled substance. ALJX 7, at 13. Zolpidem is marketed under the brand name Ambien. See GX 10, at 10. According to Dr. Chambers, Ambien is another benzodiazepine. Tr.

teachers are not likely to require enough "cognitive demand that would elicit a concern [about ADD] in a three-yearold." Id. at 90. With regard to the parents' reports, Dr. Chambers questioned their credibility, because there were other indications in the patient files that the parents themselves could be addicted to or diverting controlled substances.²¹ Id. at 94-95. In forming this opinion, Dr. Chamber's noted that F.A.'s parents were also being treated by Respondent and were prescribed a dangerous and addictive combination of controlled substances.²² Id. at 87, 94-95; RD, at 88.

Dr. Chamber's opinion was further supported by Respondent's failure to provide sound rationale for her prescriptions to F.A. in the patient records. Tr. 91–92; RD, at 89–90. Specifically, Dr. Chambers opined that, "[i]t [was] not at all clear . . . that this child, based on this document, has ADD." Tr. 92. This is because F.A.'s "symptoms describe problems that don't really fit the diagnosis of ADD . . . [they are] either inconsistent or outside the diagnosis of ADD." Id. at 91; see also RD, at 89. In fact, Dr. Chambers testified that based on the documentation, his opinion was that the ADD 23 diagnosis was outside the standard of care. Tr. 97; RD, at 89. Even if ADD had been a proper diagnosis, according to Dr. Chambers, Respondent did not issue the controlled substance prescriptions within the standard of care. Tr. 97-100; RD, at 89–90. This is because, Dr. Chambers opined, there were two other treatment options, namely behavioral therapy and methylphenidate, that should have been tried before issuing a controlled substance prescription for

Adderall.²⁴ Tr. 97–100; RD, at 89–90. Moreover, the 10–30 milligram dosages of Adderall prescribed by Respondent exceeded the 2.5 to 10 milligram dosing range that is recommend for a young child. Tr. 99, 112; RD, at 90. Dr. Chambers ultimately opined that the Adderall prescriptions that Respondent issued to F.A. were "beyond the dose range... for a child of this age and size... [and] [i]n the context of this case, it [was] outside the standard of care." Tr. 103.

Dr. Chambers also noted that Respondent did not appropriately monitor F.A.'s use of the controlled substances she was prescribed. Dr. Chambers explained that you cannot rely on a three-year-old child to accurately report on her compliance with a controlled substance treatment regimen. Tr. 105. Although Dr. Chambers noted that basic vital signs, weight, and height were recorded appropriately, id. at 105, Dr. Chambers' opinion appears to be that, under the circumstances, the standard of care required Respondent to do some form of compliance monitoring and Respondent did none. Tr. 106; RD, at 91. When asked what monitoring was required to satisfy the standard of care, Dr. Chambers testified that "the context of this case is so out of the standard of care for 10 different reasons that, for goodness sakes, do something . . . at the very least, get a urine drug screen." Tr. 106-07. Dr. Chambers testified, "if the parents are using benzos and amphetamines from some source, and there's extreme poverty, and they live really far away, [25] and now the patient's been out of [the Adderall for a month], and [it is] possible they could be selling [the controlled substances],

you might get a urine drug screen on the child, or do pill counts, or something to understand what's going on." ²⁶ *Id.* at 106: *see also id.* at 103.

As final support for his opinion that the alleged prescriptions were issued outside of the standard of care, Dr. Chambers opined that Respondent failed to appropriately document F.A.'s file. Tr. 91-92; RD, at 89. Dr. Chambers testified that the documentation had "distortions and insufficient data streams to inform a diagnosis of ADD." Tr. 91. The documentation included shorthand references suggesting that Respondent analyzed what Dr. Chambers called the DSM-IV criteria. but stated there is "not substantial narrative evidence that any of those criteria were actually well supported." Id. at 92; see also GX 1, at 12; RD, at 89. Dr. Chambers' ultimately opined that there was not a legitimate medical purpose for the prescriptions to F.A. because "[b]ased on what's documented . . . the diagnosis of ADD is not supported at a sufficient level to make the diagnosis." Tr. 103.

I find that, the twenty-three controlled substance prescriptions Respondent issued to F.A. between February 2018 and February 2019, were issued outside of the usual course of professional practice and beneath the applicable standard of care in Louisiana. This is because, based on Dr. Chambers' credible and uncontroverted expert testimony and the record as a whole, Respondent did not obtain sufficient information to diagnose, did not have sound rationale for the controlled substance prescriptions that were issued, did not monitor compliance with the prescription instructions, and failed to appropriately document any of the above in the patient file. See also RD, at 91.

²¹Respondent, likely in an attempt to challenge Dr. Chambers' credibility, argued that Dr. Chambers "offered statements in each of the five patient cases that there was subversive abuse and diversion," and "demonstrated clear suspicion of everyone, including these patients whom he has never met." Resp Posthearing, at 2. I believe Respondent missed Dr. Chambers' point. Dr. Chambers' testimony was not that every patient was abusing or diverting controlled substances, but that every patient should have been monitored to ensure that potential abuse or diversion was not occurring. Tr. 246 (Dr. Chambers testified, "I don't think every patient diverts. I think [there is] a high rate of it, and I think that you have to anticipate it could happen with any patient."); see also id. at 70, 115, 137, 149, 272-73; supra II.E.

²² F.A.'s parents were each prescribed two benzodiazepines and amphetamines by Respondent. Tr. 90, 95; RD, at 88.

²³ Dr. Chambers often referred to the diagnosis as ADD, but there are other references in the record to F.A. being diagnosed with ADHD. *See, e.g.,* Tr. 96–97; GX 1, at 15. It is clear from the testimony and the record as a whole that the acronyms ADD and ADHD are used interchangeably throughout this case.

²⁴ Respondent argued, both with regard specifically to F.A. and generally, that while Dr. Chambers described situations where a noncontrolled substance could have been used in lieu of a controlled substance, the Government failed to establish that the non-controlled substance had to be used. Resp Posthearing, at 4. The Government does not have to establish that Respondent should have prescribed a different medication or that the controlled-substances Respondent prescribed were wrong. The standard of care requires that Respondent have a sound rationale for prescribing a controlled substance, whether or not a noncontrolled substance alternative is available, and that she document her justification or rationale for prescribing any controlled-substance. Tr. 97–100, 193; supra, II.E.; La. Admin. Code tit. 46, Pt. XLVII, § 4513(D)(4) (stating that medical records "must include documentation of the . . . reason for prescribing controlled substances"). Here however, Dr. Chambers opined that Respondent did not have sound rationale for prescribing the controlled substances at issue nor did she document any rationale.

²⁵ Dr. Chambers testified that F.A. and her family "live very far away, hundreds of miles away, and so... that creates monitoring problems." Tr. 96; see also id. at 252–53.

²⁶ Dr. Chambers identified several red flags of diversion, which he testified needed to be monitored under the standard of care. Specifically, Dr. Chambers identified the following red flags: Traveling a long distance to see a practitioner, Tr. 253, 309; getting multiple controlled substance prescriptions from one practitioner, id. at 308-09; and getting controlled substance prescriptions from multiple practitioners, id. at 169. Respondent has conclusively asserted both with regard to F.A. and other patients, that there were no red flags of diversion. Resp Prehearing, at 10-12, 15; Resp Posthearing, at 6, 8. However, there is no evidence in the record to support Respondent's indications that she conducted the necessary inquiries to resolve the red flags that Dr. Chambers identified. See supra II.C. And even if Respondent had investigated any red flags, the results of those hypothetical investigations were not appropriately documented in the medical records. See supra II.E.

3. Prescribing to K.W.

Between July 2017 and April 2019, Respondent issued twenty-three ²⁷ controlled substance prescriptions to K.W. for mixed amphetamine salts and alprazolam. GX 8 (Prescriptions Issued to K.W.); Tr. 113–14; RD, at 92. Dr. Chambers testified that each of these twenty-three controlled substance prescriptions was issued outside the usual course of professional practice and without a legitimate medical purpose. Tr. 140–41, 150–52, 155–56; RD, at 95.

In support of his opinion, Dr. Chambers testified that Respondent failed to provide sound rationale for the controlled substance prescriptions issued to K.W. to treat her diagnosed ADD, bipolar disorder, and insomnia. Tr. 115, 119–20, 122–23, 128, 132–33, 142, 144, 146, 150-53, 159; RD, at 89-90. First, Dr. Chambers opined that the amphetamine salt prescriptions were contraindicated because K.W. was diagnosed as being bipolar, an "[illness] that greatly increase[s] the risk of adverse effects of controlled substances and addiction." Tr. 114; RD, at 92. Dr. Chambers explained that K.W.'s symptoms, "cutting, depression, quasipsychotic hearing voices," were coming from her mental illness, but "all of it could also be contributed to by the drugs. . . . if you put people on highdose amphetamines you can actually cause them to get psychotic as if they have schizophrenia." Tr. 159; RD, at 95. Moreover, Dr. Chambers testified that, "the patient [had] been using various drugs, street drugs, that are closely akin to the drugs that [Respondent] [was] prescribing." Tr. 114. Dr. Chambers explained that K.W.'s use of illegal street drugs; 28 including ecstasy at age fourteen, GX 7, at 272, 274; crack cocaine, GX 7, at 53, Tr. 138-39; and methamphetamines, GX 7, at 38, Tr. 38; was evidence that K.W. had a stimulant addiction and that the amphetamines should no longer have been prescribed. Tr. 115; RD, at 92.

Second, Dr. Chambers opined that the benzodiazepine prescriptions were contraindicated. According to Dr. Chambers, "benzodiazepines can

unleash out-of-control behavior, especially in people with . . . bipolar disorder who are already prone to that." Tr. 128. K.W. exhibited those side effects while on benzodiazepines. Id. at 119–20, 127. While taking prescription benzodiazepine (Ambien) at the age of fourteen, K.W. experienced hallucinations and was hearing voices, so the benzodiazepine prescription was discontinued.29 GX 7 at 293, 295; Tr. 119-20. While on a benzodiazepine (Ativan) at the age of seventeen, she suffered from blackouts that lead to her being arrested and charged with resisting arrest, domestic violence, and violence against a police officer.³⁰ Tr. 127-29; GX 7, at 133. While on a different benzodiazepine (Restoril) at the age of twenty-one,³¹ K.W. reported to Respondent that she "used a rock," became agitated, took sleeping [medication] (Restoril), blacked out, hit mom, police came, was arrested . . . 5 days in jail." 32 GX 7, at 53; see also Tr. 129. Following that incident, K.W. requested, and was prescribed by Respondent, a different benzodiazepine (Valium) 33 to be taken as needed. GX 7, at 53; Tr. 129, 144-46. By November 2017, which was in the timeframe of the prescriptions underlying the allegations in this case, Respondent was prescribing K.W. another benzodiazepine (Xanax) for insomnia. Tr. 151-52; GX 7, at 41. According to Dr. Chambers, a practitioner should "not prescribe Xanax for insomnia because it is a very short-acting benzoid and there are other ones . . . that are milder, less risky." Tr. 151-52. As explained by Dr. Chambers,

those risks played out in July 2018, when K.W. attempted suicide again and was placed in emergency detention and hospitalized. GX 7, at 29; Tr. 160–61; RD, at 94. "Grandmother stated it all started over zanie[34] bars. Patient takes zanie bars and goes in a rage. Patient went crazy because she woke up and [could not] find the zanie bars." Tr. 154; see also GX 7, at 29; RD, at 94–95.

In addition to testifying that K.W. should have been prescribed neither the amphetamines nor the benzodiazepines by themselves, he explained the compounding impact of prescribing both at the same time. Tr. 151. Dr. Chambers testified, "[w]e have an upper, which is the amphetamine, and a downer [the benzodiazepine] being delivered to a patient with a mental illness [that is] defined by out-of-control ups and downs, bipolar disorder." Id. at 132. Ultimately, Dr. Chambers opined that for K.W. "[there was] no legitimate medical indication" for prescribing "a cocktail of an upper and downer." *Id.*; see also id. at 114; RD, at 92.

In addition to not having sound rationale for prescribing, Dr. Chambers noted that Respondent did not appropriately monitor K.W.'s use of the controlled substances she was prescribed. As I found above based on Dr. Chamber's expert testimony, the standard of care requires monitoring of side effects and monitoring to ensure an appropriate outcome is reached. Supra II.E.; Tr. 118. Regarding K.W., Dr. Chambers opined that the "most important and deadly outcome of [the prescribed drugs] . . . is addiction, and death, and legal outcomes, and worsening mental illness." Tr. 115. Many of those side effects occurred. Supra. Dr. Chambers further opined that "despite the incoming evidence [of an amphetamine addiction], [there was] no attempt to actually treat or do further monitoring to investigate an addiction." Id.; see also id. at 160; RD, at 92. Dr. Chambers further stated that he "never saw evidence that [a urine drug screen] test was ordered or acted on by [Respondent] or the whole practice" as required by the standard of care. Tr. 136; see also RD, at 94.

As final support for his opinion that the alleged prescriptions were issued outside of the standard of care, Dr. Chambers opined that Respondent failed to appropriately document K.W.'s file. Tr. 124, 161; RD, at 93. Dr. Chambers testified that the documentation Respondent kept for K.W. was "a problem" because "[there was] no kind of detail." Tr. 124. As an

²⁷ The OSC alleged that there were "at least 24 prescriptions" issued to K.W. outside the usual course of professional practice. OSC, at 7. However, the Government only presented evidence on twenty-three prescriptions. See GX 8.

²⁸ Additionally, there is a Psychosocial Assessment in K.W.'s medical record that was performed on December 17, 2013, by an outside professional unaffiliated with R.V. Psychiatric Services, L.L.C. GX 7, at 223. In that assessment, K.W. reported that she "was 12 [years] old when she first drank alcohol,"..."has abused [A]mbien before, [and] was 12 [years] old when [she] first smoked marijuana." *Id.* at 224.

 $^{^{29}\,\}mathrm{K.W.}$ was first prescribed a benzodiazepine in 2009 by R.V., not Respondent. GX 7, at 295; Tr. 119–20. In 2009, K.W.'s benzodiazepine prescription was stopped in light of the side effects she experienced. GX 7, at 293.

³⁰ By the year 2014, while being treated by both Respondent and R.V., K.W. was prescribed Ativan which is "even more potent and powerful than the Ambien." Tr. 129, see also id. at 127-28; GX 7, at 133. According to Dr. Chambers, Respondent misattributed the side effects K.W. experienced, while taking Ambien to another medication K.W. was prescribed (which, according to Dr. Chambers, does not include blackouts as a side effect), and continued K.W. on the benzodiazepine. Tr. 128-29. Dr. Chambers opined that by this time in 2014, "the evidence [was] overwhelming that the diagnostic indication [was not] right, the diagnosis [was not] correct, the treatment [was] worsening the diagnosis . contributing to worsening of the mental illness," but Respondent continued to prescribe benzodiazepines. Tr. 129; RD, at 93.

³¹ By March 2017, Respondent appears to be K.W.'s only treating practitioner. *See, e.g.*, GX 7, at ⁵²

³²The quoted medical notes contained arrows between each phrase; I have replaced those arrows with commas for clarity.

³³ Dr. Chambers testified that "Valium and Restoril are both benzoids, so there is not really much gained by stopping the Restoril which she just blacked out on and merely replacing that with another benzoid." Tr. 139; RD, at 94.

 $^{^{34}\,\}mathrm{Dr}.$ Chambers testified that "zanie bars is normal street usage for Xanax." Tr. 154.

example, Dr. Chambers explained that following K.W.'s July 2018 emergency detention at a hospital, Respondent's outpatient note did not express any acknowledgment or investigation of the incident. Id. at 161. "[There was] a check-mark for billing[;] . . . [t]here [were] some check-marks in the evaluation[;] but there is no conversation here about what just happened. How did you get this way? What happened with your meds? How was it in the hospital? . . . [it is] like it never happened." Id. Dr. Chambers also stated that "any time an outside professional submitted a work-up or evaluation,[35] it provid[ed] a whole higher level of clarity and detail that is non-existent" in the medical records prepared by Respondent. *Id.* at 124.

I find that, the twenty-three controlled substance prescriptions Respondent issued to K.W. between July 2017 and April 2019, were issued outside of the usual course of professional practice and beneath the applicable standard of care in Louisiana. This is because, based on Dr. Chambers' credible and uncontroverted expert testimony and the record as a whole, Respondent did not have sound rationale for the controlled substance prescriptions that were issued, did not monitor compliance with the prescription instructions, and failed to appropriately document any of the above in the patient file. See also RD, at 95-96.

4. Prescribing to M.G.

Between February 2017 and May 2019, Respondent issued forty-two ³⁶ controlled substance prescriptions to M.G. for mixed amphetamine salts, and clonazepam. GX 4 (Prescriptions Issued to M.G.); RD, at 96. Dr. Chambers testified that each of the forty-two controlled substance prescriptions was issued outside the usual course of professional practice and without a legitimate medical purpose. Tr. 172, 175, 180, 181; RD, at 98–99.

In support of his opinion, Dr. Chambers found Respondent's diagnosis of M.G. with ADD to be problematic inlight-of the existing bipolar disorder diagnosis. Tr. 165–66; RD, at 96; supra II.F.1. Dr. Chambers opined that the benzodiazepine prescription Respondent issued to M.G. can "cause ADD symptoms because any

benzo[diazepine] causes cognitive problems and memory disturbances that look like ADD." Tr. 166.

In further support of his opinion, Dr. Chambers testified that Respondent failed to provide sound rationale for the controlled substance prescriptions issued to M.G. to treat his diagnosed ADD and bipolar disorder. Id. at 165, 166, 169, 172, 180. Dr. Chambers explained that Respondent should have treated M.G. "with mood-stabilizers[,] not an addictive drug that bipolar people are vulnerable to getting addicted to and [that] could inflame the bipolar." Tr. 165; supra II.F.1; RD, at 96. In addition to the controlled substances Respondent prescribed, on May 22 2017, M.G. informed Respondent that he was taking "Norco for back from [primary care physician]" due to "4 herniated disks [from a] motorcycle accident." GX 3, at 176. Dr. Chambers opined that the stimulant and benzodiazepine prescriptions Respondent issued to M.G. were already outside the standard of care, but they became "super-dangerous both with respect to addiction and worsening of mental illness," when M.G. started receiving narcotics from his primary care physician.37 Tr. 170; GX 3, at 176; RD, at 97. Dr. Chambers opined that "outside of an intensive care unit setting, . . . there is just no indication of any disease that would justify that kind of dangerous regimen." Tr. 170; RD, at 97. Dr. Chambers testified that it was "outside the appropriate standard of care" for Respondent to issue the clonazepam and amphetamine salt prescriptions to M.G. knowing that he was on Norco. Tr. 172; RD, at 97.

In addition to not having sound rationale for prescribing, Dr. Chambers noted that Respondent did not appropriately monitor M.G.'s use of the controlled substances he was prescribed. For example, in May 2017, Dr. Chambers testified, Respondent was aware that M.G. was taking Norco prescribed by another practitioner and vet she issued to M.G. three months of prescriptions for Adderall and Klonopin. Tr. 173. First, Dr. Chambers opined that "you would expect the patient to be back in August, but we [did not] see that . . . then there [was] a note for October and the patient [was] a no-show." Id. at 173. Dr. Chambers explained that the patient had "been

going on for five months on a lethal combination of drugs prescribed by doctors[,] and [Respondent] [knew] this." Id. at 174. Dr. Chambers explained that, at this point, some investigation was necessary to determine what had happened in the two months during which M.G., had he taken the controlled substances as prescribed, would have been out of medication. Id. at 175; RD, at 97-98. Dr. Chambers opined that there were three possible scenarios. First, the controlled substances may not have "actually gotten in his body" as he could have been "selling every bit of it." 38 Id. at 175. Alternatively, M.G. could have run out and gotten the drugs "from street sources." *Id.* A third possibility was that M.G. was "fine going with these big gaps [without controlled substances] . . . [so] he [should not] be on [them] anyway." *Id.* Dr. Chambers' testimony made clear that there was "[n]othing appropriate" going on in any of the three scenarios and that some investigation was required to appropriately monitor M.G. Id. at 175, 275. Dr. Chambers opined that "[t]his [was] not health care." Id. at 174.

Dr. Chambers testified that, for M.G., ''[t]here [was] not a single drug-screen in the record." Id. at 175; see also id. at 182. Dr. Chambers further explained that Respondent should have monitored M.G. with drug testing upon receiving the May 27, 2014 report from Dr. L.G., Ph.D. that diagnosed M.G. with "Cannabis Use Disorder—Mild to Moderate," and "Tobacco Use Disorder-Moderate." GX 3, at 39; Tr. 178–79. Dr. Chambers explained that where "there [are] substance use issues, you have to start drug-testing. People [do not] have compartmentalized addictions . . . [t]he part of the brain where addiction happens does not care what the source of the drug is." Tr. 179; RD, at 99.39

As final support for his opinion that the alleged prescriptions were issued outside of the standard of care, Dr. Chambers opined that Respondent failed to appropriately document M.G.'s file. Tr. 164, 173, 175–76. Dr. Chambers explained that "there [was] no documentation of warnings" provided

³⁵ The patient file for K.W. included copies of hospital records and of assessments performed by other practitioners. *See* GX 8, at 4–28, 188–190, 208–226.

³⁶The OSC alleged that there were "at least 57 prescriptions" issued to K.W. outside the usual course of professional practice. OSC, at 5. However, the Government only presented evidence on forty-two of those prescriptions at the hearing in this matter. See GX 4.

³⁷ According to Dr. Chambers, Respondent should have inquired about narcotic use during the February 20, 2017, visit when M.G. reported he had missed appointments because of back pain. Tr. 169; GX 3, at 179. It is also clear that Respondent was again notified that M.G. was taking narcotics on October 23, 2017 and August 1, 2018. GX 3, at 161, 171.

³⁸ Dr. Chambers later explained that "you have to assume that anybody might divert [controlled substances]" and that "without monitoring them, [you are] not applying appropriate controls to make sure [they are] not diverting. . . ." Tr. 272.

³⁹ Dr. Chambers further opined that it was outside the standard of care for Respondent to issue any controlled substance prescriptions to M.G. after receiving the May 27, 2014 report and that it was outside the standard of care for Respondent to receive the report and not act on it; however only the prescriptions issued between February 2017 and May 2019 are at issue in this case. Tr. 178, 180.

to M.G. when he was taking the "lethal combination" of a narcotic, amphetamine salts, and a benzodiazepine. Id. at 173-74; RD, at 97. And after M.G. went five months without a visit, as Dr. Chambers explained, "all you see in [the] assessment is . . . ADD and bipolar diagnosis and check-marks" for billing purposes. Tr. 174. He generally described the medical record for M.G. as being "devoid of information." Id. at 175. Dr. Chambers contrasted Respondent's documentation with the May 27, 2014 report from Dr. L.G. which, according to Dr. Chambers, provided an example of a "thorough, adequate evaluation that has a lot of information about this patient and is at the standard of care when you are taking care of people with mental illness." Id. at 176; RD, at 98.

I find that, the forty-two controlled substance prescriptions Respondent issued to M.G. between February 2017 and May 2019, were issued outside of the usual course of professional practice and beneath the applicable standard of care in Louisiana. This is because, based on Dr. Chambers' credible and uncontroverted expert testimony and the record as a whole, Respondent did not obtain sufficient information to diagnose, did not have sound rationale for the controlled substance prescriptions that were issued, did not monitor compliance with the prescription instructions, and failed to appropriately document any of the above in the patient file. See also RD, at

5. Prescribing to F.P.

Between April 2017 and May 2019, Respondent issued seventy-two controlled substance prescriptions to F.P. for mixed amphetamine salts, Vyvanse, and lorazepam. GX 6 (Prescriptions Issued to F.P.); RD, at 99. Dr. Chambers testified that each of the seventy-two controlled substance prescriptions was issued outside the usual course of professional practice and without a legitimate medical purpose. Tr. 189–90, 192–94, 196–98; RD, at 100–01.

In support of his opinion, Dr. Chambers found that Respondent's diagnosis of F.P. with depressive disorder and post-traumatic stress disorder (hereinafter, PTSD) lacked sufficient supporting clinical evidence. Tr. 191–92, 200, 202; RD, at 101. On January 6, 2017, when F.P. was eleven years old, Respondent diagnosed F.P. with depressive disorder and the medical records reflected very little information—just "circles and checkmarks, . . . father has leukemia." Tr.

192; GX 5, at 39–40. According to Dr. Chambers, "father having leukemia is terrible, but that is not a diagnosis of depression" and "there is no clinical data that would" support the depression diagnosis. Tr. 192. Respondent continued to treat F.P. for depression throughout the time period relevant to this case (April 2017 to May 2019). GX 5, at 2-40. Additionally, Dr. Chambers explained that on April 27, 2017, "now suddenly [there was] a new psychiatric diagnosis, PTSD, for which there [was] not sufficient clinical evidence to support that diagnosis." Tr. 200. Dr. Chambers noted that F.P.'s files demonstrated his father had died, "but that is not PTSD." Id. With regard to Respondent's diagnosing and treatment of F.P., Dr. Chambers testified, "[i]t just [does not] make any sense. It is like chaos." Id. at 202.

In further support of his opinion, Dr. Chambers testified that Respondent failed to provide sound rationale for the controlled substance prescriptions issued to F.P. both individually and as a group of prescriptions. Id. at 192-201. By way of background, the medical records reflect that F.P. first began visiting the practice in 2013 at the age of seven and he was seen by R.V. GX 5, at 95-99; Tr. 184. At that time, F.P.'s mother reported that F.P. experienced auditory and visual hallucinations, so R.V. diagnosed him with psychosis and prescribed Seroquel, an anti-psychotic medication. GX 5, at 75, 95-99; Tr. 184-86. Respondent first visited with F.P. on August 12, 2014, and at that time she discontinued his Seroquel prescription. GX 5, at 74. Dr. Chambers opined that it was unwise to discontinue the Seroquel because "the history of psychosis is really clear from before." Tr. 187. Beginning in October of 2016, when F.P. was eleven, and continuing throughout the relevant time period in this case, Respondent prescribed Adderall to F.P. GX 5, at 44; GX 6. Dr. Chambers testified that prescribing "Adderall, given the psychosis that happened earlier and the fact that [F.P.] is no longer on an antipsychotic, . . . [was] a mistake" and was outside the standard of care. Id. at 190; RD, at 100. Dr. Chambers also opined that there was "no adequate data or rationale explain[ing]" the prescriptions for two different stimulants, Vyvanse and Adderall,40 which were prescribed throughout the relevant time period in this case. Tr. 192; see also GX 5, at 1,

4, 7, 10, 13, 22, 25, 34, 40; RD, at 100. In January 2017, Respondent began prescribing Ativan/lorazepam, a benzodiazepine, to F.P. and continued to prescribe it throughout the relevant time period in this case. Tr. 192; GX 5, at 1, 4, 7, 10, 13, 22, 25, 34, 40. Dr. Chambers questioned the rationale for the Ativan prescription, "[F.P.'s] [s]leeping has always been poor . . . so now all of the sudden there is Ativan . . . he's had insomnia before, why the Ativan? . . . there is no adequate data or rationale explained." 41 Tr. 192. Collectively, Dr. Chambers opined that "there is no rationale" for prescribing a benzodiazepine to a "child who is also on amphetamine, and two different types." Id. at 194. Moreover, the three controlled substances were prescribed alongside a non-controlled substance, Prozac. Id. at 195. According to Dr. Chambers, prescribing Prozac and the two stimulants to "a kid with a history of psychosis" could "provoke [psychosis]." *Id.* Ultimately Dr. Chambers explained that "[t]here are four meds here . . . [and] [t]hey all could worsen the side effects of the other. [It is] not good." Id.

As final support for his opinion that the alleged prescriptions were issued outside of the standard of care, Dr. Chambers opined that Respondent failed to appropriately document F.P.'s file. Tr. 202. As with the other medical records, Dr. Chambers commented on the insufficiency of Respondent's recordkeeping for F.P., which he describes and "just some circles and check-marks." *Id.* at 191; *see also id.* at 192; RD, at 100. Additionally, he explained that there was "chaos with who [was] assessing the patient." Tr. 201. "[T]here is [a] totally different set of handwriting, so it looks like there [were] three or four people seeing the same patient and they [were] not even signing the chart, which is also not an acceptable standard of care for documentation." Id. at 201-02. When asked whether the level of documentation in F.P.'s record was "adequate given the controlled substances that [were] being prescribed," Dr. Chambers said, "No." *Id.* at 202.

I find that, the seventy-two controlled substance prescriptions Respondent issued to F.P. between April 2017 and May 2019, were issued outside of the usual course of professional practice and beneath the applicable standard of

⁴⁰ When asked how Vyvanse was different from Adderall, Dr. Chambers explained that "it is amphetamine with a slight variation on the molecule and it essentially has the same effects."

⁴¹Dr. Chambers further testified "there has been an insomnia diagnosis, but it's been there without the Ativan and it is here now, so nothing has changed in the diagnosis or the clinical data to justify the introduction of a heavy-duty benzo in a child." Tr. 193.

care in Louisiana. This is because, based on Dr. Chambers' credible and uncontroverted expert testimony and the record as a whole, Respondent did not obtain sufficient information to diagnose, did not have sound rationale for the controlled substance prescriptions that were issued, and failed to appropriately document any of the above in the patient file. See also RD, at 100–01.

6. Prescribing to M.H.⁴²

Between May 2017 and April 2018, Respondent issued forty-three ⁴³ controlled substance prescriptions to M.H. for mixed amphetamine salts, acetaminophen with codeine, clonazepam, and zolpidem tartrate. GX 10 (Prescriptions Issued to M.H.); RD, at 101. Dr. Chambers testified that each of the forty-three prescriptions was issued outside the usual course of professional practice and without a legitimate medical purpose. Tr. 207–08, 218, 235–36.

In support of his opinion, Dr. Chambers questioned Respondent's diagnosis of M.H. Id. at 209, 213, 216; RD, at 104. The medical records reflect that M.H. had been a patient of R.V.'s at the practice since 2009. GX 9, at 249. On June 10, 2016, according to the medical records, Respondent began treating Respondent and adopted R.V.'s earlier diagnoses of depressive disorder, ADD, and insomnia. GX 9, at 44-45, 47. While Respondent maintained the ADD and insomnia diagnoses for M.H. through the relevant time period in this case, her diagnosis of M.H. with depressive disorder was intermittently left off of the patient records (id. at 11, 16, 19, 22, 34, 37, 40) and on (*id.* at 25, 28, 30, 44) including during the relevant time period in this case. Dr. Chambers questioned Respondent's diagnosis of M.H. with depressive disorder, ADD, and insomnia because "depression alone, all by itself, could account for attention deficit and insomnia." Tr. 209. Additionally, Respondent added a diagnosis of anxiety on October 16, 2016, and maintained that diagnosis throughout the relevant time period in this case. GX 9, at 11, 16, 19, 22, 25, 28, 30, 34, 37. Dr. Chambers opined that there was no clear "basis for an anxiety diagnosis" in the record, Tr. 213, and that it is possible that any anxiety

symptoms could have been caused by the Adderall prescription or M.H.'s nicotine use.⁴⁴ *Id.* at 214–16, 227; RD, at 75. Finally, Respondent diagnosed M.H. with tension headaches on February 1, 2017, and maintained that diagnosis throughout the relevant time period in this case except for omitting it from the patient record on October 26, 2017. GX 9, at 11, 16, 19, 22, 25, 28, 30. Dr. Chambers noted that Respondent just "check-mark[ed] the tension headache diagnosis," without an examination or work-up, Tr. 221, and that again, the Adderall could have been the cause of the headaches.⁴⁵ Id. at 222; RD, at 102.

In further support of his opinion, Dr. Chambers testified that Respondent failed to provide sound rationale for the controlled substance prescriptions issued to M.H. See, e.g., Tr. 207, 209-16, 218, 220, 223, 227-30, 235. Dr. Chambers explained that Respondent's prescribing to M.H. showed "dose escalation over time without clear justification or diagnostic rationale." 46 Id. at 216; RD, at 102. Additionally, Dr. Chambers explained, that with regard to Klonopin, Ambien, and Butalbital,47 "just those three [prescriptions] alone could be . . . lethal." Tr. 207; RD, at 101. Dr. Chambers testified that those three prescriptions combined with codeine 48

and Adderall 49 created "a very high-risk . . an unacceptable risk" of "[a]cceleration [or] worsening of mental illness, acquisition or worsening of addiction, medical injury, legal consequences and death." Tr. 207; see also id. at 208. The record evidence demonstrates that on or about February 2018, M.H. reported to Respondent that she was hospitalized for "failure to thrive, . . . malnutrition, [being] too weak to walk." Id. at 229; see also GX 9, at 12; RD, at 76. Dr. Chambers testified that "something [was] not right, and in this collapse [Respondent had] a patient who [was] being prescribed every class of addictive drug and multiple addictive drugs and dangerous drugs within each class, a whole laundry list of controlled drugs, so it is not a surprise." Tr. 229. Dr. Chambers concluded that the prescriptions Respondent issued to M.H. were not only lacking justification, but were likely "contributing to [her] deterioration." 50

In addition to not having sound rationale for prescribing, Dr. Chambers noted that Respondent did not appropriately monitor M.H.'s use of the controlled substances that she was prescribed. Id. at 204, 211, 214-15, 219, 227-28, 230. Respondent did not monitor to ensure an appropriate outcome; according to Dr. Chambers, "if someone is on . . . that load of benzos and they are still anxious, you've got to think that the treatment doesn't work." Id. at 227. Additionally, Dr. Chambers noted several indicators that M.H. had addiction disorder and vulnerability to multiple addictions. Id. at 215-16; RD, at 101-02. First, Dr. Chambers testified that according to the Louisiana Prescription Drug Monitoring Report,⁵¹ M.H. received suboxone, which is usually used to treat opioid addiction, from another provider, Tr. 205, 208; second, she smoked a pack of cigarettes

⁴²M.H. (which appears to be her unmarried name) is also referred to as M.G. (which appears to be her married name) throughout the patient records. *See*, *e.g.*, Tr. 75, 166, 168.

⁴³The OSC alleged that there were "at least 54 prescriptions" issued to M.H. outside the usual course of professional practice. OSC, at 9. However, the Government only presented evidence on forty-three of those prescriptions at the hearing in this matter. See GX 10.

⁴⁴ Dr. Chambers testified that "there [were] all kinds of reasons the anxiety could be there that [had] nothing to do with a generalized anxiety disorder," and where "there [was] a constant march in dose escalation of the benzo[s]," and "[M.H.] [was] still anxious, [you have] got to think that the treatment [does not] work." Tr. 227.

⁴⁵ Dr. Chambers also explained that M.H. could have been diverting her medication and then "going into withdrawal from benzos and developing headaches from that." Tr. 222. Though it is clear that Dr. Chambers is speaking hypothetically when he discusses the potential causes for the anxiety symptoms or tension headaches, his point is that Respondent failed to perform an appropriate assessment to make these diagnoses. *See, e.g., id.* at 214–16, 222. I agree.

⁴⁶ Dr. Chambers specifically noted the lack of rationale for dosing increases of Ambien, Tr. 212; the addition of and then the doubling and tripling of Klonopin, Tr. 213, 220, 223; dosing increases of Adderall, Tr. 217–18; and the addition of butalbital, Tr. 220, 223.

⁴⁷ While issuing to M.H. controlled substance prescriptions for Klonopin and Ambien, Respondent also issued prescriptions for Fioricet, which contains butalbital. *See, e.g., GX 9, at 21.* The Fioricet/butalbital prescriptions are not at issue in this case and are only discussed herein as necessary to understand Dr. Chamber's opinion that the controlled substances at issue in this case were prescribed beneath the standard of care.

⁴⁸ Regarding the prescribed codeine, Dr. Chambers explained that the Louisiana Prescription Monitoring Program shows that M.H. had been prescribed Suboxone by another provider, which in his opinion, could indicate an opiate addiction. Tr. 208. According to Dr. Chambers, "if someone is treating opiate addiction with an opiate that is approved for opiate addiction, [and] you . . . are prescribing an opiate on top of that, you are directly fueling the disease." *Id.* at 208.

⁴⁹Regarding the Adderall prescription, Dr. Chambers explained that Respondent prescribed M.H. 60 and then 80 milligrams a day when the FDA guidelines recommend a maximum daily dose of 40 milligrams. Tr. 209–10. Though, Dr. Chambers explained, there are circumstances when the recommended maximum dose can be exceeded, none of those circumstances are present here. *Id.* at 210. One example of when the dosage could be higher, according to Dr. Chambers, is when there are no other controlled substances prescribed and the patient is not responding to the medication due to something like high body weight (M.H. weighed only 92 pounds). *Id.* at 210.

⁵⁰ As examples, Dr. Chambers explained that benzos can contribute to pneumonia because the patient would not be inhaling or breathing as rapidly and not aerating the lungs the same way, and opioids suppress the cough reflex which is necessary to get rid of bacteria. Tr. 229–30.

⁵¹Copies of two Louisiana Prescription Drug Monitoring Reports were contained in Respondent's patient file for M.H. at GX 9, at 9, and 93–98.

a day which is indicative of a nicotine addiction, id. at 215; and third, M.H. received dose escalations of addictive drugs over time, which is indicative of drug addiction, id. at 216, 222. Yet, as Dr. Chambers testified, there was no drug-screening of this patient.⁵² Id. at 211. Ultimately, on March 28, 2018, M.H. was "discharged from [Respondent's] care." GX 9, at 1; RD, at 104. While the discharge letter did not state the reason for the discharge, a note in the medical records for M.H. with a March 28, 2018, date indicated that M.H. was "noncompliant w[ith] medications" and that it was her '[second] time calling about her Fioricet [and] Tylenol." GX 9, at 1–2. Even after M.H. was discharged as a patient, Respondent wrote M.H. prescriptions for a two-month supply of Klonopin and Ambien. GX 9, at 2; RD, at 104. Dr. Chambers testified that "it appears that after firing the patient[,] she prescribed the patient more benzoids," and they were "prescribed without any link to a provider or any supervision or appointments." Tr. 235. Moreover, when asked whether the professional standard required a prescriber to drop a patient who was addicted, Dr. Chambers stated, "No." *Id.* at 273–74. He said "dropping them would be abandoning a sick person. . . . [it is] a failure of appropriate care for the patient." Id. at 274. Instead, Dr. Chambers testified, a prescriber should expand treatment to "include addiction treatment," and "make adjustments in [the] practice to stop the diversion but hold on to the patient." Id.

As final support for his opinion that the alleged prescriptions were issued outside of the standard of care, Dr. Chambers opined that Respondent failed to appropriately document M.H.'s file. Id. at 212-14, 221, 223, 225, 228, 235. As with the other medical records, Dr. Chambers commented on the insufficiency of Respondent's recordkeeping for M.H., which he again described as "check-marks and circles." Id. at 212; see also id. at 213, 221. Additionally, Dr. Chambers again explained that there was insufficient documentation indicating who was seeing the patient, because while Respondent's handwriting and signature appeared on the records, there was also unknown handwriting with no corresponding signature. Id. at 223, 228; RD, at 103. Dr. Chambers testified that "part of what is complicating the picture is again more unknown writers and evaluators entering the chart." Tr.

223. Moreover, with regard to the prescriptions issued to M.H. after Respondent discharged her from care, Dr. Chambers explained that there was no "charting that goes along with [those prescriptions]." ⁵³ *Id.* at 235; *see also* RD, at 104.

I find that, the forty-three controlled substance prescriptions Respondent issued to M.H. between May 2017 and April 2018, were issued outside of the usual course of professional practice and beneath the applicable standard of care in Louisiana. This is because, based on Dr. Chambers' credible and uncontroverted expert testimony and the record as a whole, Respondent did not obtain sufficient information to diagnose, did not have sound rationale for the controlled substance prescriptions that were issued, did not monitor compliance with the prescription instructions, and failed to appropriately document any of the above in the patient file. See also RD, at

7. Summary of Fact Findings Relevant to All Patients

In accordance with Dr. Chambers' testimony and the record as a whole, and in agreement with the ALJ, I find that, for each of the two-hundred and three prescriptions at issue, Respondent did not obtain sufficient information to diagnose, did not have sound rationale for the prescriptions that were issued, did not monitor compliance with the controlled substance prescriptions, and/ or did not appropriately document the file. See RD, at 105. Ultimately, I find that there is substantial evidence on the record that Respondent issued twohundred and three prescriptions without a legitimate medical purpose, outside of the usual course of professional practice and beneath the applicable standard of care in Louisiana.

III. Discussion

A. Allegation That Respondent's Registration Is Inconsistent With the Public Interest

Under Section 304 of the Controlled Substances Act, "[a] registration . . . to . . . dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render his registration under section 823 of this

title inconsistent with the public interest as determined by such section." 21 U.S.C. 824(a)(4). In the case of a "practitioner," defined in 21 U.S.C. 802(21) to include a "physician," Congress directed the Attorney General to consider the following factors in making the public interest determination:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing . . . controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the . . . distribution[] or dispensing of controlled substances.

- (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
- (5) Such other conduct which may threaten the public health and safety.
- 21 U.S.C. 823(f). These factors are considered in the disjunctive. *Robert A. Leslie, M.D.,* 68 FR 15,227, 15,230 (2003).

According to Agency decisions, I "may rely on any one or a combination of factors and may give each factor the weight [I] deem[] appropriate in determining whether" to revoke a registration. Id.; see also Jones Total Health Care Pharmacy, LLC v. Drug Enf't Admin., 881 F.3d 823, 830 (11th Cir. 2018) (citing Akhtar-Zaidi v. Drug Enf't Admin., 841 F.3d 707, 711 (6th Cir. 2016); MacKay v. Drug Enf't Admin., 664 F.3d 808, 816 (10th Cir. 2011); Volkman v. U.S. Drug Enf't Admin., 567 F.3d 215, 222 (6th Cir. 2009); Hoxie v. Drug Enf't Admin., 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I "need not make explicit findings as to each one." MacKay, 664 F.3d at 816 (quoting Volkman, 567 F.3d at 222); see also Hoxie, 419 F.3d at 482. "In short, . . . the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct." Jayam Krishna-Iyer, M.D., 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. *MacKay*, 664 F.3d at In a likely attempt to argue that her

In a likely attempt to argue that her continued registration was consistent with the public interest, Respondent stated that her practice occurred in a "Health Care Shortage Area, with very few providers accepting underserved populations," and that her practice

⁵² Dr. Chambers also testified that drug-screening was necessary to rule out diversion in light of the high doses of Adderall given. Tr. 210–11

⁵³ Dr. Chamber's exact testimony referred to "that prescription" in the singular. Tr. 235. I have edited the quote because it is clear from the context of the testimony that when Dr. Chambers refers to "that prescription" he is referencing GX 9, p. 3 which is a copy of one page of a prescription pad upon which two prescriptions for controlled substances were written. Tr. 235; GX 9, at 3.

managed a case load of 9,500 patients during the 2017-2018 period at issue in this case. Resp Posthearing, at 1. Even assuming the truth of all of these alleged "facts" that are not in evidence, community impact evidence is generally considered to be irrelevant to DEA revocation proceedings. See, e.g., Frank Joseph Stirlacci, M.D., 85 FR 45,229, 45,239 (2020) (declining to consider Respondent's argument that his revocation "would deprive the lowincome and homeless patients . . . of his medical services"); Mark De La Lama, P.A., 76 FR 20,011, 20,020 n.20 (2011) (declining to consider a registrant's service to underserved and underinsured persons).

Respondent also argued that "the [G]overnment failed to produce evidence of actual abuse or diversion [for] the 750,000 doses/year [prescribed] . . . by way of arrest records, law enforcement testimony, or drug rehabilitation admissions of patients." 54 Resp Posthearing, at 3. Respondent does not, however, cite legal authority for the proposition that I must find that patients became addicted or drugs were sold before I can find that continued registration is inconsistent with the public interest. Agency decisions have found that "diversion occurs whenever controlled substances leave 'the closed system of distribution established by the ČSA. . . .'" Id. (citing Roy S. Schwartz, 79 FR 34,360, 34,363 (2014)). See also, Jeanne E. Germeil, M.D., 85 FR 73,786, 73,799 (rejecting Respondent's argument that "no reported overdoses or deaths" was indicative of positive dispensing experience).

DEA regulations state, "[a]t any hearing for the revocation . . . of a registration, the . . . [Government] shall have the burden of proving that the requirements for such revocation . . . pursuant to . . . 21 U.S.C. [§] 824(a) . . . are satisfied." 21 CFR 1301.44(e). In this matter, while I have considered all of the factors, 55 the relevant evidence

is confined to Factors Two and Four. I find that the evidence satisfies the Government's *prima facie* burden of showing that Respondent's continued registration would be "inconsistent with the public interest." 21 U.S.C. 824(a)(4). I further find that Respondent failed to produce sufficient evidence to rebut the Government's *prima facie* case.

1. Factors Two and Four—the Respondent's Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances

(a) Allegation That Respondent Issued Prescriptions for Controlled Substances Outside the Usual Course of the Professional Practice in Violation of Both Federal and State Law

According to the CSA's implementing regulations, a lawful controlled substance order or prescription is one that is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 CFR 1306.04(a).⁵⁶ The Supreme Court has stated, in the context of the CSA's requirement that schedule II controlled substances may be dispensed only by written prescription, that "the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse . . . [and] also bars doctors from peddling to patients who crave the drugs for those prohibited uses." Gonzales v. Oregon, 546 U.S. 243, 274 (2006).

Under the CSA, it is fundamental that a practitioner must establish and maintain a legitimate doctor-patient relationship in order to act "in the usual

course of . . . professional practice" and to issue a prescription for a "legitimate medical purpose." Ralph J. Chambers, 79 FR 4962 at 4970 (2014) (citing Paul H. Volkman, 73 FR 30,629, 30,642 (2008), pet. for rev. denied Volkman v. Drug Enf't Admin., 567 F.3d 215, 223-24 (6th Cir. 2009)); see also U.S. v. Moore, 423 U.S. 122, 142-43 (1975) (noting that evidence established that the physician exceeded the bounds of professional practice, when "he gave inadequate physical examinations or none at all," "ignored the results of the tests he did make," and "took no precautions against . . . misuse and diversion"). The CSA, however, generally looks to state law to determine whether a doctor and patient have established a legitimate doctor-patient relationship. Volkman, 73 FR 30,642.

Based on the credible expert testimony on the record, I found above that the standard of care for prescribing controlled substances in Louisiana requires the following: (1) An appropriate assessment and evaluation to make a diagnosis; (2) sound rationale for prescribing controlled substances related to that diagnosis; (3) ongoing monitoring to ensure that the desired outcome is achieved and undesirable side effects are not experienced; and (4) appropriate documentation. See supra II.E. Based on the credible expert testimony on the record, I also found above that each of the two-hundred and three prescriptions at issue in Respondent's case were issued without an appropriate assessment to diagnose, sound rationale for prescribing, adequate monitoring, and/or appropriate documentation. See supra II.F.7. Accordingly, I found that Respondent dispensed controlled substances beneath the applicable standard of care and outside of the usual course of the professional practice in Louisiana. See supra II.F.7. I find that in issuing two-hundred and three prescriptions beneath the applicable standard of care and outside the usual course of professional practice in Louisiana, Respondent violated 21 CFR 1306.04(a). Similarly, I find that Respondent violated La. Admin. Code tit. 46, Pt. LIII, § 2745(B)(1) by issuing two-hundred and three prescriptions without a legitimate medical purpose and outside the usual course of professional practice.

Respondent, however, appears to have argued and believed that her actions were permissible and were supported by scientific evidence. Resp Posthearing, at 5–8. I have already rejected these arguments because they were based solely on facts that were not in evidence. Supra II.C. However, even if

⁵⁴Respondent also argued that the Government has only alleged CSA violations related to "0.052% of patients." Resp Posthearing, at 1. Assuming the truth of these facts not in evidence, the Agency already assumes that all of the prescriptions Respondent issued were issued lawfully, except for those prescriptions that the Government alleged and established were issued unlawfully. See Wesley Pope, M.D., 82 FR 14,944, 14,982–84 (2017).

⁵⁵ As to Factor One, there is no evidence in the record of any recommendation from Respondent's state licensing board or professional disciplinary authority. 21 U.S.C. 823(f)(1). State authority to practice medicine is "a necessary, but not a sufficient condition for registration. . . ." Robert A. Leslie, M.D., 68 FR at 15,230. Therefore, "[t]he fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of Respondent's DEA certification is

consistent with the public interest." Roni Dreszer, M.D., 76 FR 19,434, 19,444 (2011).

As to Factor Three, there is no evidence in the record that Respondent has a "conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances." 21 U.S.C. 823(f)(3). However, as Agency cases have noted, there are a number of reasons why even a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay, M.D.*, 75 FR 49,956, 49,973 (2010). Agency cases have therefore held that "the absence of such a conviction is of considerably less consequence in the public interest inquiry" and is therefore not dispositive. *Id.*

⁵⁶ Similarly, La. Admin. Code tit. 46, Pt. LIII, § 2745(B)(1) (2021) (last amended July 2016) states that "[a] prescription for a controlled substance shall be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of [her] professional practice." Additionally, La. Admin. Code tit. 46, Pt. XLVII, § 4513(D)(2)(b)(xi) states that "no APRN shall prescribe any controlled substance or other drug having addiction-forming or addiction sustaining liability without a good faith . . . medical indication."

Respondent believed the controlled substance prescriptions she issued were issued within the usual course of professional practice, DEA has found that "just because misconduct is unintentional, innocent, or devoid of improper motive, [it] does not preclude revocation or denial. Careless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify the revocation of an existing registration. Bobby D. Reynolds, N.P., Tina L. Killebrew, N.P., & David R. Stout, N.P., 80 FR 28,643, 28662 (2015) (quoting Paul J. Caragine, Jr., 63 FR 51,592, 51,601 (1998).

(b) Allegation That Respondent Violated State Law

I have found that Respondent issued prescriptions for controlled substances without a "legitimate medical purpose" and outside of "the usual course of [her] professional practice" in violation of La. Admin. Code tit. 46, Pt. LIII, § 2745(B)(1) for the same reasons that I found she violated 21 CFR 1306.04(a). La. Admin. Code tit. 46, Pt. LIII, § 2745(B)(1). I also find that the record contains substantial evidence that Respondent's actions violated La. Admin. Code tit. 46, Pt. XLVII, § 4513(D), which addresses the prescriptive authority of advanced practice registered nurses in Louisiana.

Under that section, "no APRN shall prescribe any controlled substance or other drug having addiction-forming or addiction-sustaining liability without a good faith prior examination and medical indication." Id. at § 4513(D)(2)(b)(ix) (2019). Dr. Chambers testified repeatedly about Respondent's failure to perform an appropriate assessment to make a diagnosis prior to prescribing controlled substances, and testified to instances where "the evidence [was] overwhelming that the diagnostic indication [was not] right." Tr. 129. See also id. at 88-92, 97, 166, 191-93, 200, 202, 209, 213, 216. Dr. Chambers also testified that the controlled substances prescribed by Respondent were often contraindicated. Id. at 115, 141, 170, 221, 270. Repeatedly, Dr. Chambers testified that "[there is] no legitimate medical indication" for "prescribing . . . a cocktail of an upper and downer." Id. at 132; see also id. at 133, 146, 170, 198. For these reasons, I find that Respondent violated La. Admin. Code tit. 46, Pt. XLVII, § 4513(D)(2)(b)(ix) by prescribing controlled substances without a good faith prior examination and medical indication.

Moreover, even if Respondent had conducted a good faith examination and

established a medical indication prior to prescribing the controlled substances, her failure to document appropriately is an independent violation of Louisiana law. Under Louisiana law, "[a]n APRN who prescribes a controlled substance shall maintain a complete record of the examination, evaluation and treatment of the patient which must include documentation of the diagnosis and reason for prescribing controlled substances." La. Admin. Code tit. 46, Pt. XLVII, § 4513(D)(4)(a) (2019). Dr. Chambers repeatedly testified regarding the deficiencies in Respondent's documentation and explained that there was no documentation of Respondent's reasons for prescribing the controlled substances at issue. Tr. 213-14, 335. Specifically, Dr. Chambers described Respondent's documentation as "a facade," id. at 92; "check-marks" with "no conversation . . . about what just happened," id. at 161; and "superficial [and] not credible," id. at 258. See also id. at 174, 192, 212, 221. For these reasons, I find that Respondent violated La. Admin. Code tit. 46, Pt. XLVII, § 4513(D)(4)(a) by failing to "maintain a complete record of the examination, evaluation and treatment of the patient . . . includ[ing] . . . [the] reason for prescribing controlled substances.

For all these reasons, I find that the record contains substantial evidence that Respondent violated La. Admin. Code tit. 46, Pt. LIII, § 2745(B)(1), and La. Admin. Code tit. 46, Pt. XLVII, § 4513(D).

In total, I find that the record contains substantial evidence that Respondent issued two-hundred and three controlled substance prescriptions without a legitimate medical purpose and outside of the usual course of professional practice and beneath the applicable standard of care in Louisiana in violation of 21 CFR 1306.04(a), La. Admin. Code tit. 46, Pt. LIII, § 2745(B)(1), and La. Admin. Code tit. 46, Pt. XLVII, § 4513(D). As Respondent issued these prescriptions without complying with her obligations under the CSA and Louisiana law, I find that Factors Two and Four weigh in favor of revocation. See George Mathew, M.D., 75 FR 66,138, 66,148 (2010)). Overall, I find that the Government has established a prima facie case that Respondent's continued registration is inconsistent with the public interest.

B. Summary of Factors Two and Four and Imminent Danger

As found above, there is substantial record evidence that Respondent issued controlled substance prescriptions outside the usual course of the professional practice and beneath the

applicable standard of care in Louisiana and in violation of state law. I, therefore, have concluded that Respondent engaged in misconduct which supports the revocation of her registration. See Wesley Pope, 82 FR 14,944, 14,985 (2017).

For purposes of the imminent danger inquiry, my findings also lead to the conclusion that Respondent has "fail[ed] . . . to maintain effective controls against diversion or otherwise comply with the obligations of a registrant" under the CSA. 21 U.S.C. 824(d)(2). The uncontroverted, substantial evidence that Respondent repeatedly issued prescriptions without having a sound rationale or legitimate medical purpose for doing so establishes "a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance . . . [would] occur in the absence of the immediate suspension" of Respondent's registration. Id.; see also Tr. 79, 115 (testimony of Dr. Chambers that Respondent was prescribing a "whole host of highvolume addictive drugs" which could have a "deadly outcome"); 143, 171 (testimony of Dr. Chambers that "the combination of a benzo and opiate is an imminently lethal combo"), 207, 228,

Not only was Respondent prescribing highly addictive drugs with a potentially "deadly outcome" without a legitimate medical purpose for so doing, but she was prescribing combinations of controlled substances known to be "imminently lethal." *Id.* at 115, 171; *see also supra* IV (providing examples of egregious misconduct by Respondent which had a substantial likelihood of causing serious bodily harm or leading to abuse of a controlled substance).

Thus, as I have found above, at the time the Government issued the OSC/ISO, the Government had clear evidence of violations of law based on the two-hundred and three controlled substance prescriptions Respondent issued without obtaining sufficient information to diagnose, having sound rationale to prescribe, monitoring compliance with the controlled substance prescriptions, and appropriately documenting the file. See supra III.A.1.a.

IV. Sanction

Where, as here, the Government has met its *prima facie* burden of showing that Respondent's continued registration is inconsistent with the public interest, the burden shifts to the Respondent to show why she can be entrusted with a registration. *Garrett Howard Smith*, *M.D.*, 83 FR 18,882, 18,910 (2018) (collecting cases). Respondent has made

no effort to establish that she can be trusted with a registration.

The CSA authorizes the Attorney General to "promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter." 21 U.S.C. 871(b). This authority specifically relates "to 'registration' and 'control,' and 'for the efficient execution of his functions' under the statute." Gonzales v. Oregon, 546 U.S. 243, 259 (2006). A clear purpose of this authority is to "bar[§] doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking." Id. at 270.

In efficiently executing the revocation and suspension authority delegated to me under the CSA for the aforementioned purposes, I review the evidence and arguments Respondent submitted to determine whether or not she has presented "sufficient mitigating evidence to assure the Administrator that [s]he can be trusted with the responsibility carried by such a registration." Samuel S. Jackson, D.D.S., 72 FR 23,848, 23,853 (2007) (quoting Leo R. Miller, M.D., 53 FR 21,931, 21,932 (1988)). "Moreover, because 'past performance is the best predictor of future performance," ALRA Labs, Inc. v. DEA, 54 F.3d 450, 452 (7th Cir. 1995), [the Agency] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [the registrant's] actions and demonstrate that [registrant] will not engage in future misconduct.''' Jayam Krishna-Iyer, 74 FR 459, 463 (2009) (quoting Medicine Shoppe, 73 FR 364, 387 (2008)); see also Jackson, 72 FR at 23,853; John H. Kennnedy, M.D., 71 FR 35,705, 35,709 (2006); Prince George Daniels, D.D.S., 60 FR 62,884, 62,887 (1995).

The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent; therefore, the Agency looks at factors, such as the acceptance of responsibility and the credibility of that acceptance as it relates to the probability of repeat violations or behavior and the nature of the misconduct that forms the basis for sanction, while also considering the Agency's interest in deterring similar acts. See Arvinder Singh, M.D., 81 FR 8247, 8248 (2016).

Here, Respondent has presented no evidence on the record that I could consider as accepting responsibility and I agree with the ALJ's finding that "the Respondent has failed to unequivocally accept any responsibility in this

matter." RD, at 118. Respondent has maintained throughout these proceedings that she believes that her prescribing to the five individuals in question, was proper. See RD, at 117; supra II.C. Respondent did admit that she "agree[d] that the documentation [was] lacking," but she seemed to minimize her inadequate documentation when she stated that "[e]very spoken word that a patient says in a visit, as well as every thought that crosses a clinician's mind in making a decision, cannot possibly be written down on paper." 57 Tr. 22. Respondent also stated in her opening statements, that she "suspect[ed] that the reason that we're really here is because of a pattern of behaviors by the previous owner of the practice . . . [who was] also [her] ex-husband." Tr. 21. Specifically, she suggested that her exhusband had maliciously reported her actions to various places "hoping that [she] would lose [her] license." Id. The limited evidence presented by Respondent and her failure to testify substantively demonstrate a complete unwillingness to accept responsibility for her actions or to appreciate the seriousness of her misconduct.

In all, Respondent failed to explain why, in spite of her misconduct, she can be entrusted with a registration. "The degree of acceptance of responsibility that is required does not hinge on the respondent uttering 'magic words' of repentance, but rather on whether the respondent has credibly and candidly demonstrated that [s]he will not repeat the same behavior and endanger the public in a manner that instills confidence in the Administrator."

Jeffrey Stein, M.D., 84 FR 46968, 49973.

Even if I were to consider her remedial measures, in spite of her complete lack of acceptance of responsibility,58 Respondent's statements that she adjusted her forms following an insurance company's review of her records for quality compliance is nonetheless insufficient to ensure me that her documentation deficiencies will not be repeated in the future. Tr. 22; 332 (Dr. Chambers testified that "at the end of the day, [it is] not the form, [it is] what goes in it' that matters, and that he cannot tell from Respondent's blank forms how she would "change [her] practice mode.").

The Agency also looks to the egregiousness and extent of the

misconduct which are significant factors in determining the appropriate sanction. Garrett Howard Smith, M.D., 83 FR at 18,910 (collecting cases). Here, the ALJ found, and I agree, that the evidence suggests that Respondent's violations "were egregious." RD, at 105. Respondent prescribed controlled substances to three year old F.A. that were "beyond the dose range . . . for a child of [F.A.'s] age and size," Tr. 103, to treat ADD when "it [was] not at all clear to [Dr. Chambers] that [F.A.] . . . [had] ADD." Id. at 92; see also supra II.F.2. Respondent prescribed addictive medications to F.P. at age eleven when "the brain is especially vulnerable to addiction." Id. at 195; see also id. at 120. Respondent prescribed benzodiazepines to K.W. (who already had a history of blackouts, violence, and arrests while on benzodiazepines, supra II.F.3.) that sent K.W. into "a rage," caused her to attempt suicide, and necessitated her being placed in emergency detention and hospitalized. GX 7, at 29. Respondent prescribed "every class of addictive drug and multiple addictive drugs," to M.H., which Dr. Chambers stated likely "contribut[ed] to [her] deterioration" and hospitalization. Tr. 229; see also supra II.F.6. Respondent prescribed both "uppers and downers" to K.W., M.G., F.P., and M.H., the combination of which Dr. Chambers testified is often used for "illicit substance use," and "can create a bipolar pattern of symptoms in someone who [does not] even have bipolar, but if they do have bipolar it could make it worse." Tr. 146.

Indeed, Respondent's found violations go to the heart of the CSA by not complying with the closed regulatory system devised to "prevent the diversion of drugs from legitimate to illicit channels." *Gonzales* v. *Raich*, 545 U.S. 1, 13–14, 27 (2005).

In sanction determinations, the Agency has historically considered its interest in deterring similar acts, both with respect to the respondent in a particular case and the community of registrants. See Joseph Gaudio, M.D., 74 FR 10,083, 10,095 (2009); Singh, 81 FR at 8248. I find that considerations of both specific and general deterrence weigh in favor of revocation in this case. There is simply no evidence that Respondent's egregious behavior is not likely to recur in the future such that I can entrust her with a CSA registration; in other words, the factors weigh in favor of revocation as a sanction.

I will therefore order that Respondent's registration be revoked as contained in the Order below.

⁵⁷ Obviously, capturing "every spoken word" and "every thought that crosses a clinician's mind" is not the documentation standard of care to which Respondent has been held in this matter. *See supra* II.E; Tr. 335.

⁵⁸ See Jones Total Health Care Pharmacy, L.L.C., 81 FR 79,202–03.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. MV3148257 issued to Melanie Baker, N.P., and deny any pending applications for renewal or modification of that registration. This Order is effective June 4, 2021.

D. Christopher Evans,

Acting Administrator.

[FR Doc. 2021–09463 Filed 5–4–21; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Michele L. Martinho, M.D.; Decision and Order

On December 4, 2019, the Drug **Enforcement Administration** (hereinafter, DEA or Government) Administrative Law Judge Mark M. Dowd (hereinafter, ALJ), issued a Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (hereinafter, RD) on the action to revoke the DEA Certificate of Registration Number BM9434440 of Michele L. Martinho, M.D. The ALI transmitted the record to me on January 7, 2020, and asserted that no exceptions were filed by either party. ALJ Transmittal Letter, at 1. Having reviewed and considered the entire administrative record before me, I adopt the ALJ's RD with minor modifications, where noted herein.*

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby dismiss the Order to Show Cause issued to Michele L. Martinho, M.D. This Order is effective immediately.

D. Christopher Evans,

Acting Administrator.

Paul E. Soeffing, Esq., for the Government

Douglas M. Nadjari, Esq. and David Durso, Esq., for the Respondent

Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge

The Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (DEA), issued an Order to Show Cause (OSC),1 dated February 26, 2019, seeking to revoke the Respondent's Certificate of Registration (COR), number BM9434440, pursuant to 21 U.S.C. 824(a)(5), and deny any applications for renewal or modification of such registration and any applications for any other DEA registrations pursuant to 21 U.S.C. 824(a)(5), because the Respondent has been excluded from participation in a program pursuant to section 1320a-7(a) of Title 42. The Respondent requested a hearing on March 13, 2019,² and prehearing proceedings were initiated.3 A hearing was conducted in this matter on October 3, 2019, at the DEA Hearing Facility in Arlington, Virginia.

The issue ultimately to be adjudicated by the Acting Administrator, with the assistance of this recommended decision, is whether the record as a whole establishes by a preponderance of the evidence that the Respondent's subject registration with the DEA should be revoked pursuant to 21 U.S.C. 824(a)(5).

After carefully considering the testimony elicited at the hearing, the admitted exhibits, the arguments of counsel, and the record as a whole, I have set forth my recommended findings of fact and conclusions of law below.

The Allegations

In the OSC, the Government contends that the DEA should revoke the Respondent's DEA COR because she has been excluded from participation in a program pursuant to section 1320a–7(a) of Title 42.

Specifically, the Government alleges the following:

1. The Respondent is registered with the DEA as a practitioner in Schedules II through V under DEA COR BM9434440. The Respondent's COR expires by its terms on January 31, 2020.

2. On June 14, 2017, the Respondent was found guilty in the United States District Court for the District of New Jersey of "Transporting in Aid of-Travel Act-Accepting Bribes in Violation of the Travel Act." Judgment was entered in U.S. v. Michele Martinho, No. 2:14–CR–00271–SRC–1 (D.N.J. filed June 14, 2017).

3. Based on the Respondent's conviction, the U.S. Department of Health and

Human Services, Office of Inspector General ("HHS/OIG"), by letter dated July 31, 2018, mandatorily excluded the Respondent from participation in Medicare, Medicaid, and all federal health care programs for a minimum period of five years pursuant to 42 U.S.C. 1320a-7(a), effective August 20, 2018. Notwithstanding the fact that the underlying conduct for which the Respondent was convicted had no nexus to controlled substances, mandatory exclusion from Medicare, Medicaid, and all federal health care programs by HHS/OIG warrants revocation of the Respondent's registration pursuant to 21 U.S.C. 824(a)(5).

The Hearing

Government's Opening Statement

In the Government's Opening Statement, the Government indicated that revocation is sought for the Respondent's COR involving Schedules II through V, pursuant to 21 U.S.C. 824(a)(5). Tr. 10. The facts in this matter are undisputed and have been stipulated to by the parties. Id. The Respondent was found guilty in U.S. District Court of transporting in aid of the Travel Act and accepting bribes in violation of the Travel Act. Id. The following year, HHS/OIG mandatorily excluded the Respondent from participation in Medicare, Medicaid, and all federal health care programs. Id. at 10-11. Pursuant to 42 U.S.C. 1320a-7(a), the Respondent's exclusion remains in effect, which is the basis upon which the DEA seeks to revoke the Respondent's COR. Id. at 11.

Respondent's Opening Statement

The Respondent asserted in her opening statement that this matter is not about controlled substances, and it has nothing to do with the issuance of prescriptions or record keeping for controlled substances. Id. at 11. The Respondent admitted that the Government is correct that she accepted cash payments in exchange for referring blood work to a particular lab, that she pleaded guilty to a single count violation of the Travel Act, and that she has been excluded by HHS/OIG from participation in Medicare, Medicaid, and all federal health care programs. Id. at 11-12. The Respondent maintained that the evidence will show that the she can be entrusted to maintain and properly use her DEA COR. Id. at 12. Revocation in this matter is not mandatory. Id. at 12. The Respondent

^{*}AI have made minor, nonsubstantive, grammatical changes to the RD. Where I have made any substantive changes, omitted language for brevity or relevance, or where I have added to or modified the ALJ's opinion, I have bracketed the modified language and explained the edit in a footnote marked with an asterisk and a letter in alphabetical order.

¹ ALJ Ex. 1.

² ALJ Ex. 2.

³ ALJ Ex. 3.

asserted that she has accepted responsibility and has demonstrated that she will not engage in misconduct again. *Id.* at 12.

Dr. Martinho completed courses of study in medical ethics before her criminal proceedings began. Id. at 12-13. She also began to lecture other doctors and medical students about her experiences to help prevent them from making the same choices she did. *Id.* at 13-14. She has given over 60 lectures during her own time and at her own expense. Id. at 14. During her sentencing hearing at the U.S. District Court, the presiding judge said that "he felt that her talks had a greater deterrent impact than anything that the court or the U.S. Attorney could have done to prevent other people—to deter other people from engaging in this kind of conduct." Id. at 14. Dr. Martinho's efforts have been featured in the Washington Post, the Wall Street Journal, and on NPR. Id. at 14. The Respondent submitted that the evidence will show that she can be entrusted to maintain her DEA COR. Id. at 15. She has used her COR properly throughout her life. Id. The Respondent argued that the evidence will demonstrate that the Government's application to revoke the Respondent's COR should be denied. Id.

Government's Case in Chief

Before presenting witnesses, the Government offered the sworn and notarized COR history for the Respondent, which was admitted without objection. See GX 1.5 The Government otherwise presented its case in chief through the testimony of a single witness. The Government presented the testimony of a Diversion Investigator (hereinafter, the DI).

The DI

The DI is a Diversion Investigator for the DEA and has been employed by the DEA for two years, currently assigned to the New York Division. Tr. 20. He previously served with the New York City Police Department for 23 years, retiring as a Detective Sergeant. *Id.* at 20. He also served in the U.S. Army Reserves, retiring as a Lieutenant Colonel. *Id.* at 20. He additionally served for four years in the United Nations International Police Task Force in Kosovo, including one year as a Regional Security Officer in Liberia and six months in Iraq working with the

Iragi Police Department. Id. at 20. He has a Bachelor's Degree from City College of New York. Id. at 21. The DI indicated that he was assigned this matter by his group supervisor. Id. at 22. The DI identified the criminal judgment in the criminal case of U.S. v. Michele *Martinho* from the U.S. District Court in Newark, New Jersey. Id. at 23; GX 2. He obtained a copy of the judgment via email from the District Court. Tr. 23. Next, he identified a letter from the HHS/OIG regarding the exclusion of the Respondent from all federal health care programs. Id. at 24; GX 3. He obtained it via email from the OIG. Tr. 25.

The DI identified a screenshot from the OIG's website that demonstrated that the Respondent was still excluded from all federal health care programs as of the morning of October 3, 2019, the date of the hearing in this matter. Tr. 25–26; GX 4. He obtained this document by going to the OIG's website and taking a screenshot of the Respondent's information. Tr. 26. He verified the information on the morning of the hearing by going to the OIG's website, entering the Respondent's name, and confirmed that she was still excluded. *Id.* at 27.

Respondent's Case in Chief

Dr. Michele Martinho, M.D.

The Respondent currently lives in New York, where she has been licensed to practice medicine since 2005. Id. at 29. The Respondent is forty-five years old and has two children for whom the Respondent is the primary caretaker. Id. at 45. She is first generation American, with both of her parents being Portuguese immigrants. Id. She went to Catholic school from grades K-12 and received her undergraduate degree in psychology from New York University. She went on to attend Ross University for medical school for two years in the Caribbean and returned to the United States for her clinical rotations for the last two years, from which she graduated in 2002. Id. at 47. She completed her residency at Mount Sinai Elmhurst Hospital with a focus in internal medicine, which lasted another three years. Id. After completing her residency, she worked at a satellite clinic for the hospital for almost three years in preparation for private practice. *Id.* at 48. She then went into private practice and eventually purchased the practice. Id. at 48-49. Her practice is located in the Lower East Side of Manhattan. *Id.* at 49. It is surrounded by a significant amount of government public housing whose tenants make up a large portion of her practice. Id. Over the years, as the population of

Manhattan has changed, her patients have transitioned to younger patients. *Id.*

The Respondent explained the genesis of her involvement in the criminal activity for which she was convicted. Id. at 50. Prior to her purchasing the practice, the Respondent was introduced by a lab testing representative to K.K., a sales representative for Biodiagnostic Testing Laboratories (BIL), a blood testing lab. Id. at 29-30, 50. BIL was located in New Jersey, but was looking to gain business in New York. Id. at 50-51. The unnamed lab testing representative introduced the Respondent to the owner of BIL. The three of them had dinner together where they offered the Respondent what amounted to a referral fee for referring bloodwork to their lab, to which the Respondent conceded that such financial arrangement does not exist in the medical field. Id. at 51.

She was paid every month by the laboratory's representative with an envelope of cash. Id. Over the course of two and a half years, she received \$155,000. *Id.* at 51–52. When asked about the process that resulted in the bribes, the Respondent explained that patients would come into her office and she would conduct a blood draw on the patients who needed it, including new patients. *Id.* at 80. She decided which lab would get the blood depending on which insurance company the patient had. Id. She testified that BTL lied to her and said they took all insurances. When she found out that they did not take certain insurances, she stopped sending certain patients' blood work to that lab, because she did not want patients getting a bill. Id. She said that either she or a member of her staff would conduct the draw and a note would be placed in the patient's file designating the blood testing lab. Id. at 80–81. She had billing software set up with the lab so she could order the lab tests online. Id. at 81.

The Respondent stopped taking the cash payments once the laboratory owner and a few laboratory representatives were arrested on April 13, 2013, for bribery. *Id.* at 53. The Respondent explained that while she did not know that the referral fee was illegal, she did know that what she was doing in taking the cash was wrong and admitted "[t]hat I own 100 percent." Id. at 53-54. The Respondent admitted that she knew it was wrong to accept the payments at the time she accepted them. Id. at 52. Although the Respondent did not realize that the referral fees would be considered bribes under the law, she admitted that she accepted the money and now realizes they constituted illegal

⁴The Respondent noted that all of the Government's evidence had been stipulated to and that there were no objections to any of the Government's exhibits. Tr. 18.

⁵ GX—Government Exhibit

⁶ The DI was called to sponsor the Government's exhibits. Tr. 18–19.

bribes. Id. at 51. The Respondent understood what she did was also wrong from a moral standpoint. *Id.* at 56. She claimed that she understood that she violated her fiduciary responsibility to her patients, and that she had been questioned by patients at her practice when they learned about the allegations. Id. She found that when she was questioned by patients as to the medical necessity of the blood draws and whether she had only done it for the money, it was a "big moment" for her. Id. at 56-57, 58. She explained that a moderator at one of the health care courses she has attended explained this violation of patient trust aspect to her, and it has affected how she has attempted to remediate herself. Id. at 57. She again claimed full responsibility for her actions and did not place blame on the laboratory or the laboratory representative. Id. When asked pointedly by the Government whether she accepted responsibility for the acts that led to her criminal conviction, the Respondent answered, "[o]ne hundred percent, yes." Id. at 74. She further confirmed that she considers those criminal actions to be serious violations of the law and that she is remorseful. Id. at 74-75. Apart from copays, she had not ever taken cash payments before that time, and has not since. Id. at 52.

The Respondent asserted that while she now understands that ignorance of the law is no excuse, at the time, she did not fully understand what bribery meant. Id. at 54-55. The Respondent ultimately amended her tax returns and paid the taxes on the cash payments. As part of her criminal sentence, the Respondent paid back the \$155,000. Id. at 52, 55-56. She stated that she never conducted medically unnecessary blood draws. Id. at 55. As developed in her criminal case, there was never any allegation by the Government that the blood testing lacked medical necessity. Id. at 58.

The Government's investigation into BTL resulted in the prosecution and conviction of a large number of physicians, including the Respondent. *Id.* at 30. The Respondent cooperated with the Government in the investigation and prosecution involving BTL. The Respondent ultimately pled guilty to violating the federal Travel Act by accepting bribes for sending some of her blood work to BTL. *Id.* at 30. The Respondent continued to lawfully send blood work to two other laboratories, including Quest Diagnostics and Bio Reference. *Id.* at 30–31.

The Respondent testified that her federal criminal case did not involve controlled substances, prescriptions for controlled substances, or record keeping

for controlled substances. Id. at 31. She has never before been disciplined or sanctioned for her prescribing methods with respect to controlled substances or her record keeping practices. Id. The Respondent discussed each of her proposed documentary evidentiary exhibits.7 Id. at 31-32. The Respondent identified a presentencing memorandum given to the District Court judge before her sentencing in 2017. Id. at 32; RX 1.8 The Respondent identified a flyer for Boston Medical Center, which advertised an event, in which she was the keynote speaker for their Ethics and Compliance Week in 2017. Tr. 33; RX 2. The Respondent indicated that this was an example of the type of lectures she has given and continues to give, as discussed in her opening statement. The flyer included a picture, a description of the crime of conviction and the purpose of the lecture. Id. at 33.

The Respondent offered a letter from Dr. B.F., who is an orthopedic surgeon at MD Anderson. Tr. 34; RX 3. Dr. B.F. invited the Respondent to speak with his orthopedic fellows to tell her story and hopefully deter them from engaging in similar behavior for which she had been convicted. Tr. 34. It was submitted to the District Court in conjunction with the presentencing memorandum. Id.; see RX 1. The Respondent offered a letter from Dr. J.E., a professor of philosophy at Marin University. Tr. 35-36; RX 4. The Respondent contacted him and offered to give her presentation to his medical students, which he accepted. Tr. 36. It was also submitted to the District Court in conjunction with the presentencing memorandum. Id.

The Respondent offered a letter from J.W., an ethics professor from Ohio University. Tr. 36-37; RX 5. J.W. arranged for the Respondent to provide a radio presentation on NPR regarding her crime. Tr. 37. The Respondent offered a newspaper article from the Washington Post, featuring the Respondent and her presentation at Georgetown University. Tr. 38; RX 6. The Respondent offered certificates for completion of programs in health care ethics. Tr. 39-41; RX 7, 8. The Respondent offered the transcript of her sentencing hearing before the U.S. District Court conducted on June 14, 2017. Tr. 41; RX 9.

Finally, the Respondent offered a consent agreement between her and the New York State Department of Health State Board for Professional Medical Conduct. Tr. 42; RX 10. The Respondent explained that after her sentencing in

the District Court, a pre-hearing was conducted with the New York State Department of Health, Office of Professional and Medical Conduct, and based upon her efforts at remediation, the Respondent was allowed to continue practicing medicine with no interruptions or restrictions placed on her state license. Tr. 44–45.

Following completion of her ethical course of study at Creighton University, the Respondent discovered that the prosecutor on her criminal case was going to law schools to discuss health care fraud. She offered to go with the prosecutor and tell her side of the story to the students. Tr. 60-61. While the prosecutor declined her invitation, she began to research medical schools, law schools, ethics societies, and medical societies to share her story to whomever would listen and would benefit from her presentation. Id. at 61-62. She sent out a cold email and offered to pay her own travel and expenses for the opportunity to share her story, which has cost approximately \$20,000, in addition to taking her away from her current practice. Id. at 62, 68, 74. As of the date of the instant hearing, the Respondent indicated that she had completed sixtynine of these speaking engagements and continues to do them. Id. at 62-63.

The Respondent discovered "restorative justice" during one of her medical ethics courses and began to focus on that. Id. at 63-64. She found it was not just about being sorry for your conduct, but how she could do better and correct her mistake. Id. at 64. She explained that she understood her crime had affected her patients, other physicians, and the community. Id. at 64-65. The Respondent indicated that medical school does not adequately prepare students for these real-life issues and that she wanted to share her experience as an example. Id. at 65. The Respondent reported that J.W. (see RX 5) was an educator of health care ethics, and that J.W. told the Respondent that she was changing her curriculum to include scenarios such as the Respondent's experience. Id. The Respondent further advised that at one of the schools she spoke, New York Medical College, they established a medical legal course for their law students and medical students to discuss situations similar to the Respondent's in order to better prepare their students. Id. at 66.

The Respondent opened her presentation by giving her name, explaining that she is an internal medicine physician from New York, and that she was convicted of a crime in 2014, referring to herself as a felon. *Id.* at 67. She testified that she always refers

⁷The Government did not object to any of the Respondent's proposed documentary evidence.

⁸ RX—Respondent's Exhibit

to herself as a felon as that is part of her story. *Id.* The Respondent noted statements made by the prosecutor, the sentencing judge, and probation department during her sentencing hearing in support of the Respondent and her remedial actions taken since pleading guilty. Tr. 68–71; RX 9, pp. 9, 13–14.

The Respondent was questioned regarding whether the underlying criminal conduct was "aberrational" and how she can be entrusted to maintain her DEA COR. Id. at 71-72. The Respondent testified that for the past six years, she has been able to reach thousands of medical students and physicians. Id. at 72. She said that some of her presentations at universities have been recorded and are required to be watched by students, so she knows she is making an impact on medicine in this way. Id. She stated that she wants to continue in her profession because it is what she has wanted for her entire life.

When questioned, she indicated that while she had been ordered to complete thirty lectures by the sentencing judge, she had already completed twenty-six speaking engagements by the date of the sentencing hearing. *Id.* at 73. She was ordered to complete thirty presentations within two years of sentencing, which she completed in only six months. *Id.* She further indicated that she has no plans to stop doing her speaking engagements, even though her probation term ended on June 14, 2019. *Id.* at 73–77, 90.

She further offered her cooperation to a number of government agencies as part of her remedial efforts. Tr. 85–87; RX 1, p. 463. She testified that she brought information concerning other potential criminal activity to approximately seven other state and federal law enforcement agencies across the federal government and two states, for which she received a 5K reduction letter for those efforts.9 Tr. 87. The Respondent scored a level 19 of the sentencing guidelines, which would normally carry a punishment of thirty to thirty-seven months in prison. Id. at 88. The prosecutors in the criminal case filed a 5K1 recommendation letter, which recommended that she be sentenced within a guideline level which would make her probation eligible. *Id.* at 88–89. She stated that

every other physician involved in the matter went to prison. *Id.* at 89.

The Respondent indicated that she plans to reapply to participate in Medicare and Medicaid when her exclusion is over. *Id.* at 77. She explained that she had been excluded from Medicare, Medicaid, and the State of New York's Medicaid program, which she appealed and had rescinded. *Id.* at 77–78. She stated that she had been excluded from the state program even though she hadn't been participating in the program following her residency. *Id.* at 78–79.

When I asked the Respondent if she had ever before taken the position that she did not commit the bribery, she responded, no, she had never taken that position, nor the position that bribery was not a serious offense warranting punishment. Id. at 83. She testified that after she had found out she had committed a crime, she had her office manager pick a random selection of patients to determine whether the rate of ordering bloodwork had increased at all based on the bribes. Id. at 84. The office manager picked one-hundred random patients established before the Respondent purchased the practice, one-hundred new patients before using BTL, and one-hundred new patients after starting to use BTL. Id. The office manager found that there was essentially no difference in the rate or frequency of ordering or what types of tests were ordered. Id. at 84.

I asked why she believed that the Acting Administrator should trust her with her COR. Id. at 121. The Respondent asserted credibly that her efforts over the past six years is evidence of her contrition and trying to "pay it forward to the next generation of physicians." Id. at 121–22. She cannot imagine repeating any part of her life from the past six years due to fear of going to jail, not being able to support her children, or not being able to take care of them. Id. at 122. She expressed that she would "never do anything to compromise [her] license ever again." Id.

P.R., J.D., M.S.W., M.Bioethics

P.R. is currently a professor at Temple University's Lewis Katz School of Medicine and the Center for Bioethics Urban Health and Policy. *Id.* at 94. She also serves as the Assistant Director of the Master's program in Urban Bioethics. *Id.* She received her bachelor's degree in political science, a master's degree in social work from the University of Pennsylvania, School of Social Policy and Practice, and a law degree from Temple University's law school. *Id.* at 93. She has previously

taught at Drexel University, Simmons College, and previously worked as a geriatric social worker for approximately five years. *Id.* at 94.

P.R. met the Respondent through an email the Respondent sent to the Center for Urban Bioethics approximately one year before P.R. started at the Center. Id. at 95. After a review of the Respondent's email, P.R. contacted the Respondent to hear more about her experiences and to determine if it would be appropriate for the Respondent to come to the University and speak to the students. *Id.* at 95. P.R. found that the Respondent's experience "would be a good fit for their program" and she invited the Respondent to come and talk to her class of physician assistants in the summer of 2017. Id. at 96. Since that time, the Respondent has spoken to several classes at Temple University. P.R. also invited her to speak to her students at Simmons College, including social work students, and undergraduate health care administration students at Drexel University. Id. at 97.

P.R. described the Respondent's lecture and her presentation to the students. Id. at 97-98. She found the Respondent's story very "honest, raw, and compelling." *Id.* at 97. The Respondent did not minimize her actions or try to make excuses, but explained what she had done and how it had happened. Id. at 98-99. The Respondent explained that apart from the medical knowledge required of health care professionals, it is also important to "have a sense of how to run a business" and other necessary considerations before entering the health care field. Id. at 98.

P.R. expressed that the Respondent showed contrition during her presentation. *Id.* at 100. She also expressed that the Respondent "[a]bsolutely" accepted responsibility for her actions. *Id.*. She found that the Respondent's reputation among the students was one of respect for being candid about her story, and that the students found her talk to be very relevant to their education, and what it looks like to be confronted with ethical decisions in the field. *Id.* at 100–01.

I asked P.R. if the Respondent appeared sincere in her presentations to students. *Id.* at 101. P.R. indicated that the Respondent "could not have been more sincere." *Id.* P.R. expressed that it was clear from the Respondent's demeanor that she was being truthful and honest about her story. *Id.* at 102. There was no doubt in P.R.'s mind that she was absolutely sincere in her presentations. *Id.* The Respondent gave live presentations twice at the Center for Urban Bioethics. She gave four live

⁹ A "5K reduction" refers to USSG § 5Kl.l— Substantial Assistance to Authorities. Upon motion of the Government stating that the defendant has provided substantial assistance in the investigation or prosecution of another person who has committed an offense, the court may depart from the guidelines.

presentations for P.R. in total. Id. at 102-03. She found that the Respondent's talk was beneficial to the students as it demonstrated what a realworld ethical dilemma looks like and not only showed the consequences of making a bad decision, but also what a person can do to correct their mistake. *Id.* at 103–04. P.R. explained what she perceived to be a lack of ethical training in medical school, and found that the Respondent's presentations provided a bridge between this gap. Id. at 104-06. P.R. stated that the Respondent is "exactly the type of doctor I would want to have" and that "we're wanting our students to be." Id. at 105.

Dr. J.G., M.D.

Dr. J.G. received her undergraduate degree from Stony Brook, her master's degree from Brooklyn College, and finally her medical degree at Ross University. Id. at 108. She completed her residency in obstetrics and gynecology at George Washington University. Tr. Id. Afterwards, she began working at Columbia University, Columbia Presbyterian in the Allen Pavilion for two years. Id. at 109. She then joined Mt. Sinai Hospital and Icahn School of Medicine as an Assistant Professor in obstetrics, gynecology, reproduction, endocrine and fertility, and minimally invasive surgery, where she worked until the end of 2013. Id. She went on to BronxCare Health System as an Assistant Professor in obstetrics and gynecology. Id. After her time in academia, she moved into private practice at Maiden Lane Medical before presently moving to join the Respondent at the Respondent's practice as a gynecologist. Id. at 110.

Dr. J.G. met the Respondent during medical school and they became close friends. Id. They have been friends for about 21 years. Id. at 118. She has referred patients to the Respondent and the Respondent has referred patients to her. Id. at 111. Dr. J.G. opined that the Respondent provides excellent care to her patients, is a very thorough and excellent clinician, and that she trusts the Respondent with their care. Id. at 111. Dr. J.G. has found that her patients greatly enjoy being treated by the Respondent. Id. at 111–12. Despite being aware of the Respondent's conviction and the circumstances surrounding it, Dr. J.G. continues to refer patients to the Respondent. Id. at 112. From her observations, she found that one particular patient was "remarkably healthier" after being treated by the Respondent. Id.

Dr. J.G. says that she has personally observed that the Respondent has accepted responsibility for the conduct

which led to her conviction. Id. at 113-14. She has observed the Respondent not only show remorse for her conduct and to try and better understand what she did wrong, but that the Respondent has gone out to share her experiences with medical students and residents. Id. at 114–15. Dr. J.G. reiterated that ethics education is lacking in medical school, and she found the Respondent's lectures to be "beyond remarkable." *Id.* at 115. Based upon her professional and personal interactions with the Respondent, Dr. J.G. has found that the Respondent is an excellent judge of medical treatment. Id. at 115. The Respondent is a thorough clinician and takes her time with each patient to provide thorough treatment. Id. at 115-16. Although Dr. J.G. is preparing to join the Respondent's practice, she does not currently have a financial relationship with the Respondent. Tr. 116. When she refers patients to the Respondent, there is no referral fee or fee sharing and Dr. J.G. noted that that is illegal within the profession. Id. at 117. When Dr. J.G. enters into a practice arrangement with the Respondent, she expects they will share expenses equally for staff, rent and utilities. Id. at 116-17.

Dr. J.G. holds a DEA Certificate of Registration and is familiar with the responsibilities of being a registration holder. *Id.* at 117–18. She believes that the Respondent possesses all of the necessary requirements, ethics, judgment, and aptitude to hold a DEA COR. *Id.* at 118.

The Facts

Stipulations of Fact

The Government and the Respondent have agreed to five stipulations, which I recommend be accepted as fact in these proceedings:

- 1. Respondent is registered with the DEA as a practitioner in Schedules II through V under DEA Certificate of Registration BM9434440 with a registered address of 308A East 15 Street, New York, NY 10003, and a mailing address of 20 River Terrace, Apt. 23E, New York, NY 10282. Respondent's registration expired by its terms on January 31, 2020.
- 2. On June 14, 2017, Respondent was found guilty in the United States District Court for the District of New Jersey of "Transporting in Aid of Travel Act-Accepting Bribes in Violation of the Travel Act," in violation of 18 U.S.C. 1952(a)(3) and 18 U.S.C. 2. Judgment was entered against Respondent in *U.S.* v. *Michele Martinho*, No. 2:14–CR–00271–SRC–1 (D.N.J. filed June 14, 2017).

- 3. Based on Respondent's conviction, the U.S. Department of Health and Human Services, Office of Inspector General ("HHS/OIG"), by letter dated July 31, 2018, mandatorily excluded Respondent from participation in Medicare, Medicaid and all federal health care programs for the minimum period of five years pursuant to 42 U.S.C. 1320a–7(a), effective August 20, 2018.
- 4. Reinstatement of eligibility to participate in Medicare, Medicaid and all federal health care programs after exclusion by HHS/OIG is not automatic.
- 5. Respondent is currently excluded from participation in Medicare, Medicaid and all federal health care programs.

Findings of Fact

The factual findings (FoF) below are based on a preponderance of the evidence, including the detailed, credible, and competent testimony of the aforementioned witnesses, the exhibits entered into evidence, and the record before me.

- 1. The Respondent currently holds DEA COR BM9434440 in Schedules II through V with a registered address of 308A East 15 Street, New York, NY 10003, and a mailing address of 20 River Terrace, Apt. 23E, New York, NY 10282. The Respondent's COR expires by its terms on January 31, 2020. ALJ Ex. 1, 9.
- 2. The Respondent received her undergraduate degree in psychology from New York University. *Id.* at 47.
- 3. The Respondent attended Ross University for medical school and returned to the United States for her clinical rotations, from which she graduated in 2002. *Id.* at 47.
- 4. The Respondent completed her residency at Mount Sinai Elmhurst Hospital with a focus in internal medicine. *Id.* at 47.
- 5. The Respondent worked at a satellite clinic for the hospital for almost three years after her residency. *Id.* at 48.
- 6. The Respondent went into private practice and eventually purchased the practice, which is an internal medicine practice on the Lower East Side of Manhattan. *Id.* at 48–49.
- 7. The Respondent has been licensed to practice medicine in the state of New York since 2005. *Id.* at 29; RX 10.

Respondent's Criminal Act, Conviction, and Exclusion

1. The Respondent pled guilty to "[v]iolating the federal Travel Act for accepting bribes for sending [her patients'] blood work to a laboratory." Tr. 30. She was sentenced to probation for a period of two years, of which the

first twelve months were served in home confinement. RX 9.

- 2. The Respondent has never been disciplined or sanctioned concerning her prescribing of controlled substances. Tr. 30.
- 3. The Respondent's conviction did not involve any controlled substances. *Id.* at 31.
- 4. After her sentencing in her criminal case, the New York State Department of Health, Office of Professional and Medical Conduct, allowed the Respondent "to continue to practice medicine with no interruption and no restriction." *Id.* at 44–45; RX 10.
- 5. The Respondent accepted a referral fee or bribe to send her patients' blood work to Biodiagnostic Testing Labs. Tr. 50–51.
- 6. Every month the lab test representative would give the Respondent an envelope of cash as payment for her use of the lab. *Id.* at 51.
- 7. Over the course of two and a half years, the Respondent received \$155,000 in payments from the testing lab. *Id.*
- 8. The Respondent knew it was wrong to take these payments at the time that she accepted them. *Id.* at 52.
- 9. The Respondent eventually paid taxes on these payments and forfeited them. *Id.*
- 10. The Respondent continued to accept the referral fees until the lab owner and some of the lab representatives were arrested on April 13, 2013. *Id.* at 53.
- 11. When the lab owner was arrested, the Respondent knew that she was in trouble for accepting the cash payments, but that she did not know at the time that the referral fees were illegal. *Id.* at 53–54.
- 12. The Respondent "never put a needle in anyone's arm to draw their blood for any reason except for medical necessity." *Id.* at 55, 58. The Respondent continued to send bloodwork to other labs in the area, without receiving a kickback from those labs. *Id.* at 29–30.
- 13. The Respondent knew accepting the cash payments was wrong as a tax issue. *Id.* at 56.
- 14. The rate of blood work the Respondent ordered was either less than before or "there was essentially no difference in the rate of ordering, in the types of tests" after she started taking the payments. *Id.* at –84.
- 15. There were 29 doctors prosecuted in the Respondent's criminal case. Tr. 65.

- Respondent's Acceptance of Responsibility and Corrective Action
- 1. The Respondent testified that "I blame myself only" and that "I was responsible for all of it." *Id.* at 57.
- 2. The Respondent admits that she violated her fiduciary duty to her patients. *Id.* at 56.
- 3. The Respondent presented her cautionary story to medical students, practicing physicians, health care ethics students and educators. *Id.* at 61–62.
- 4. The Respondent was ordered by the District Court to complete thirty speaking engagements as community service work over a period of two years. GX 2, p. 2.
- 5. The Respondent completed the thirty speaking engagements within six months. Tr. 73.
- 6. The Respondent has completed sixty-nine of these speaking engagements as of the date of the DEA hearing and continues to perform them. *Id.* at 62–63, 66, 73.
- 7. The Respondent makes her presentations to provide "restorative justice" and "to try to make it up to my community." *Id.* at 63–64.
- 8. The Respondent refers to herself as a felon because it is part of her story and will never go away. *Id.* at 67, 75–76.
- 9. The Respondent accepts "one hundred percent" responsibility for the acts that led to her criminal conviction. *Id.* at 74, 83.
- 10. The Respondent has never taken the position that she did not commit the crime to which she eventually pled guilty. *Id.* at 83.
- 11. The Respondent believes her criminal acts were serious violations of the law. *Id.* at 74, 83.
- 12. The Respondent is remorseful for her crime. *Id.* at 75.
- 13. The Respondent has been excluded from Medicare and the State of New York's Medicaid program. *Id.* at 77–78.
- 14. The Respondent plans to reapply to participate with Medicare and Medicaid when her exclusion is over. *Id.* at 77, 87.
- 15. Every doctor in the Respondent's criminal case went to prison except for her and she believes her speaking engagements made the difference in her avoiding jail time. *Id.* at 88–89.
- 16. The Respondent completed her probation on June 14, 2019. *Id.* at 89-90. *P.R.*
- 1. P.R. is a professor at Temple University's Lewis Katz School of Medicine and the Center for Bioethics Urban Health and Policy and also the Assistant Director of the master's program in Urban Bioethics. *Id.* at 94.

- 2. The Respondent has spoken to several of P.R.'s classes including a PA class, a class at Temple University that included a variety of students, two MSW classes and two classes of undergraduate health care administration students at Drexel University. *Id.* at 96–97. Four of these lectures were live, and not recorded. *Id.* at 103.
- 3. The Respondent told these classes her cautionary story and shared that she is a convicted felon. *Id.* at 98.

Dr. J.G.

- 1. Dr. J.G. is a physician who practices in obstetrics and gynecology. *Id.* at 108–
- 2. The Respondent is Dr. J.G.'s best friend and colleague, having met in medical school. *Id.* at 108, 118.
- 3. Dr. J.G. plans to join the Respondent in her office to practice gynecology. *Id.* at 110.
- 4. The Kespondent and Dr. J.G. refer many patients to each other. *Id.* at 111.
- 5. When Dr. J.G. enters into a practice arrangement with Respondent, she expects they will share expenses equally for staff, rent and utilities. *Id.* at 116–17.
- 6. According to Dr. J.G., the Respondent has accepted responsibility for her conduct. She is remorseful and has made remarkable efforts to correct her mistakes by cautioning others about these real pitfalls. *Id.* at 114–115.
- 7. Dr. J.G. believes that the Respondent possesses the necessary ethics, intelligence and aptitude to properly hold a registration and administer and prescribe controlled substances. *Id.* at 118.

Analysis

Credibility Analysis of Fact Witness: The DI

The DI's uncontroverted testimony, while generally limited to the initiation of the investigation and authentication of the Government's exhibits in this matter, was consistent, genuine and credible. The DI effectively explained how the investigation of the Respondent began, and how the DI verified the fact of the Respondent's exclusion from all federal health care programs.

The DI, as a public servant, typically has no personal stake in the outcome of the instant investigation or in the revocation of the Respondent's registration. I noted no animus on the DI's part as to the Respondent. Although he may be viewed as being part of the prosecution team, I saw no indication from his testimony that any partiality interfered with his reliable testimony. Based on a complete review of the DI's presentation of testimony, I find his testimony to be entirely credible.

Credibility Analysis of Fact Witness: P.R.

P.R. is currently a professor at Temple University's Lewis Katz School of Medicine and the Center for Bioethics Urban Health and Policy. Tr. 94. She also serves as the Assistant Director of the Master's program in Urban Bioethics. *Id.* She met the Respondent through an email the Respondent sent to the Center for Urban Bioethics about a year before P.R. started at the Center. *Id.* at 95.

She has gotten to know the Respondent throughout the course of the Respondent's presentations to P.R.'s students. P.R. expressed that the Respondent showed contrition during her presentation. Id. at 100. She also expressed that the Respondent "[a]bsolutely" accepted responsibility for her actions. Id. at 100. P.R. indicated that the Respondent "could not have been more sincere." Id. at 101. P.R. expressed that it was clear from the Respondent's demeanor that she was being truthful and honest about her story. Id. at 102. There was no doubt in P.R.'s mind that the Respondent was absolutely sincere in her presentations.

P.R. presented clear and candid testimony. She shared only a professional relationship with the Respondent. She appeared to be sincere in her description of the Respondent's presentations and corroborated the Respondent's testimony. I find her testimony to be entirely credible.

Credibility Analysis of Fact Witness: Dr. J.G.

Dr. J.G. has prepared to move into the Respondent's private practice as a gynecologist after a career working in hospitals and academia. *Id.* at 108–10. She met the Respondent during medical school and they became close friends. *Id.* at 110. They have been friends for about 21 years. *Id.* at 118. She has referred patients to the Respondent and the Respondent has referred patients to her. *Id.* at 111.

Dr. J.G. reports that she has observed that the Respondent has accepted responsibility for her conduct leading to her conviction. *Id.* at 113–14. She has observed the Respondent not only show remorse for her conduct and try to better understand what she did wrong, but also go out to share her cautionary tale to medical students and residents. *Id.* at 114–15. Based upon her professional and personal interactions with the Respondent, Dr. J.G. has found that the Respondent is an excellent medical diagnostician. *Id.* at 115. The Respondent is a thorough clinician and

takes her time with each patient to provide thorough medical care. *Id.* at 115–16. Dr. J.G. holds a DEA Certificate of Registration and is familiar with the responsibilities of being a registration holder. *Id.* at 117–18. She believes that the Respondent possesses all of the necessary requirements, ethics, judgment, and aptitude to hold a DEA COR. *Id.* at 118.

Dr. J.G. presented clear and candid testimony. She appeared to be sincere in her description of the Respondent's remorse and acceptance of responsibility, and corroborated the Respondent's testimony. Although they have been lifelong friends and soon-to-be business partners, I do not find that Dr. J.G. was unduly influenced by any personal relationship, or financial gain, or overt loyalty to the Respondent such that it interfered with her testimony. I find her testimony to be entirely credible.

Credibility Analysis of Fact Witness: Dr. Michele Martinho

The Respondent explained the circumstances leading up to her underlying criminal conviction. She met with a lab testing representative who offered the Respondent referral fees to send their laboratory bloodwork. Tr. 50-51. The Respondent was paid every month in cash by the representative. Id. at 51. Over the course of two-and-a-half years, she was paid \$155,000, which the Respondent indicated has been forfeited, and the taxes paid. Id. at 51-52, 55-56. On June 14, 2017, the Respondent was found guilty in the United States District Court for the District of New Jersey of "Transporting in Aid of Travel Act-Accepting Bribes in Violation of the Travel Act," in violation of 18 U.S.C. 1952(a)(3) and 18 U.S.C. 2. See Stipulation 2.

The Respondent admitted that she knew it was wrong to accept the payments at the time she accepted them. Id. at 52. Apart from copays, she had not ever taken cash payments before that time, and has not since. Id. The Respondent asserted that while she now understands that ignorance of the law is no excuse, at the time, she did not fully understand what bribery meant. Id. at 54-55. She stated that she never conducted medically unnecessary blood draws. *Id.* at 55. The Respondent provided lengthy testimony that she has fully accepted responsibility for her conduct. She further testified as to her remedial efforts and how she has continued speaking engagements on her own in order to share her story and help prevent others from making the same decisions that she made that resulted in

her criminal conviction and exclusion from all federal health care programs.

The Respondent presented clear and candid testimony. She appeared to be sincere in her remorse and acceptance of responsibility. Although the stakes are very high in this proceeding, as the Agency's investigation and prosecution could effectively preclude the Respondent from practicing medicine, the Respondent did not appear to color her testimony. She appeared sincere and authentic. Her commitment to remedial efforts in the form of numerous cautionary lectures to health care professionals and to medical students is probably the most convincing evidence of the Respondent's acceptance of responsibility, remorse, and evidence she is trustworthy of her responsibilities as a possessor of a DEA COR. She presented her testimony in a consistent and convincing manner, and I find her testimony to be entirely credible.

Findings as to Allegations

The Government alleges that the Respondent's COR should be revoked and any pending applications be denied because the Respondent has been excluded from all federal health care programs, pursuant to 21 U.S.C. 824(a)(5). The Agency has held that section 824(a)(5) authorizes the revocation of existing registrations, as well as the denial of applications. Dinorah Drug Store, Inc., 61 FR 15972 (1996); Kuen H Chen, MD., 58 FR 65401 (1993).

In the adjudication of a revocation or suspension of a DEA COR, DEA has the burden of proving that the requirements for such revocation or suspension are satisfied. 21 CFR 1301.44(e) (2010). Where the Government has sustained its burden and made its prima facie case, a respondent must both accept responsibility for her actions and demonstrate that she will not engage in future misconduct. Patrick W Stodola. MD., 74 FR 20727, 20734 (2009). Acceptance of responsibility and remedial measures are assessed in the context of the "egregiousness of the violations and the [DEA's] interest in deterring similar misconduct by [the] Respondent in the future as well as on the part of others." David A. Ruben, M.D., 78 FR 38363, 38364 (2013). Where the Government has sustained its burden, that registrant must present sufficient mitigating evidence to assure the Acting Administrator that he/she can be entrusted with the responsibility commensurate with such a registration. Medicine Shoppe-Jonesborough, 73 FR 364387 (2008).*B

^{*}B [Text omitted for brevity].

Exclusion Under U.S.C. 1320a–7(a)

The Government has alleged that the Respondent has been excluded from participation in a program pursuant to section 1320a-7(a) of Title 42. The Government can meet its burden under § 824(a)(5) simply by advancing evidence that the registrant has been excluded from a federal health care program under 42 U.S.C. 1320a-7(a). Johnnie Melvin Turner, MD., 67 FR 71203 (2002); Dinorah Drug Store, Inc., 61 FR at 15973. The Administrator has sanctioned registrants where the Government introduced evidence of a registrant/applicant's plea agreement and judgment, and the resulting letter of exclusion from the U.S. Department of Health and Human Services, Office of Inspector General, imposing mandatory exclusion under section 1320a-7(a). See Richard Hauser, MD., 83 FR 26308

Additionally, the Agency has consistently held that the underlying conviction that led to mandatory exclusion does not need to involve controlled substances to support a revocation or denial. See, e.g., Mohammed Asgar, MD., 83 FR 29569 (2018); Narciso A. Reyes, MD., 83 FR 61678 (2018); Richard Hauser, M.D., 83 FR at 26308; Orlando Ortega-Ortiz, M.D., 70 FR 15122 (2005); Juan Pillot-Costas, MD., 69 FR 62804 (2004). However, evidence that the underlying conviction does not relate to controlled substances can be used in mitigation. Mohammed Asgar, MD., 83 FR at 29573 (noting respondent's conviction "did not involve the misuse of his registration to handle controlled substances"); Kwan Bo Jin, M.D., 77 FR 35021, 35027 (2012) (showing a lack of evidence concerning respondent's 'prescribing practices''). The Agency must determine if a sanction is appropriate where the record demonstrates "questions as to the" registrant's integrity. Anibal P. Herrera, MD., 61 FR 65075, 65078 (1996).

Government's Burden of Proof and Establishment of a Prima Facie Case

Based upon my review of the allegations by the Government, it is necessary to determine if it has met its *prima facie* burden of proving the requirements for a sanction pursuant to 21 U.S.C. 824(a).

It is clear from the stipulations, the Government's evidence, and the Respondent's position in this matter that there is no controversy between the parties that the Respondent was convicted of the underlying criminal charge in the U.S. District Court for the District of New Jersey, and was

subsequently mandatorily excluded from all federal health care programs by HHS/OIG, pursuant to 42 U.S.C. 1320a–7(a). The Government's evidence clearly demonstrates the necessary elements of proof under 21 U.S.C. 824(a)(5) and I find that the Government has established a *prima facie* case for revocation of the Respondent's COR and denial of any pending applications.

Therefore, the remaining issue, and the central focus for determination in this matter, is whether the Respondent has sufficiently demonstrated that she has accepted responsibility for her actions, has demonstrated remorse, and has taken sufficient rehabilitative and remedial steps to demonstrate to the Acting Administrator that she can be entrusted to maintain her COR. Kwan Bo Jin, MD., 77 FR at 35021. The Agency must determine whether revocation is the appropriate sanction "to protect the public from individuals who have misused controlled substances or their DEA Certificate of Registration and who have not presented sufficient mitigating evidence to assure the Administrative that they can be trusted with the responsibility carried by such a registration." Jeffrey Stein, M.D., 84 FR 46968, 46973 (2019) (quoting Leo R. Miller, MD., 53 FR 21931, 21932 (1988)). "The Agency also looks to the nature of the crime in determining the likelihood of recidivism and the need for deterrence." Id. In determining whether and to what extent a sanction is appropriate, consideration must be given to both the egregiousness of the offenses established by the Government's evidence and the Agency's interest in both specific and general deterrence. David A. Ruben, M.D., 78 FR 38363, 38364, 38385 (2013).*C

Acceptance of Responsibility and Rehabilitative Measures

The Government's prima facie burden having been met, []*D the Respondent must present sufficient mitigating evidence to assure the Administrator that she can be entrusted with the responsibility incumbent with such registration. Medicine Shoppe, 73 FR at 387; Samuel S. Jackson, 72 FR 23848, 23853 (2007). *[]The egregiousness and extent of an applicant's misconduct are significant factors in determining the appropriate sanction. See Jacobo Dreszer, 76 FR 19386, 19387–88 (2011) (explaining that a respondent can "argue that even though the

Government has made out a *prima facie* case, his conduct was not so egregious as to warrant revocation"); *Paul H. Vollanan*, 73 FR 30630, 30644 (2008); *Gregory D. Owens*, 74 FR 36751, 36757 n.22 (2009).

Since the exposure of the "kick-back" scheme, the Respondent has maintained a consistent posture of acknowledging the impropriety and illegality of her actions, of cooperation with the Government and of truly commendable and extensive remedial efforts toward her goal of "restorative justice." She has fully accepted responsibility for her conduct, which led to the underlying criminal conviction, both in her criminal prosecution, as well as in the instant proceeding. Tr. 83; FoF 33. The Respondent testified credibly during the hearing that "I blame myself only" and that "I was responsible for all of it." Tr. 57; FoF 24. When directly asked by Government counsel during crossexamination if she accepted responsibility, she stated that she accepts "one-hundred percent" responsibility for the acts that led to her criminal conviction. Tr. 74, 83; FoF 32. The Respondent has further demonstrated remorse for her crime. Tr. 75; FoF 35. She has repaid the bribes, amended her tax returns, and paid the taxes on the money she took. Tr. 52; FoF 17. As for her speaking engagements, the Respondent has completed sixtynine speaking engagements, far beyond the required thirty speaking engagements ordered by the District Court, and continues to complete speaking engagements even though she is no longer required to do so. Tr. 61-63, 66, 73; GX 2, p.2; FoF 26-29. She completed all requirements for her probation on June 14, 2019. Tr. 89–90; FoF 39. She has consistently demonstrated that she has taken the necessary steps to rehabilitate herself and has demonstrated contrition for her conduct that led to her underlying conviction.

During the underlying criminal proceedings, both the Assistant United States Attorney (AUSA) and the sentencing U.S. District Court Judge believed that the Respondent had accepted responsibility for her conduct. The AUSA stated during the Respondent's sentencing hearing that the Respondent "had demonstrated a level of contrition that has been unique among the many, many doctors that we've dealt with in this case." Tr. 68–69; RX 9. Further, U.S. District Court Judge Stanley R. Chesler found that the

 $^{^{\}star \mathrm{C}}$ Analysis of public interest factors omitted for relevance.

^{*}DOmitted text for clarity and omitted text throughout this section where noted with an asterisk to remove the public interest analysis.

Respondent had accepted responsibility. medical staff and to students has RX 9.*E

Although correcting improper behavior and practices is very important to establish acceptance of responsibility, conceding wrongdoing is critical to reestablishing trust with the Agency. Holiday CVS, L.L.C., 77 FR 62316, 62346 (2012); Daniel A. Glick, D.D.S., 80 FR at 74801. Based upon the evidence presented, I find that the Respondent has demonstrated the full measure of acceptance of responsibility, and has fully demonstrated that she is remorseful of her actions and has taken considerable rehabilitative steps to ensure that this conduct will not be repeated.

Loss of Trust

Where the Government has sustained its burden and established that a registrant has committed acts inconsistent with the public interest, that registrant must present sufficient mitigating evidence to assure the Acting Administrator that he can be entrusted with the responsibility commensurate with such a registration. *Medicine Shoppe*, 73 FR at 387.

As demonstrated by the evidence presented in this matter, it is clear to me that the Respondent has unequivocally accepted responsibility for her conduct. She continues to not only improve herself, but works to ensure that current and future practitioners learn from her past criminal conduct and will not make the same choices. [I also find credible Respondent's statement that she would "never do anything to compromise [her] license ever again." Tr. 122.] Her underlying criminal conduct did not relate to her handling of controlled substances and the Government has not alleged any deficiencies by the Respondent related to controlled substances. The Government argues that revocation in this matter is appropriate for its deterrent effect. *[]*[Further, although I am not bound by them in this case, I agree with the statements of U.S. District Court Judge Chesler found that "in many ways your efforts may have as much, if not more, impact than the prosecutions per se because it sends out a message and it sends out a message from someone who has personally impacted by having made the wrong decision." RX 9. It appears the Respondent's outreach to physicians,

provided and continues to provide valuable deterrence to the medical community. The Respondent's efforts have greatly satisfied the need for deterrence. At sentencing, the AUSA stated that the Respondent's "efforts have been substantial, including the speaking engagements that she's been involved with. I can tell you, your Honor, that I have heard unsolicited from folks in the medical field about the work that she has been doing and folks who are involved in educating physicians and supervising physicians have reported to me that her efforts have made an impact in educating the community, which is meaningful thing from the government's perspective." RX 9. *[In this case,] the Respondent has clearly demonstrated that she can be entrusted to properly maintain her COR.

Recommendation

Considering the entire record before me, the conduct of the hearing, and observation of the testimony of the witnesses presented, I find that the Government has met its burden of proof and has established a prima facie case for revocation. However, *[] the evidence overwhelmingly suggests that the Respondent has unequivocally accepted responsibility, is remorseful for her conduct, has worked to rehabilitate herself, has taken extraordinary steps to educate medical personnel and students, and has presented convincing evidence demonstrating that the Agency can entrust her to maintain her COR. Therefore, I recommend the Respondent's DEA COR BM9434440 should Not be Revoked and any pending applications for renewal or modification of such registration, or for additional DEA registrations, be Granted

December 4, 2019
Mark M. Dowd,
U.S. Administrative Lay

U.S. Administrative Law Judge.

[FR Doc. 2021–09464 Filed 5–4–21; 8:45 am] BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration [Docket No. 20–21]

Emmanuel A. Ayodele, M.D.; Decision and Order

On April 29, 2020, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Emmanuel Ayodele, M.D. (hereinafter, Applicant) of Compton, California. OSC, at 1. The OSC proposed the denial of Applicant's application for a DEA Certificate of Registration. *Id.* It alleged that Applicant is without "authority to handle controlled substances in California, the state in which [Applicant] seek[s] registration with DEA." *Id.* (citing 21 U.S.C. 824(a)(3)).

Specifically, the OSC alleged that the Medical Board of California (hereinafter, MBC) issued an order on February 3, 2020, revoking Applicant's California Physician's and Surgeon's Certificate. *Id.* at 2. The OSC further alleged that, because the Board revoked Applicant's medical license, Applicant lacks the authority to handle controlled substances in the State of California. *Id.*

The OSC notified Applicant of the right to request a hearing on the allegations or to submit a written statement, while waiving the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 2–3 (citing 21 CFR 1301.43). The OSC also notified Applicant of the opportunity to submit a corrective action plan. *Id.* at 3 (citing 21 U.S.C. 824(c)(2)(C)).

On June 24, 2020, Applicant, through counsel, requested a hearing, stating that Applicant "has filed a writ of administrative mandate in the Superior Court of California, San Francisco Division . . . for judicial review of the decision of the Medical Board of California" and that "DEA should await the final judgment." Request for a Hearing, at 1.

The Office of Administrative Law Judges put the matter on the docket and assigned it to Chief Administrative Law Judge John J. Mulrooney II (hereinafter, Chief ALJ), who issued an Order Directing the Filing of Government Evidence Regarding its Lack of State Authority Allegation and Briefing Schedule on June 25, 2020, with which the Government complied by filing a Motion for Summary Disposition (hereinafter, Govt Motion) on July 7, 2020.

In its Motion, the Government submitted evidence that the MBC "found [Applicant] non-compliant with the probationary terms of its June 2017 order, ultimately resulting in the revocation of his California Physician's and Surgeon's Certificate." Govt Motion, at 3–4. Further, the Government noted that the MBC had denied Applicant's Petition for Review of his revocation on April 14, 2020. *Id.* In light of these facts, the Government argued that DEA must deny Applicant's application. *Id.* at 5.

On July 15, 2020, Applicant filed "Applicant's Reply" (hereinafter, App

^{*}E Removed text. I agree with the Government that the District Court's findings on acceptance of responsibility are not binding on this agency, see Govt Posthearing Brief, at 9; however, I also agree with the ALJ that these findings are relevant in that they further support the ALJ's finding of Respondent's credible acceptance of responsibility. See Mohammed Asgar, MD., 83 FR at 29573 n.3.

Reply), in which he argued that there are no proceedings to stay, because Applicant is not requesting an action on his application at this time; therefore, he argued that the "sole issue presented is whether the DEA should withhold action on [Applicant's] application—which was submitted before his [California] medical license was revoked—until a final judgment is entered on his state petition for judicial review of the MBC's decision." App Reply, at 1.

On July 21, 2020, the Chief ALJ issued an Order Granting the Government's Motion for Summary Disposition, and Recommended Rulings, Findings of Fact, Conclusions of Law, and Recommended Decision of the Administrative Law Judge (hereinafter, Summary Disposition or SD). The Chief ALJ noted that, "[c]ontrary to the [Applicant's] assertions . . . the instant proceedings are, in fact, proceedings.' SD, at 4 (citations omitted). Further, the ALJ noted that it appeared that Applicant was not contesting the underlying facts surrounding the grounds for the proceedings. Id. at 5. Therefore, the Chief ALI determined that "in view of the Applicant's current lack of state authority, denial of the Applicant's application stands as the only legally available resolution." Id. The Chief ALJ further concluded that "[s]ummary disposition is proper in an administrative enforcement proceeding where no genuine factual dispute exists." Id. at 6 (citing Veg-Mix, Inc. v. U.S. Dept. of Agriculture, 832 F.3d 601, 607 (D.C. Cir. 1987) (comparing the standard for summary disposition in an administrative proceeding to summary judgment in a civil proceeding); Citizens for Allegan County, Inc. v. Federal Power Commission, 414 F.2d 1125, 1128 (D.C. Cir. 1969) (affirming that "the right of opportunity for hearing does not require a procedure that will be empty sound and show, signifying nothing")).

By letter dated August 18, 2020, the ALJ certified and transmitted the record to me for final Agency action. In that letter, the ALJ advised that neither party filed exceptions. I find that the time period to file exceptions has expired. See 21 CFR 1316.66.

I issue this Decision and Order based on the entire record before me. 21 CFR 1301.43(e). I make the following findings of fact.

Findings of Fact

Applicant's DEA Registration

On or about June 6, 2018, Applicant filed an application (Application Control No. H18074119C) for a DEA Certificate of Registration as a practitioner in schedules II–V, with the proposed registered location of 1406 W 134th Street, Compton, California 90222. Govt Motion Exhibit (hereinafter, GX) 2 (Certification of Registration History), at 1.

The Status of Applicant's California License

On February 3, 2020, the MBC revoked Applicant's medical license. GX 3 (MBC Order), at 19. According to the Order, Applicant was suspended by the MBC following Applicant's October 10, 2013 felony conviction for health care fraud. Id. On June 16, 2017, the MBC adopted a Stipulated Settlement and Disciplinary Order, which imposed a period of probation, during which Applicant would be required to complete continuing medical education coursework, perform community service, obtain a psychological evaluation at his own expense, pay all probation costs, and complete a clinical competence assessment program. Id. at 3. Applicant failed to meet the terms of his probation and therefore, the MBC revoked Applicant's medical license. GX 3, at 19. The Applicant petitioned the MBC for reconsideration and his petition was denied on April 14, 2020. GX 4 (MBC Order Denying Petition for Reconsideration).

According to the online records of the California Department of Consumer Affairs, of which I take official notice, Applicant's license remains revoked.¹ https://search.dca.ca.gov/results (last visited date of signature of this Order). California's online records show that Applicant's medical license remains revoked and that Applicant is not authorized in California to practice medicine. Id.

As the Chief ALJ noted, Applicant does not appear to contest the status of his medical license or his state authorization to handle controlled substances. See SD, at 5 (citing App Reply, at 2). Based on the entire record

before me, I find that Applicant currently is not licensed to engage in the practice of medicine in California.

Discussion

Applicant's application requests registration as a "practitioner" in California. GX 1 (Applicant's Application). With respect to a practitioner, the DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. See, e.g., James L. Hooper, M.D., 76 FR 71371 (2011), pet. for rev. denied, 481 F. App'x 826 (4th Cir. 2012); Frederick Marsh Blanton, M.D., 43 FR 27616, 27617 (1978).

This rule derives from the text of two provisions of the Controlled Substances Act (hereinafter, CSA). Controlled Substances Act (hereinafter, CSA). Pursuant to section 303(f) of the CSA, a prerequisite to registration as a practitioner is authorization to dispense controlled substances under the laws of the state in which the Applicant seeks to be registered.² 21 U.S.C. 823(f) ("The Attorney General shall register practitioners . . . to dispense . . controlled substances . . . if the Applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices."). Further, the CSA defines "practitioner" as "a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice." 21 U.S.C. 802(21).

The Agency has long interpreted these statutory requirements strictly. The "controlling question" is "whether the Applicant is currently authorized to handle controlled substances in the state." Anne Lazar Thorn, M.D., 62 FR 12847, 12848 (1997); see also Frederick Marsh Blanton, M.D., 43 FR 27616 (1978). Accordingly, the Agency has rejected arguments that it should relax these statutory requirements. For example, the Agency rejected as "of no consequence" the fact that the MBC summarily suspended a doctor's California medical license. Robert T. Perez, M.D., 84 FR 3247, 3248 (2019). "What is consequential," the Agency

¹ Under the Administrative Procedure Act, an agency "may take official notice of facts at any stage in a proceeding-even in the final decision. United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), "[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary." Accordingly, Applicant may dispute my finding by filing a properly supported motion for reconsideration within fifteen calendar days of the date of this Order. Any such motion shall be filed with the Office of the Administrator and a copy shall be served on the Government. In the event Applicant files a motion, the Government shall have fifteen calendar days to file a response. Any such motion and response may be filed and served by email (dea.addo.attorneys@dea.usdoj.gov).

² "[D]ispense[] means to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance. . . ." 21 CFR 802(10).

determined, "is my finding that Registrant is no longer currently authorized to dispense controlled substances in California, the State in which he is registered." Id. Similarly, the Agency rejected as "of no consequence" the argument that the MBC had not vet afforded the doctor a hearing to challenge the suspension of his California medical license. Frank D. Li, M.D., 82 FR 11238, 11240 (2017). See also Miles J. Nelson, M.D., 84 FR 3248, 3250 (2019) (summary suspension of state authority or state authority pending a final decision on the merits are of no consequence); Bourne Pharmacy, Inc., 72 FR 18273, 18274 (2007) ("Under the . . . [CSA], it is irrelevant that Applicant's state registration is being held in escrow pending state proceedings. Under the . . . [CSA], a practitioner must be currently authorized to handle controlled substances in 'the jurisdiction in which [it] practices' in order to maintain its DEA registration.").

According to California statute, "[n]o person other than a physician . . . shall write or issue a prescription." Cal. Health & Safety Code § 11150 (West 2021). Further, "physician," as defined by California statute, is a person who is "licensed to practice" in California. *Id*. at § 11024.

Here, the undisputed evidence in the record is that Applicant currently lacks authority to practice medicine in California. As already discussed, a physician must be a licensed practitioner to dispense a controlled substance in California. Thus, because Applicant lacks authority to practice medicine in California and, therefore, is not authorized to handle controlled substances in California, Applicant is not eligible to be granted a DEA registration. Accordingly, I will order that Applicant's application for a DEA registration be denied.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny the application submitted by Emmanuel Ayodele, M.D for a Certificate of Registration, Control Number H18074119C, as well as any other pending application of Emmanuel Ayodele, M.D. for additional registration in California. This Order is effective June 4, 2021.

D. Christopher Evans,

Acting Administrator.

[FR Doc. 2021–09461 Filed 5–4–21; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Trade Adjustment Assistance

In accordance with the Section 223 (19 U.S.C. 2273) of the Trade Act of 1974 (19 U.S.C. 2271, et seq.) ("Act"), as amended, the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance under Chapter 2 of the Act ("TAA") for workers by (TA-W) number issued during the period of March 1, 2021 through March 31, 2021. (This Notice primarily follows the language of the Trade Act. In some places however, changes such as the inclusion of subheadings, a reorganization of language, or "and," "or," or other words are added for clarification.)

Section 222(a)—Workers of a Primary Firm

In order for an affirmative determination to be made for workers of a primary firm and a certification issued regarding eligibility to apply for TAA, the group eligibility requirements under Section 222(a) of the Act (19 U.S.C. 2272(a)) must be met, as follows:

(1) The first criterion (set forth in Section 222(a)(1) of the Act, 19 U.S.C. 2272(a)(1)) is that a significant number or proportion of the workers in such workers' firm (or "such firm") have become totally or partially separated, or are threatened to become totally or partially separated;

AND (2(A) or 2(B) below)

(2) The second criterion (set forth in Section 222(a)(2) of the Act, 19 U.S.C. 2272(a)(2)) may be satisfied by either (A) the Increased Imports Path, or (B) the Shift in Production or Services to a Foreign Country Path/Acquisition of Articles or Services from a Foreign Country Path, as follows:

(A) Increased Imports Path

(i) The sales or production, or both, of such firm, have decreased absolutely;

AND (ii and iii below)

(ii) (I) imports of articles or services like or directly competitive with articles produced or services supplied by such firm have increased; OR

(II)(aa) imports of articles like or directly competitive with articles into which one or more component parts produced by such firm are directly incorporated, have increased; OR

(II) (bb) imports of articles like or directly competitive with articles which are produced directly using the services supplied by such firm, have increased; OR

(III) imports of articles directly incorporating one or more component parts produced outside the United States that are like or directly competitive with imports of articles incorporating one or more component parts produced by such firm have increased:

AND

(iii) the increase in imports described in clause (ii) contributed importantly to such workers' separation or threat of separation and to the decline in the sales or production of such firm; OR

(B) Shift in Production or Services to a Foreign Country Path OR Acquisition of Articles or Services From a Foreign Country Path

- (i) (I) there has been a shift by such workers' firm to a foreign country in the production of articles or the supply of services like or directly competitive with articles which are produced or services which are supplied by such firm; OR
- (II) such workers' firm has acquired from a foreign country articles or services that are like or directly competitive with articles which are produced or services which are supplied by such firm;

AND

(ii) the shift described in clause (i)(I) or the acquisition of articles or services described in clause (i)(II) contributed importantly to such workers' separation or threat of separation.

Section 222(b)—Adversely Affected Secondary Workers

In order for an affirmative determination to be made for adversely affected secondary workers of a firm and a certification issued regarding eligibility to apply for TAA, the group eligibility requirements of Section 222(b) of the Act (19 U.S.C. 2272(b)) must be met, as follows:

(1) A significant number or proportion of the workers in the workers' firm or an appropriate subdivision of the firm have become totally or partially separated, or are threatened to become totally or partially separated;

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(2) the workers' firm is a supplier or downstream producer to a firm that employed a group of workers who received a certification of eligibility under Section 222(a) of the Act (19 U.S.C. 2272(a)), and such supply or production is related to the article or service that was the basis for such certification (as defined in subsection 222(c)(3) and (4) of the Act (19 U.S.C. 2272(c)(3) and (4));

AND

(3) either—

(A) the workers' firm is a supplier and the component parts it supplied to the firm described in paragraph (2) accounted for at least 20 percent of the production or sales of the workers' firm; OR

(B) a loss of business by the workers' firm with the firm described in paragraph (2) contributed importantly to the workers' separation or threat of separation determined under paragraph (1).

Section 222(e)—Firms Identified by the International Trade Commission

In order for an affirmative determination to be made for adversely affected workers in firms identified by the International Trade Commission and a certification issued regarding eligibility to apply for TAA, the group eligibility requirements of Section 222(e) of the Act (19 U.S.C. 2272(e))must be met, by following criteria (1), (2), and (3) as follows:

(1) The workers' firm is publicly identified by name by the International

Trade Commission as a member of a domestic industry in an investigation resulting in—

(A) an affirmative determination of serious injury or threat thereof under section 202(b)(1) of the Act (19 U.S.C. 2252(b)(1)); OR

(B) an affirmative determination of market disruption or threat thereof under section 421(b)(1)of the Act (19 U.S.C. 2436(b)(1)); OR

(C) an affirmative final determination of material injury or threat thereof under section 705(b)(1)(A) or 735(b)(1)(A) of the Tariff Act of 1930 (19 U.S.C. 1671d(b)(1)(A) and 1673d(b)(1)(A));

AND

(2) the petition is filed during the 1year period beginning on the date on which—

(A) a summary of the report submitted to the President by the International Trade Commission under section 202(f)(1) of the Trade Act (19 U.S.C. 2252(f)(1)) with respect to the affirmative determination described in paragraph (1)(A) is published in the **Federal Register** under section 202(f)(3) (19 U.S.C. 2252(f)(3)); OR

(B) notice of an affirmative determination described in subparagraph (B) or (C)of paragraph (1) is published in the **Federal Register**;

ND.

- (3) the workers have become totally or partially separated from the workers' firm within—
- (A) the 1-year period described in paragraph (2); OR
- (B) notwithstanding section 223(b) of the Act (19 U.S.C. 2273(b)), the 1-year period preceding the 1-year period described in paragraph (2).

Affirmative Determinations for Trade Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of Section 222(a)(2)(A) (Increased Imports Path) of the Trade Act have been met.

TA-W No.	Subject firm	Location	Impact date
95,380	Columbian Home Products, LLC	Terre Haute, IN	November 15, 2018.
95,484	Anthony Timberlands, Inc	Beirne, AR	December 16, 2018.
95,769	Stewart and Stevenson, LLC, Manufacturing, Kirby, TPI Staffing, Weldforce Fabricators, etc.	Houston, TX	March 3, 2019.
96,080	Hemlock Semiconductor Operations LLC, HSC Holdings LLC, Qualified Staffing Services, Adecco USA Inc.	Hemlock, MI	July 22, 2019.
96,120	Sunbury Textile Mills, Inc., Glen Raven Custom Fabrics, LLC, Ravenwood International Corp.	Sunbury, PA	August 4, 2019.
96,175	Exterran Energy Solutions, L.P., Compression Fabrication Services, Exterran, Aerotek, etc.	Houston, TX	September 2, 2019.
96,196	Cameron International Corporation, Schlumberger Limited	Little Rock, AR	September 16, 2019.
96,402	JSW Steel (USA), Inc	Baytown, TX	September 25, 2019.
96,553	Entergy Nuclear Operations, Inc	Buchanan, NY	September 28, 2019.
96,610	Kennametal, Industrial	Johnson City, TN	November 10, 2019.
96,671	Tube Forgings of America, Inc	Portland, OR	January 14, 2020.
96,721	EVRAZ Oregon Steel	Portland, OR	April 20, 2020.

The following certifications have been issued. The requirements of Section 222(a)(2)(B) (Shift in Production or

Services to a Foreign Country Path or Acquisition of Articles or Services from a Foreign Country Path) of the Trade Act have been met.

TA-W No.	Subject firm	Location	Impact date
95,839	IPSCO Koppel Tubulars, Inc., Tenaris S.A	Baytown, TX	March 23, 2019.
96,081	Overhead Door Corporation, TODCO Division, Surge and Custom Staffing	Marion, OH	July 22, 2019.
96,098	PK USA, Inc., Press Kogyo Co., Ltd	Shelbyville, IN	July 24, 2019.
96,507		Hampton, VA	September 30, 2019.
96,542	Choice Hotels International Services Corp., Customer Care/Customer Engagement and Support Department.	Phoenix, AZ	October 8, 2019.
96,552	DUS—Operations Inc., Operations and Controlled Systems Division Dura Automotive Systems LLC.	Milan, TN	October 12, 2019.
96,562	Lee Enterprises, Incorporated, Lee BHM Corp., Omaha World-Herald, Advertising Department Lee BHM Corp., and under BH Media Group, Inc.	Omaha, NE	October 16, 2019.
96,642	SuperVista North America, Inc., Marketing	Irvine, CA	December 10, 2019.
96,675	Cardinal Health, Inc., Presource Division	Fort Mill, SC	January 19, 2020.
96,688	Torax Medical Inc	Saint Paul, MN	January 27, 2020.
96,690	HSBC Technology and Services, USA, U.S. Operational Risk Oversight team.	Depew, NY	February 12, 2021.
96,695	Grass Valley USA LLC, Global Billing/Finance	Grass Valley, CA	January 29, 2020.

TA-W No.	Subject firm	Location	Impact date
96,706	Betsy & Adam Ltd	New York, NY	January 19, 2020.
96,722	Eaton Corporation	Watertown, WI	February 11, 2020.
96,723	West Penn Wire, Assembly Dept	Washington, PA	February 11, 2020.
96,726	Zimmer, Inc. and Zimmer US, Inc., Finance, HR, & Global Customer Operations, wholly owned subsidiaries of Zimmer Biomet Holdings.	Warsaw, IN	February 12, 2020.
96,728	G-III Leather Fashions, JH, VC, and EJ divisions	New York, NY	January 30, 2020.
96,729	Industrial Connections & Solutions LLC	West Burlington, IA	February 12, 2020.
96,730	Philips, Sleep & Respiratory Care/Service	Mount Pleasant, PA	February 15, 2020.
96,732	Breg, Inc	Grand Prairie, TX	July 4, 2021.
96,733	3M Technical Ceramics, Inc. (Formerly Ceradyne Inc.), Lexington North	Lexington, KY	February 16, 2020.
96,734	Medtronic Plc, Manufacturing	Boulder, CO	February 17, 2020.
96,737	Philips Healthcare, Invivo Manufacturing	Gainesville, FL	July 23, 2021.
96,740	Savant Systems, Inc., Savant Technologies, LLC dba GE Lighting, a Savant company's Bucyrus Lamp Plant General Electric Company.	Bucyrus, OH	February 19, 2020.
96,741	Eaton Corporation, Power Systems Division Cooper Power Systems	Pewaukee, WI	February 19, 2020.
96,743	Standard Insurance Company	Portland, OR	February 22, 2020.
96,764	Alex Apparel Group, Inc	New York, NY	February 24, 2020.
96,765	LEDVANCE LLC, Headquarters	Wilmington, MA	September 26, 2021.
96,768	Marley Precision, Inc	Battle Creek, MI	March 4, 2020.
96,768A	Marley Precision, Inc	Battle Creek, MI	March 4, 2020.
96,773	Hitachi Cable America, Inc., Automotive Products Division	Pensacola, FL	March 8, 2020.

The following certifications have been issued. The requirements of Section 222(b) (supplier to a firm whose workers

are certified eligible to apply for TAA) of the Trade Act have been met.

TA-W No. Subject firm		Location	Impact date	
96,673	Mid-Continent Instrument Co., Inc Umbra Cuscinetti, Inc United States Steel Corporation, Annandale Archives		December 3, 2019. January 14, 2020. February 1, 2020.	

The following certifications have been issued. The requirements of Section 222(e) (firms identified by the

International Trade Commission) of the Trade Act have been met.

TA-W No.	Subject firm	Location	Impact date
96,406	GRI Texas Tower	Amarillo, TX	August 25, 2019.

Negative Determinations for Worker Adjustment Assistance

In the following cases, the investigation revealed that the eligibility

criteria for TAA have not been met for the reasons specified.

The investigation revealed that the requirements of Trade Act section 222(a)(1) and (b)(1) (significant worker

total/partial separation or threat of total/ partial separation), or (e) (firms identified by the International Trade Commission), have not been met.

TA-W No.	Subject firm	Location	Impact date
96,193	The Bank of New York Mellon Corp., Operations and Shared Technology (BUD) of Technology II division.	East Syracuse, NY.	

The investigation revealed that the criteria under paragraphs (a)(2)(A)(i) (decline in sales or production, or both), or (a)(2)(B) (shift in production or services to a foreign country or

acquisition of articles or services from a foreign country), (b)(2) (supplier to a firm whose workers are certified eligible to apply for TAA or downstream producer to a firm whose workers are certified eligible to apply for TAA), and (e) (International Trade Commission) of section 222 have not been met.

TA-W No.	Subject firm	Location	Impact date
96,676		Cheney, KS. New Braunfels, TX. Allentown, PA.	

The investigation revealed that the criteria under paragraphs (a)(2)(A) (increased imports), (a)(2)(B) (shift in production or services to a foreign country or acquisition of articles or

services from a foreign country), (b)(2) (supplier to a firm whose workers are certified eligible to apply for TAA or downstream producer to a firm whose workers are certified eligible to apply

for TAA), and (e) (International Trade Commission) of section 222 have not been met.

TA-W No.	Subject firm	Location	Impact date
94,838	Medical Depot Inc., Drive DeVilbiss Healthcare, Medical Depot Holdings Inc	Santa Fe Springs, CA.	
94,968	Reflection Foods, BBSI	Tucson, AZ.	
95,287	The Yankee Candle Company, Inc., Home Fragrance Business Unit Distribution Center, Newell Brands, etc.	South Deerfield, MA.	
95,287A	The Yankee Candle Company, Inc., Home Fragrance Business Unit Head- quarters Offices, Newell Brands, etc.	South Deerfield, MA.	
96,053	Trane US Inc., Commercial HVAC Americas, Trane Technologies, Remedy	La Crosse, WI.	
96,105	Ulterra Drilling Technologies	Fort Worth, TX.	
	Ulterra Drilling Technologies	Williston, ND.	
96,309	Howmet Castings and Services, Howmet Aerospace	LaPorte, IN.	
96,664	LSC Communications, Kendallville Division	Kendallville, IN.	
96,669	The Roanoke Times	Roanoke, VA.	
96,699	Godiva Chocolatier, Inc., Retail	Saint Louis, MO.	
96,713	Simple Finance Technology Corporation	Portland, OR.	

Determinations Terminating Investigations of Petitions for Trade Adjustment Assistance

After notice of the petitions was published in the **Federal Register** and

on the Department's website, as required by Section 221 of the Act (19 U.S.C. 2271), the Department initiated investigations of these petitions. The following determinations terminating investigations were issued because the petitioner has requested that the petition be withdrawn.

TA-W No.	Subject firm	Location	Impact date
95,187	Apricot Power Inc	Lakeport, CA.	

The following determinations terminating investigations were issued

in cases where the petition regarding the investigation has been deemed invalid.

TA-W No.	Subject firm	Location	Impact date
96,193A	The Bank of New York Mellon Corp., Operations and Shared Technology (BUD) of Technology II division.	Pittsburgh, PA.	

The following determinations terminating investigations were issued because the petitioning group of workers is covered by an earlier petition that is the subject of an ongoing

investigation for which a determination has not yet been issued.

TA-W No.	Subject firm	Location	Impact date
96,766	EFCO Corporation	Springfield, MO.	

I hereby certify that the aforementioned determinations were issued during the period of March 1, 2021 through March 31, 2021. These determinations are available on the Department's website https://www.doleta.gov/tradeact/petitioners/taa_search_form.cfm under the searchable listing determinations or by calling the Office of Trade Adjustment Assistance toll free at 888–365–6822.

Signed at Washington, DC, this 21st day of April 2021.

Hope D. Kinglock,

 $\label{lem:continuous} \textit{Certifying Officer, Office of Trade Adjustment } Assistance.$

[FR Doc. 2021–09473 Filed 5–4–21; 8:45 am]

BILLING CODE 4510-FN-P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of a Change in Status of the Extended Benefit (EB) Program for the Virgin Islands

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice.

SUMMARY: This notice announces a changes in benefit period eligibility under the EB program that have occurred since the publication of the

last notice regarding the State's EB status: Based on the data submitted by the Virgin Islands for the week ending April 10, 2021, the Virgin Islands' 13-week IUR was 4.83 percent, falling below the 5.0 percent IUR threshold necessary to remain "on" EB. Therefore, the EB period for the Virgin Islands ends on May 1, 2021. The state will remain in an "off" period for a minimum of 13 weeks.

FOR FURTHER INFORMATION CONTACT: U.S. Department of Labor, Employment and Training Administration, Office of Unemployment Insurance Room S–4524, Attn: Thomas Stengle, 200 Constitution Avenue NW, Washington, DC 20210, telephone number (202) 693–2991 (this is not a toll-free number) or by email: Stengle.Thomas@dol.gov.

SUPPLEMENTARY INFORMATION: The trigger notice covering state eligibility for the EB program can be found at: http://ows.doleta.gov/unemploy/claims_arch.as.

Information for Claimants

The duration of benefits payable in the EB program, and the terms and conditions on which they are payable, are governed by the Federal-State Extended Unemployment Compensation Act of 1970, as amended, and the operating instructions issued to the states by the U.S. Department of Labor. In the case of a state beginning an EB period, the State Workforce Agency will furnish a written notice of potential

entitlement to each individual who has exhausted all rights to regular benefits and is potentially eligible for EB (20 CFR 615.13(c)(1)).

Persons who believe they may be entitled to EB, or who wish to inquire about their rights under the program, should contact their State Workforce Agency.

Signed in Washington, DC.

Suzan G. LeVine,

Principal Deputy Assistant Secretary for Employment and Training.

[FR Doc. 2021–09472 Filed 5–4–21; 8:45 am]

BILLING CODE 4510-FW-P

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 ("the Act") and are identified in the Appendix to this notice. Upon receipt of these petitions, the Administrator of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221(a) of the Act.

The purpose of each of the

The purpose of each of the investigations is to determine whether the workers are eligible to apply for

adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing provided such request is filed in writing with the Administrator, Office of Trade Adjustment Assistance, at the address shown below, no later than May 17, 2021.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Administrator, Office of Trade Adjustment Assistance, at the address shown below, not later than May 17, 2021.

The petitions filed in this case are available for inspection at the Office of the Administrator, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, Room N–5428, 200 Constitution Avenue NW, Washington, DC 20210.

Signed at Washington, DC, this 21st day of April 2021.

Hope D. Kinglock,

 ${\it Certifying Officer, Office of Trade Adjustment } \\ Assistance.$

Appendix

64 TAA PETITIONS INSTITUTED BETWEEN 3/1/21 AND 3/31/21

TA-W	Subject firm (petitioners)	Location	Date of institution	Date of petition
96754	Catalytic Combustion Corporation (State Official)	Bloomer, WI	01-Mar-2021	26-Feb-2021.
96755	Dayco Products (Company Official)	Mount Pleasant, MI	01-Mar-2021	26-Feb-2021.
96756	Monotype (State Official)	Woburn, MA	01-Mar-2021	28-Feb-2021.
96757	Woodgrain (State Official)	Marion, VA	02-Mar-2021	26-Feb-2021.
96758	Forge Product, Inc. (State Official)	Houston, TX	02-Mar-2021	01-Mar-2021.
96759	Bucyrus Precision Tech, Inc. (Company Official)	Bucyrus, OH	02-Mar-2021	01-Mar-2021.
96760	Mondelez Global LLC Fair Lawn Bakery (State Official)	Fair Lawn, NJ	02-Mar-2021	01-Mar-2021.
96761	Delaware Dynamics (State Official)	Muncie, IN	03-Mar-2021	02-Mar-2021.
96762	Clayton Manufacturing Company (American Job Center)	City of Industry, CA	03-Mar-2021	02-Mar-2021.
96763	Georgia-Pacific Consumer Operations LLC (Union Official)	Easton, PA	03-Mar-2021	02-Mar-2021.
96764	Alex Apparel Group, Inc. (Company Official)	New York, NY	03-Mar-2021	24-Feb-2021.
96765	LEDVANCE LLC (Company Official)	Wilmington, MA	04-Mar-2021	03-Mar-2021.
96766	EFCO Corporation (State Official)	Springfield, MO	05-Mar-2021	03-Mar-2021.
96767	Bed Bath and Beyond (Worker)	Ocoee, FL	05-Mar-2021	04-Mar-2021.
96768	Marley Precision, Inc. (State Official)	Battle Creek, MI	05-Mar-2021	04-Mar-2021.
96769	Col-fin Specialty Steel Corporation (Authorized Representa-	Monaca, PA	08-Mar-2021	05-Mar-2021.
	tive).			
96770	Hologic, Inc. (Company Official)	Marlborough, MA	08-Mar-2021	05-Mar-2021.
96771	Albany Democrat Herald (State Official)	Albany, OR	08-Mar-2021	05-Mar-2021.
96772	BASF (State Official)	Muskegon, MI	09-Mar-2021	08-Mar-2021.
96773	Hitachi Cable America, Inc. (American Job Center)	Pensacola, FL	09-Mar-2021	08-Mar-2021.
96774	Northern Engraving (Union Official)	Sparta, WI	09-Mar-2021	08-Mar-2021.
96775	Levolor (American Job Center)	Ogden, UT	09-Mar-2021	08-Mar-2021.
96776	Vestas Blades America, Inc. (State Official)	Brighton, CO	10-Mar-2021	09-Mar-2021.
96777	Siemens Energy (State Official)	Olean, NY	10-Mar-2021	09-Mar-2021.
96778	Trace-A-Matic Corporation (Company Official)	Houston, TX	10-Mar-2021	09-Mar-2021.
96779	Prosource Trace a Matic (State Official)	Houston, TX	10-Mar-2021	09-Mar-2021.

64 TAA PETITIONS INSTITUTED BETWEEN 3/1/21 AND 3/31/21—Continued

TA-W	Subject firm (petitioners)	Location	Date of institution	Date of petition
96780	TNN Manufacturing (State Official)	Houston, TX	10-Mar-2021	09-Mar-2021.
96781	Ellwood Texas Forge (State Official)	Houston, TX	10-Mar-2021	09-Mar-2021.
96782	Hitachi ABB Power Grids (Union Official)	Mount Pleasant, PA	10-Mar-2021	10-Mar-2021.
96783	Acument Gloabl Technologies (State Official)	Rochester, IN	10-Mar-2021	10-Mar-2021.
96784	Delta Galil (State Official)	Williamsport, PA	11-Mar-2021	10-Mar-2021.
96785	Butterball LLC (American Job Center)	Carthage, MO	11-Mar-2021	10-Mar-2021.
96786	Deluxe Corporation (State Official)	Groton, MA	12-Mar-2021	11-Mar-2021.
96787	BASF Corporation (Company Official)	West Memphis, AR	12-Mar-2021	11-Mar-2021.
96788	Connecticare Capital, LLC (State Official)	Farmington, CT	12-Mar-2021	11-Mar-2021.
96789	Boeing Distribution Services Inc. (State Official)	Chambersburg, PA	12-Mar-2021	11-Mar-2021.
96790	Industrial Preventive Maintenance (State Official)	Usk, WA	12-Mar-2021	10-Mar-2021.
96791	Eastham Forge, Inc. (State Official)	Beaumont, TX	15-Mar-2021	12-Mar-2021.
96792	Pacific Life Insurance Company (State Official)	Aliso Viejo, CA	15-Mar-2021	12-Mar-2021.
96793	Carlyle (Company Official)	Stone Mountain, GA	16-Mar-2021	15-Mar-2021.
96794	Register Guard—Gannett (Gatehouse Media) (State Official)	Eugene, OR	17-Mar-2021	16-Mar-2021.
96795	Electrical Geodesics, Inc. (State Official)	Eugene, OR	17-Mar-2021	16-Mar-2021.
96796	Orchid Orthopedic Solutions (State Official)	Oregon City, OR	17-Mar-2021	16-Mar-2021.
96797	Schaffner Manufacturing Company, Inc. (State Official)	Pittsburgh, PA	17-Mar-2021	16-Mar-2021.
96798	Avtech Tyee (State Official)	Everett, WA	18-Mar-2021	11-Mar-2021.
96799	XPO Logistics Supply Chain, Inc. (State Official)	Everett, WA	18-Mar-2021	16-Mar-2021.
96800	Sensitech Inc. (Company Official)	Beverly, MA	19-Mar-2021	18-Mar-2021.
96801	Boehringer Ingelheim (State Official)	Ridgefield, CT	22-Mar-2021	19-Mar-2021.
96802	Numerical Precision (State Official)	Crosby, TX	22-Mar-2021	19-Mar-2021.
96803	Wabtec Corporation (Wilmerding Plant) (Union Official)	Wilmerding, PA	23-Mar-2021	22-Mar-2021.
96804	Insurity (State Official)	Hartford, CT	23-Mar-2021	22-Mar-2021.
96805	Tory Burch LLC (Worker)	New York, NY	23-Mar-2021	22-Mar-2021.
96806	B & R Sheet Metal, Inc. (State Official)	Eugene, OR	23-Mar-2021	22-Mar-2021.
96807	Transco Industries Inc. (State Official)	Portland, OR	23-Mar-2021	22-Mar-2021.
96808	Pacific Wood Laminates, Inc. (State Official)	Brookings, OR	26-Mar-2021	25-Mar-2021.
96809	Cascade Wood Products, Inc. (State Official)	White City, OR	26-Mar-2021	25-Mar-2021.
96810	Jeld-Wen, Inc (State Official)	Chiloquin, OR	26-Mar-2021	25-Mar-2021.
96811	Bright Wood Corporation (State Official)	Madras, OR	26-Mar-2021	25-Mar-2021.
96812	PlusOne Communications LLC (State Official)	Akron, OH	29-Mar-2021	26-Mar-2021.
96813	Allstate Insurance Company (Worker)	Northbrook, IL	29-Mar-2021	28-Mar-2021.
96814	The Anthem Companies, Inc. (State Official)	Wallingford, CT	29-Mar-2021	29-Mar-2021.
96815	Halliburton Energy Services (State Official)	Duncan, OK	31-Mar-2021	30-Mar-2021.
96816	Gates Corporation (American Job Center)	Galesburg, IL	31-Mar-2021	30-Mar-2021.
96817	Gilster-Mary Lee Corporation (State Official)	Wilson, AR	31-Mar-2021	31-Mar-2021.

[FR Doc. 2021–09474 Filed 5–4–21; 8:45 am]

DEPARTMENT OF LABOR

Employment and Training Administration

Post-Initial Determinations Regarding Eligibility To Apply for Trade Adjustment Assistance

In accordance with Sections 223 and 284 (19 U.S.C. 2273 and 2395) of the Trade Act of 1974 (19 U.S.C. 2271, et seq.) ("Act"), as amended, the Department of Labor herein presents Notice of Affirmative Determinations Regarding Application for Reconsideration, summaries of Negative Determinations Regarding Applications

for Reconsideration, summaries of Revised Certifications of Eligibility, summaries of Revised Determinations (after Affirmative Determination Regarding Application for Reconsideration), summaries of Negative Determinations (after Affirmative Determination Regarding Application for Reconsideration), summaries of Revised Determinations (on remand from the Court of International Trade), and summaries of Negative Determinations (on remand from the Court of International Trade) regarding eligibility to apply for trade adjustment assistance under Chapter 2 of the Act ("TAA") for workers by (TA-W) number issued during the period of March 1, 2021 through March 31, 2021. Post-initial determinations are issued after a petition has been certified or denied. A post-initial determination

may revise a certification, or modify or affirm a negative determination.

Affirmative Determinations Regarding Applications for Reconsideration

The following Applications for Reconsideration have been received and granted. See 29 CFR 90.18(d). The group of workers or other persons showing an interest in the proceedings may provide written submissions to show why the determination under reconsideration should or should not be modified. The submissions must be sent no later than ten days after publication in Federal Register to the Office of the Director, Office of Trade Adjustment Assistance, **Employment and Training** Administration, U.S. Department of Labor, Room N-5428, 200 Constitution Avenue NW, Washington, DC 20210. See 29 CFR 90.18(f).

TA-W-No.	Subject firm	Location
	IPSCO Koppel Tubulars, LLC	Ambridge, PA. Prince George, VA.

Revised Certifications of Eligibility

The following revised certifications of eligibility to apply for TAA have been

issued. The date following the company name and location of each determination references the impact date for all workers of such determination, and the reason(s) for the determination.

The following revisions have been issued.

TA-W-No.	Subject firm	Location	Impact date	Reason(s)
96,737	Philips Healthcare	Gainesville, FL	7/23/2021	Technical Error.

Revised Determinations (After Affirmative Determination Regarding Application for Reconsideration)

The following revised determinations on reconsideration, certifying eligibility

to apply for TAA, have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following revised determinations on reconsideration, certifying eligibility to apply for TAA, have been issued. The requirements of Section 222(a)(2)(A) (Increased Imports Path) of the Trade Act have been met.

TA-W-No.	Subject firm	Location	Impact date
95,355	Morgantown Machine & Hydraulics of West Virginia	Morgantown, WV	11/1/2018

The following revised determinations on reconsideration, certifying eligibility to apply for TAA, have been issued. The requirements of Section 222(a)(2)(B) (Shift in Production or Services to a Foreign Country Path or Acquisition of Articles or Services from a Foreign Country Path) of the Trade Act have been met.

TA-W-No.	Subject firm	Location	Impact date
96,048	Vallourec Star, LP	Youngstown, OH	7/8/2019

I hereby certify that the aforementioned determinations were issued during the period of March 1, 2021 through March 31, 2021. These determinations are available on the Department's website https://www.doleta.gov/tradeact/petitioners/taa_search_form.cfm under the searchable listing determinations or by calling the Office of Trade Adjustment Assistance toll free at 888–365–6822.

Signed at Washington, DC, this 21st day of April 2021.

Hope D. Kinglock,

 ${\it Certifying Officer, Office of Trade Adjustment } \\ Assistance.$

[FR Doc. 2021–09475 Filed 5–4–21; 8:45 am] BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; DOL-Only Performance Accountability, Information, and Reporting System

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Employment and Training Administration (ETA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with

the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before June 4, 2021.

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) if the information will be processed and used in a timely manner; (3) 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; (4) ways to enhance the quality, utility and clarity of the information collection; and (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.

FOR FURTHER INFORMATION CONTACT: Mara Blumenthal by telephone at 202–

693–8538, or by email at *DOL_PRA_PUBLIC@dol.gov*.

SUPPLEMENTARY INFORMATION: This ICR is the product of a joint effort among the DOL offices responsible for the following programs: WIOA Adult, WIOA Dislocated Worker, WIOA Youth, National Dislocated Worker Grants, Dislocated Worker Projects authorized under WIOA sec. 169(c), Wagner Peyser **Employment Service**, National Farmworker Jobs Program, Job Corps, YouthBuild, Indian and Native American Program, as well as non-WIOA covered programs, including Trade Adjustment Assistance (TAA), Reentry Employment Opportunities (REO), H-1B discretionary grants, Senior Community Service Employment Program (SCSEP), Apprenticeship grants, and the Jobs for Veterans' State Grants Programs. While H-1B grants, TAA, SCSEP, Apprenticeship grants and the REO programs are not authorized under WIOA, these programs will be utilizing the data element definitions and reporting templates proposed in this ICR. For additional substantive information about this ICR, see the related notice published in the Federal Register on November 25, 2020 (85 FR 75376).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. See 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–ETA.

Title of Collection: DOL-Only
Performance Accountability,
Information, and Reporting System.

OMB Control Number: 1205–0521. Affected Public: Individuals or Households; State, Local, and Tribal Governments; Private Sector— Businesses or other for-profits and notfor-profit institutions.

Total Estimated Number of Respondents: 17,583,750.

Total Estimated Number of Responses: 41,064,037.

Total Estimated Annual Time Burden: 10,459,627 hours.

Total Estimated Annual Other Costs Burden: \$9,491,287.

Authority: 44 U.S.C. 3507(a)(1)(D).

Dated: April 28, 2021. Mara Blumenthal,

Senior PRA Analyst.

[FR Doc. 2021–09471 Filed 5–4–21; 8:45 am]

BILLING CODE 4510-FM-P

OFFICE OF MANAGEMENT AND BUDGET

Methods and Leading Practices for Advancing Equity and Support for Underserved Communities Through Government

AGENCY: Office of Management and Budget, Executive Office of the President.

ACTION: Request for Information (RFI).

SUMMARY: Recent Executive Orders have charged the Office of Management and Budget (OMB), in partnership with the heads of agencies, to identify, by July 2021, effective methods for assessing whether agency policies and actions (e.g., programs, services, processes, and operations) equitably serve all eligible individuals and communities, particularly those that are currently and historically underserved. As part of this

effort, agencies are directed to consult with members of communities that have been historically underrepresented in the Federal Government and underserved by, or subject to discrimination in, Federal policies and programs, and to evaluate opportunities, as allowable, to increase coordination, communication, and engagement with community-based and civil rights organizations. Through this request for information (RFI), OMB seeks input, information, and recommendations from a broad array of stakeholders in the public, private, advocacy, not-for-profit, and philanthropic sectors, including State, local, Tribal, and territorial areas, on available methods, approaches, and tools that could assist in this effort. OMB will consider the usability, applicability, and rigor of submissions in response to this RFI as OMB gathers resources to support agencies as they conduct internal assessments on the state of equity in their policies, programs, services, processes, and operations. OMB will also use what it learns from responses to this RFI as OMB works to expand use of equityassessment methods and approaches across the Federal Government, as agencies develop agency Equity Action Plans (due to the Domestic Policy Council by January 19, 2022) outlining steps they will take to address identified gaps in equity.

DATES: Responses to this RFI should be received by July 6, 2021.

ADDRESSES: You should submit comments via the Federal eRulemaking Portal at https://www.regulations.gov/. Follow the instructions for submitting comments. All public comments received are subject to the Freedom of Information Act and will be posted in their entirety at https://www.regulations.gov/, including any personal and/or business confidential information provided. Do not include

personal and/or business confidential information provided. Do not include any information you would not like to be made publicly available.

Written responses should not exceed 20 pages, inclusive of a 1-page cover page as described below. Attachments or linked resources or documents are not included in the 20-page limit. Please respond concisely, in plain language, and in narrative format. You may respond to some or all of the questions listed in the RFI. Please ensure it is clear which question you are responding to. You may also include links to online material or interactive presentations but please ensure all links are publicly available. Each response should include:

• The name of the individual(s) and/or organization responding.

- The Area section(s) (1, 2, 3, 4 and/ or 5) that your submission and materials support.
- A brief description of the responding individual(s) or organization's mission and/or areas of expertise, including any public-private partnerships with Federal, State, tribal, territorial, or local governments within the past three years that are relevant to this RFI.
- A contact for questions or other follow-up on your response.

By responding to the RFI, each participant (individual, team, or legal entity) warrants that they are the sole author or owner of, or has the right to use, any copyrightable works that the Submission comprises, that the works are wholly original (or is an improved version of an existing work that the participant has sufficient rights to use and improve), and that the Submission does not infringe any copyright or any other rights of any third party of which participant is aware.

By responding to the RFI, each participant (individual, team, or legal entity) consents to the contents of their submission being made available to all Federal agencies and their employees on an internal-to-government website accessible only to agency staffpersons.

Participants will not be required to transfer their intellectual property rights to OMB, but Participants must grant to the Federal government a nonexclusive license to apply, share, and use the materials that are included in the Submission. To participate in the RFI, each participant must warrant that there are no legal obstacles to providing the above-referenced nonexclusive licenses of participant rights to the Federal government.

Interested parties who respond to this RFI may be contacted for a follow-on strategic agency assessment dialogue, discussion, event, crowdsource campaign, or competition.

FOR FURTHER INFORMATION CONTACT:

Issues regarding submission or questions on this RFI can be sent to Amira Boland at 202–395–5222 or to equityRFI@omb.eop.gov.

SUPPLEMENTARY INFORMATION:

I. Background

E.O. 13985 states: "Equal opportunity is the bedrock of American democracy, and our diversity is one of our country's greatest strengths. But for too many, the American Dream remains out of reach. Entrenched disparities in our laws and public policies, and in our public and private institutions, have often denied that equal opportunity to individuals and communities. Our country faces

converging economic, health, and climate crises that have exposed and exacerbated inequities, while a historic movement for justice has highlighted the unbearable human costs of systemic racism. Our Nation deserves an ambitious whole-of-government equity agenda that matches the scale of the opportunities and challenges that we face.

It is therefore the policy of my Administration that the Federal Government should pursue a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality. Affirmatively advancing equity, civil rights, racial justice, and equal opportunity is the responsibility of the whole of our Government. Because advancing equity requires a systematic approach to embedding fairness in decision-making processes, executive departments and agencies (agencies) must recognize and work to redress inequities in their policies and programs that serve as barriers to equal opportunitv.'

Within 200 days of the date of the E.O. (by August 8, 2021), agencies must submit to the Assistant to the President for Domestic Policy an assessment of the state of equity for underserved communities and individuals, including on the following points, for example:

• Barriers that underserved communities and individuals may face to enrollment in and access to benefits and services in Federal programs;

 Barriers that underserved communities and individuals may face in participation in agency procurement and contracting opportunities;

 Barriers that underserved communities and individuals may face in participation in agency grant programs and other forms of financial assistance;

 Opportunities in current agency policies, regulations, and guidance to address affirmatively and equitably the underlying causes of systemic inequities in society;

 Opportunities in agency community engagement processes to engage with and empower marginalized, vulnerable, or underserved communities more directly to advance equitable policymaking; and

• The operational status and level of institutional resources available to agency offices or divisions responsible for advancing civil rights or required to serve underrepresented or disadvantaged communities.

Within one year of the date of E.O. 13985 (by January 19, 2022), the head of

each agency will develop a plan for addressing any barriers to full and equal participation in programs and procurement opportunities identified in its assessment. Such a plan could include establishing ongoing routines to assess and rectify gaps in full and equal participation in programs and procurement opportunities.

E.O. 13985 uses the following definitions, which OMB adopts for

purposes of this RFI.

The term "equity" means the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as women and girls; Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; persons facing discrimination or barriers on account of gender identity; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.

The term "underserved communities" refers to populations sharing a particular characteristic, as well as geographic communities, that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life, as exemplified by the list in the preceding definition of

"equity."

Information and Key Questions

OMB seeks input in the following areas:

1. Equity Assessments and Strategies. Approaches and methods for holistic and program- or policy-specific assessments of equity for public sector entities, including but not limited to the development of public policy strategies that advance equity and the use of data to inform equitable public policy strategies.

2. Barrier and Burden Reduction. Approaches and methods for assessing and remedying barriers, burden, and inequities in public service delivery and access.

3. Procurement and Contracting. Approaches and methods for assessing equity in agency procurement and contracting processes.

4. Financial Assistance. Approaches and methods for assessing equity in the administration of agency grant programs and other forms of financial assistance.

5. Stakeholder and Community Engagement. Approaches and methods for accessible and meaningful agency engagement with underserved communities.

The descriptions below represent a non-exhaustive accounting of issues that may fall under each topic area. These may assist in the formulation of comments. The list is not intended to restrict submissions. For all prompts, OMB requests that commenters incorporate examples, data, and, in particular, research or academic literature whenever possible.

For Area 1 on equity assessments and

str<u>a</u>tegies:

The work of advancing equity requires a holistic assessment of agency practices and policies. Some Federal agencies will need to implement new approaches to assess whether future proposed policies, budgets, regulations, grants, or programs will be effective in advancing equity. OMB welcomes submissions that provide resources, tools, and examples of how agencies might conduct effective equity assessments, with the goal of embedding equity throughout agency practices and policies. Submissions might consider questions such as:

• What are some promising methods and strategies for assessing equity in internal agency practices and policies? What knowledge, skills, or supports do practitioners need to use such tools effectively?

• What are some promising methods and strategies for identifying systemic inequities to be addressed by agency

policy?

• Jurisdictions at the State, local, Tribal, and territorial level have implemented equity assessment tools to inform their policymaking, budgetary, or regulatory processes. What are the lessons these jurisdictions have learned from implementing or interacting with those tools?

• What are some promising methods and strategies for advancing equity on urgent or immediate agency priorities?

• What types of equity assessment tools are especially useful for agencies with national security, foreign policy or law enforcement missions?

 How might agencies collect data and build evidence in appropriate and protected ways to reflect underserved individuals and communities and support greater attention to equity in future policymaking?

 How might agencies build capacity and provide training and support for

teams conducting this work?

• How can community engagement or feedback from underserved individuals with lived expertise on a given policy problem be integrated meaningfully in an agency's use of equity assessment methods? For Area 2 on barrier and burden reduction:

Members of underserved communities may experience a variety of external factors that may disproportionately affect their access to information about programs or program eligibility, applying for benefits, conducting postaward reporting, and recertification of eligibility. These barriers may include, but are not limited to: Non-traditional or inflexible work hours, childcare needs, housing insecurity, limited transportation access, limited proficiency in English, disability, low literacy, income or other resource constraints, stigma in accessing public programs, and limited access to technology.

Other barriers are internal to the administration of programs. While certain program rules may ensure that benefits are awarded to eligible individuals or are otherwise required by law, others are not necessary for ensuring benefits are awarded to eligible individuals and may be remedied via administrative or regulatory changes. The latter category of program rules may include: Unnecessary questions or requirements to produce documentation; complex eligibility formulas; forms or web applications that are confusingly designed; complicated instructions; long delays between application and adjudication; the need for third-party (e.g., advocacy organization, legal counsel) support or consultation; frequent recertification of eligibility; processes that require multiple forms or touch-points; and duplicative or similar information collections by multiple agencies.

Responses should include, but not be limited to, information on any or all of the following points:

- How can agencies address known burdens or barriers to accessing benefits programs in their assessments of benefits delivery?
- What data, tools, or evidence are available to show how particular underserved communities or populations disproportionately encounter these barriers? Which underserved communities experience multiple, cumulative barriers and are disproportionately burdened by specific administrative processes or requirements?
- Are there specific requirements or processes (e.g., in-person visits, frequency of recertification of eligibility) that have been shown in rigorous research to cause program drop-off or churn by underserved individuals and communities? Similarly, is there rigorous evidence available that certain

requirements or processes have little actual effect on program integrity?

- How could agencies incorporate considerations of the psychological costs of qualifying or applying for Federal benefits programs into their assessments of equitable service delivery?
- What kinds of equity assessment tools are more useful for addressing urgent agency priorities versus making systemic change?
- What types of overarching metrics (e.g., program uptake, over- or underpayments) might an agency use to measure a benefit program's outcomes [or whether it is implemented as intended?]?
- How might an agency assess or balance prioritization of potentially competing values associated with program administration, such as program uptake, program integrity, privacy protection, and resource constraints, in the context of addressing equity for underserved individuals and communities?
- How might agencies assess if specific barriers (e.g., specific questions on forms or requirements such as inperson interviews) are achieving their intended purpose?
- How might agencies incorporate into their equity assessments barriers or duplicative burdens a participant is likely to experience when seeking services from multiple agencies?
- How can agencies best balance collecting demographic information about program applicants and participants with the potential effect on program participation that these questions may cause? What does rigorous research show about the effect of demographic questions on program participation?

For Area 3, on procurement and contracting:

The Federal Government is the world's largest purchaser of goods and services, with acquisitions totaling over \$650 billion per year. As the Federal Government's purchasing power is used to fight COVID-19, increase domestic productivity, combat climate change, and address other Administration priorities, agencies will need to assess opportunities to invest in underserved individuals and communities by promoting business diversity (including, but not limited to, professional services, financial services, and technology) and resiliency. Agencies will need to assess opportunities to direct more procurement and contracting dollars to underserved individuals and communities so that a broad crosssection of American businesses can share in the jobs and opportunities

created by Federal buying activities. Economic research shows that investing in underserved communities and closing racial wealth gaps yields economic growth and job creation that benefits all Americans.

OMB welcomes submissions that address questions such as:

- How do we achieve equity in a procurement system that must balance competing economic and social goals, including the need to conduct procurements in a streamlined and rapid manner?
- What kinds of equity assessment tools might agencies use to identify inequity in their standard practices throughout the acquisition lifecycle, including, but not limited to, the development of requirements, market research (including outreach to businesses), selection of contract type, availability of financing, incentive structure, negotiation and evaluation of interested sources, debriefings of unsuccessful offerors, management of contracts, evaluation of contractor performance, and use of past performance in selection of sources?
- What kinds of tools might agencies use to determine when there is inequity in the award of subcontracts under prime contracts and the cause of such?
- How might agencies identify opportunities to engage with business owners and entrepreneurs who are members of underserved communities to promote doing business with the Federal Government? What kinds of training and capacity building within agency teams would support equitable procurement and contracting efforts?
- What kinds of benchmarks and assessment techniques might support equitable procurement and contracting efforts?
- What kinds of data should agencies collect and use to assess equity in their procurement practices?

For Area 4, financial assistance:
Federal agencies run financial
assistance programs, including grant
opportunities, that have the potential,
and in many cases, a stated intent, to
channel resources to underserved
communities. OMB welcomes
submissions that address questions such
as:

• How might agencies identify opportunities to adjust current practices in grants and other financial assistance programs to expand access for underserved communities and to achieve equity-oriented results? What are some promising approaches to the award and administration of Federal awards (including, for example, the integration of program planning and design) that should be considered?

- What are promising practices for equitable grantmaking and the administration of financial assistance programs that agencies should consider in the course of their equity assessments?
- How might agencies engage in outreach and stakeholder engagement to identify opportunities to make Federal grants and other financial assistance processes more accessible?
- What kinds of training and capacity building within agencies would support equitable grantmaking and financial assistance efforts?
- What kinds of benchmarks and assessment techniques would support equitable grantmaking and financial assistance efforts?
- What kinds of data should agencies collect and use to assess equity in their grantmaking and financial assistance practices?

For Area 5, on stakeholder and community engagement:

Section 8 of E.O. 13985 instructs agencies to expand their use of stakeholder and community engagement in carrying out the Order. OMB seeks specific approaches to stakeholder and community engagement with underserved communities that others have successfully used and that Federal agencies could adapt or apply.

Accordingly, OMB welcomes submissions that address questions such as:

- What processes should agencies have in place to engage proactively with the underserved individuals and communities that will be most affected by agency programs, policies, rules, processes, or operations? How can agencies design and implement community engagement practices that are accessible to underserved communities? How might affected communities be engaged pro-actively and early to shape agency policy priorities and strategies?
- What tools and best practices might agencies deploy to establish advisory boards, task forces, and commissions that are inclusive of underserved communities?
- How can an agency assess the accessibility of the agency's rulemaking and policymaking commenting and engagement processes, including for individuals that experience barriers to participation? Examples of barriers may include limited language access assistance, online-only engagement, and minimal proactive notification of opportunities to provide comment.
- Do feedback mechanisms for customers, beneficiaries, and communities affected by Government programs exist to inform policy research

- and evaluation processes? If so, are these feedback mechanisms accessible to underserved communities? If not, what are best practices that agencies should consider?
- What tools could agencies develop for expanding stakeholder input into programmatic and regulatory changes to minimize barriers and burden? How may existing processes (e.g., notice and comment on information collections) be enhanced to improve accessibility by stakeholders?
- What tools can agency offices, including communications, civic engagement, enforcement, and policymaking offices, use to better engage or reach underserved communities?
- What are some of the barriers or factors that challenge underserved communities' interactions with Federal agencies and programs?
- What practices should agencies put in place to reach underserved communities in rural areas or underserved communities that otherwise are not able to visit Washington, DC, to engage with policymakers?

Shalanda Young,

Acting Director, Office of Management and Budget.

[FR Doc. 2021–09109 Filed 5–4–21; 8:45 am] BILLING CODE 3110–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

30-Day Notice for the "NEA Panelist Profile Data"

AGENCY: National Endowment for the Arts.

ACTION: Notice of proposed collection; comment request.

SUMMARY: The National Endowment for the Arts (NEA), as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the NEA is soliciting comments concerning the proposed

information collection for the NEA Panelist Profile Data. Copies of this ICR, with applicable supporting documentation, may be obtained by visiting www.Reginfo.gov.

DATES: Interested persons are invited to submit comments within 30 days from the date of this publication in the **Federal Register**.

ADDRESSES: Comments should be sent to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the National Endowment for the Arts, Office of Management and Budget, Room 10235, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: The Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the National Endowment for the Arts, Office of Management and Budget, Room 10235, Washington, DC 20503, (T) 202–395–7316.

SUPPLEMENTARY INFORMATION: The Office of Management and Budget (OMB) is particularly interested in comments which: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Could help minimize the burden of the collection of information on those who are to respond, including through the use of electronic submission of responses through Grants.gov.

Agency: National Endowment for the Arts.

Title: NEA Panelist Profile Data Collection.

OMB Number: 3135–0098. Frequency: Annually. Affected Public: Individuals. Estimated Number of Respondents: 600.

Total burden hours: 100 hours. Total annualized capital/startup costs: 0.

Total annual costs (operating/maintaining systems or purchasing services): 0.

The NEA's mission is "to strengthen the creative capacity of our communities by providing all Americans with diverse opportunities for arts participation." With the advice of the National Council on the Arts and advisory panels, the Chairman establishes eligibility requirements and criteria for the review of applications for funding. Section 959(c) of the NEA's enabling legislation, as amended, directs

the Chairman to utilize advisory panels to review applications and to make recommendations to the National Council on the Arts, which in turn makes recommendations to the Chairman.

The legislation requires the Chairman "(1) to ensure that all panels are composed, to the extent practicable, of individuals reflecting a wide geographic, ethnic, and minority representation as well as to (2) ensure that all panels include representation of lay individuals who are knowledgeable about the arts . . ." These panels are considered to be committees under the Federal Advisory Committee Act (FACA), which also requires that committees be balanced geographically and ethnically. In addition, the membership of each panel must change substantially from year to year and each individual is ineligible to serve on a panel for more than three consecutive vears. To assist with efforts to meet these legislated mandates regarding representation on advisory panels, the NEA has established a database of names, addresses, areas of expertise and other basic information on individuals who are qualified to serve as panelists for the NEA.

The Panelist Profile Data Collection, for which clearance is requested, is used to gather basic information from qualified individuals recommended by the arts community; arts organizations; Members of Congress; the general public; local, state and regional arts organizations; NEA staff, and others.

Dated: April 30, 2021.

Daniel Beattie,

Director, Office of Guidelines and Panel Operations, Administrative Services National Endowment for the Arts.

[FR Doc. 2021–09484 Filed 5–4–21; 8:45 am]

BILLING CODE 7537-01-P

NUCLEAR REGULATORY COMMISSION

[NRC-2021-0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of May 3, 10, 17, 24, 31, June 7, 2021.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and closed.
MATTERS TO BE CONSIDERED:

Week of May 3, 2021

There are no meetings scheduled for the week of May 3, 2021.

Week of May 10, 2021—Tentative

Tuesday, May 11, 2021

10:00 a.m. Briefing on Security Issues (Closed Ex. 1)

Week of May 17, 2021—Tentative

There are no meetings scheduled for the week of May 17, 2021.

Week of May 24, 2021—Tentative

Tuesday, May 25, 2021

9:00 a.m. Strategic Programmatic Overview of the Fuel Facilities and the Spent Fuel Storage and Transportation Business Lines (Public Meeting). (Contact: Damaris Marcano: 301–415–7328)

Additional Information: Due to COVID–19, there will be no physical public attendance. The public is invited to attend the Commission's meeting live by webcast at the Web address—https://video.nrc.gov/.

Week of May 31, 2021—Tentative

There are no meetings scheduled for the week of May 31, 2021.

Week of June 7, 2021

Tuesday, June 8, 2021

10:00 a.m. Briefing on Human Capital and Equal Employment Opportunity (Public Meeting). (Contact: Anne DeFrancisco: 610– 337–5078)

Additional Information: Due to COVID–19, there will be no physical public attendance. The public is invited to attend the Commission's meeting live by webcast at the Web address—https://video.nrc.gov/.

Thursday, June 10, 2021

10:00 a.m. Briefing on Results of the Agency Action Review Meeting (Public Meeting). (Contact: Nicole Fields: 630–829–9570)

Additional Information: Due to COVID–19, there will be no physical public attendance. The public is invited to attend the Commission's meeting live by webcast at the Web address—https://video.nrc.gov/.

CONTACT PERSON FOR MORE INFORMATION:

For more information or to verify the status of meetings, contact Wesley Held at 301–287–3591 or via email at Wesley.Held@nrc.gov. The schedule for Commission meetings is subject to change on short notice.

The NRC Commission Meeting Schedule can be found on the internet at: https://www.nrc.gov/public-involve/public-meetings/schedule.html.

The NRC provides reasonable accommodation to individuals with

disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings or need this meeting notice or the transcript or other information from the public meetings in another format (e.g., Braille, large print), please notify Anne Silk, NRC Disability Program Specialist, at 301–287–0745, by videophone at 240–428–3217, or by email at Anne.Silk@nrc.gov. Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555, at 301–415–1969, or by email at *Tyesha.Bush@nrc.gov*.

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated: April 29, 2021.

For the Nuclear Regulatory Commission.

Wesley W. Held,

Policy Coordinator, Office of the Secretary. [FR Doc. 2021–09381 Filed 5–3–21; 11:15 am] BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket No. MC2021-78; Order No. 5880]

Transfer of Bound Print Matter Parcels

AGENCY: Postal Regulatory Commission. **ACTION:** Notice.

SUMMARY: The Commission is extending the comment deadline in this docket. **DATES:** Comments are due: May 17,

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at http://www.prc.gov. Those who cannot submit comments electronically should contact the person identified in the FOR FURTHER INFORMATION CONTACT section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT:

David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION: On March 30, 2021, the Commission established Docket No. MC2021–78 to consider the Postal Service's request to transfer Bound Printed Matter Parcels from the market dominant product list to the competitive product list.¹ Since the

Continued

¹Notice and Order Concerning Transfer of Bound Printed Matter Parcels to the Competitive Product

opening of the docket the Commission has received numerous motions from members of the public and the Public Representative requesting that the Commission issue information requests to obtain additional relevant data from the Postal Service, along with motions for access under protective conditions to non-public materials filed in the record.²

To give all interested parties sufficient time to review the responses to the information requests and formulate their comments, the Commission hereby extends the deadline for filing comments from May 7, 2021 to May 17, 2021.

It is ordered:

- 1. Comments by interested persons are due by May 17, 2021.
- 2. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Erica A. Barker,

Secretary.

[FR Doc. 2021-09404 Filed 5-4-21; 8:45 am]

BILLING CODE 7710-FW-P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal ServiceTM.

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: May 5, 2021.

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 April 20, 2021, it filed with the Postal Regulatory Commission a USPS Request to Add Priority Mail Contract 696 to Competitive Product List. Documents

are available at *www.prc.gov*, Docket Nos. MC2021–86, CP2021–89.

Sean Robinson,

Attorney, Corporate and Postal Business Law. [FR Doc. 2021–09506 Filed 5–4–21; 8:45 am]
BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-91730; File No. SR-NYSENAT-2021-10]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending NYSE National, Inc.'s Price List

April 29, 2021.

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 April 16, 2021, 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 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 the Exchange's Price List regarding colocation services and fees to add further specificity as to how monthly fees for dedicated cabinets are calculated. 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 its Price List regarding colocation services and fees ⁴ to add further specificity as to how monthly fees for dedicated cabinets are calculated. The proposed change is not substantive and would not change the amount or structure of the fees.

The Exchange offers Users ⁵ dedicated and partial cabinets to house their servers and other equipment. ⁶ Each dedicated cabinet has a standard power allocation of either 4 kilowatts ("kW") or 8 kW, but additional power can be added if the User requests. ⁷ Users may request that such additional power be allocated to a dedicated cabinet when it is first set up or later.

A User pays a monthly fee based on the power allocated to its dedicated cabinets. As previously indicated, at the tiered fee is based on the total kWs allocated to all of a User's dedicated cabinets, not the kWs allocated to an individual dedicated cabinet. For example, a User that has two dedicated cabinets with a total power allocation of 12 kW has a monthly charge of \$1,200 per kW for the first eight kW and \$1,050 per kW for the next four kW (between 9 kW and 12 kW), for a total of \$13,800,

List, March 30, 2021; see United States Postal Service Request to Transfer Bound Printed Matter Parcels to the Competitive Product List, March 26, 2021.

² See, e.g., Motion of Scholastic Inc. for Issuance of Information Request, April 9, 2021; Motion of the Public Representative for Issuance of Information Request, April 19, 2021; Parcel Shippers Association's Motion Requesting Access to Non-Public Materials Under Protective Conditions, April 14, 2021.

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a

^{3 17} CFR 240.19b-4.

⁴The Exchange initially filed rule changes relating to its co-location services with the Securities and Exchange Commission ("Commission") in 2018. See Securities Exchange Act Release No. 83351 (May 31, 2018), 83 FR 26314 (June 6, 2018) (SR–NYSENAT–2018–07). The Exchange is an indirect subsidiary of Intercontinental Exchange, Inc. ("ICE"). Through its ICE Data Services business, ICE operates a data center in Mahwah, New Jersey, from which the Exchange provides co-location services to Users.

⁵For purposes of the Exchange's co-location services, a "User" means any market participant that requests to receive co-location services directly from the Exchange. See id., at note 9. As specified in the Price List, a User that incurs co-location fees for a particular co-location service pursuant thereto would not be subject to co-location fees for the same co-location service charged by the Exchange's affiliates New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., and NYSE Chicago, Inc. (together, the "Affiliate SROs"). Each Affiliate SRO has submitted substantially the same proposed rule change to propose the changes described herein. See SR–NYSE-2021–26, SR–NYSEAMER-2021–22, SR–NYSEArca-2021–26, and SR–NYSECHX-2021–08.

⁶ See 83 FR 26314, supra note 4.

⁷ Presently, the maximum amount of power that can be allocated to one dedicated cabinet is 15 kW.

⁸ See Securities Exchange Act Release No. 65237 (August 31, 2011), 76 FR 55432 (September 7, 2011) (SR-NYSE-2011-46).

irrespective of how the User divides the 12 kW between its two cabinets.

To further clarify how the fees are calculated, in a non-substantive change, the Exchange proposes to make the following edits to the Price List:

- Revise the title "Monthly Fee per Cabinet" to read "Monthly Fee for Cabinets"; and
- under the heading "Dedicated Cabinet," add the following text: "Monthly fee is based on total kWs allocated to all of a User's dedicated cabinets".

The Exchange does not propose to change the fees.

Application and Impact of the Proposed Changes

The proposed change is not expected to have any impact on Users. Users are currently subject to the described services and fees, none of which is new or novel. Current Users would not incur any new or changed fees and the Exchange does not expect to attract any new Users as a result of the proposed change. The change would simply add clarity to the Price List concerning the monthly fee for dedicated cabinets.

The proposed change is not targeted at, or expected to be limited in applicability to, a specific segment of market participant, as colocation is available to any market participant that wishes to be a User.

The proposed change is not otherwise intended to address any other issues, and the Exchange is not aware of any problems that member organizations would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,9 in general, and furthers the objectives of Section 6(b)(5) of the Act,10 in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange further believes that the

proposed rule change is consistent with Section 6(b)(4) of the Act,¹¹ because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed rule change is reasonable because it would add clarity to the Price List regarding how the monthly fee for dedicated cabinets is calculated, clarifying that the monthly fee for dedicated cabinets is based on the aggregate number of kW allocated to all the User's dedicated cabinets, and not charged on a per-cabinet basis. It would add detail previously stated in rule filings with the Commission 12 to the Price List. Doing so would remove impediments to, and perfecting the mechanisms of, a free and open market and a national market system and, in general, protecting investors and the public interest because the change would add clarity and transparency to the Exchange rules, alleviating potential investor or market participant confusion.

The proposed change is equitable, as it would add clarity for all market participants with respect to how the monthly fee for dedicated cabinets is calculated. At the same time, it is a non-substantive change that would not impact the services available to Users or the fees charged for such services. The Exchange does not expect to attract any new Users as a result of the proposed change. The proposed change is not expected to have any impact on Users. Users are currently subject to the described services and fees, none of which is new or novel.

For the reasons above, the proposed changes do not unfairly discriminate between or among market participants that are otherwise capable of satisfying any applicable colocation fees, requirements, terms, and conditions established from time to time by the Exchange.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,¹³ the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act because it is ministerial in nature and is not designed to have any competitive impact. Rather, the change would simply add clarity to the Price List regarding how the monthly fee for dedicated cabinets is calculated, clarifying that the monthly fee for dedicated cabinets is based on the aggregate number of kW allocated to all the User's dedicated cabinets, and not charged on a per-cabinet basis. The change would add clarity and transparency to the Exchange rules, alleviating potential investor or market participant confusion.

For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

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 Act 14 and Rule 19b-4(f)(6) thereunder. 15 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.16

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

^{9 15} U.S.C. 78f(b).

¹⁰ 15 U.S.C. 78f(b)(5).

^{11 15} U.S.C. 78f(b)(4).

¹² See 76 FR 55432, supra note 8.

^{13 15} U.S.C. 78f(b)(8).

¹⁴ 15 U.S.C. 78s(b)(3)(A)(iii).

^{15 17} CFR 240.19b-4(f)(6).

^{16 17} CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires the Exchange 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.

under Section 19(b)(2)(B) ¹⁷ 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 (http://www.sec.gov/rules/sro.shtml); or
- Send an email to *rule-comments@* sec.gov. Please include File Number SR-NYSENAT-2021-10 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-2021-10. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (http://www.sec.gov/ rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSENAT-2021-10 and

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. 18

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–09449 Filed 5–4–21; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-91712; File No. SR-NYSEAMER-2021-22]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the NYSE American Equities Price List and Fee Schedule and the NYSE American Options Fee Schedule

April 29, 2021.

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 April 16, 2021, 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 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 the NYSE American Equities Price List and Fee Schedule and the NYSE American Options Fee Schedule (together, the "Price List and Fee Schedule") regarding colocation services and fees to add further specificity as to how monthly fees for dedicated cabinets are calculated. 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 its Price List and Fee Schedule regarding colocation services and fees ⁴ to add further specificity as to how monthly fees for dedicated cabinets are calculated. The proposed change is not substantive and would not change the amount or structure of the fees.

The Exchange offers Users ⁵ dedicated and partial cabinets to house their servers and other equipment. ⁶ Each dedicated cabinet has a standard power allocation of either 4 kilowatts ("kW") or 8 kW, but additional power can be added if the User requests. ⁷ Users may request that such additional power be allocated to a dedicated cabinet when it is first set up or later.

A User pays a monthly fee based on the power allocated to its dedicated cabinets. As previously indicated,⁸ the

should be submitted on or before May 26, 2021.

^{18 17} CFR 200.30-3(a)(12).

² 15 U.S.C. 78a. ³ 17 CFR 240.19b–4.

¹ 15 U.S.C. 78s(b)(1).

⁴ The Exchange initially filed rule changes relating to its co-location services with the Securities and Exchange Commission ("Commission") in 2010. See Securities Exchange Act Release No. 62961 (September 21, 2010), 75 FR 59299 (September 27, 2010) (SR–NYSEAmex-2010–80). The Exchange is an indirect subsidiary of Intercontinental Exchange, Inc. ("ICE"). Through its ICE Data Services business, ICE operates a data center in Mahwah, New Jersey, from which the Exchange provides co-location services to Users.

⁵For purposes of the Exchange's co-location services, a "User" means any market participant that requests to receive co-location services directly from the Exchange. See Securities Exchange Act Release No. 76009 (September 29, 2015), 80 FR 60213 (October 5, 2015) (SR-NYSEMKT-2015-67). As specified in the Price List and Fee Schedule, a User that incurs co-location fees for a particular colocation service pursuant thereto would not be subject to co-location fees for the same co-location service charged by the Exchange's affiliates New York Stock Exchange LLC, NYSE Arca, Inc., NYSE Chicago, Inc., and NYSE National, Inc. (together, the "Affiliate SROs"). Each Affiliate SRO has submitted substantially the same proposed rule change to propose the changes described herein. See SR-NYSE-2021-26, SR-NYSEArca-2021-26, SR-NYSECHX-2021-08, and SR-NYSENAT-2021-

⁶ See Securities Exchange Act Release No. 71131 (December 18, 2013), 78 FR 77750 (December 24, 2013) (SR-NYSEMKT-2013-103).

 $^{^{7}}$ Presently, the maximum amount of power that can be allocated to one dedicated cabinet is 15 kW.

⁸ See Securities Exchange Act Release No. 65239 (August 31, 2011), 76 FR 55435 (September 7, 2011) (SR-NYSEAmex-2011–66).

^{17 15} U.S.C. 78s(b)(2)(B).

tiered fee is based on the total kWs allocated to all of a User's dedicated cabinets, not the kWs allocated to an individual dedicated cabinet. For example, a User that has two dedicated cabinets with a total power allocation of 12 kW has a monthly charge of \$1,200 per kW for the first eight kW and \$1,050 per kW for the next four kW (between 9 kW and 12 kW), for a total of \$13,800, irrespective of how the User divides the 12 kW between its two cabinets.

To further clarify how the fees are calculated, in a non-substantive change, the Exchange proposes to make the following edits to the Price List and Fee Schedule:

- Revise the title "Monthly Fee per Cabinet" to read "Monthly Fee for Cabinets"; and
- under the heading "Dedicated Cabinet," add the following text: "Monthly fee is based on total kWs allocated to all of a User's dedicated cabinets".

The Exchange does not propose to change the fees.

Application and Impact of the Proposed Changes

The proposed change is not expected to have any impact on Users. Users are currently subject to the described services and fees, none of which is new or novel. Current Users would not incur any new or changed fees and the Exchange does not expect to attract any new Users as a result of the proposed change. The change would simply add clarity to the Price List and Fee Schedule concerning the monthly fee for dedicated cabinets.

The proposed change is not targeted at, or expected to be limited in applicability to, a specific segment of market participant, as colocation is available to any market participant that wishes to be a User.

The proposed change is not otherwise intended to address any other issues, and the Exchange is not aware of any problems that member organizations would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,⁹ in general, and furthers the objectives of Section 6(b)(5) of the Act,¹⁰ in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in

regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange further believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,¹¹ because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed rule change is reasonable because it would add clarity to the Price List and Fee Schedule regarding how the monthly fee for dedicated cabinets is calculated, clarifying that the monthly fee for dedicated cabinets is based on the aggregate number of kW allocated to all the User's dedicated cabinets, and not charged on a per-cabinet basis. It would add detail previously stated in rule filings with the Commission 12 to the Price List and Fee Schedule. Doing so would remove impediments to, and perfecting the mechanisms of, a free and open market and a national market system and, in general, protecting investors and the public interest because the change would add clarity and transparency to the Exchange rules, alleviating potential investor or market participant confusion.

The proposed change is equitable, as it would add clarity for all market participants with respect to how the monthly fee for dedicated cabinets is calculated. At the same time, it is a non-substantive change that would not impact the services available to Users or the fees charged for such services. The Exchange does not expect to attract any new Users as a result of the proposed change. The proposed change is not expected to have any impact on Users. Users are currently subject to the described services and fees, none of which is new or novel.

For the reasons above, the proposed changes do not unfairly discriminate between or among market participants that are otherwise capable of satisfying any applicable colocation fees, requirements, terms, and conditions established from time to time by the Exchange.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,13 the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act because it is ministerial in nature and is not designed to have any competitive impact. Rather, the change would simply add clarity to the Price List and Fee Schedule regarding how the monthly fee for dedicated cabinets is calculated, clarifying that the monthly fee for dedicated cabinets is based on the aggregate number of kW allocated to all the User's dedicated cabinets, and not charged on a per-cabinet basis. The change would add clarity and transparency to the Exchange rules, alleviating potential investor or market participant confusion.

For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

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 Act 14 and Rule 19b-4(f)(6) thereunder.15 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.16

⁹ 15 U.S.C. 78f(b).

¹⁰ 15 U.S.C. 78f(b)(5).

^{11 15} U.S.C. 78f(b)(4).

¹² See 76 FR 55435, supra note 8.

^{13 15} U.S.C. 78f(b)(8).

¹⁴ 15 U.S.C. 78s(b)(3)(A)(iii).

¹⁵ 17 CFR 240.19b–4(f)(6).

¹⁶ 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires the Exchange to give the Commission written notice of its intent to file the proposed rule change, along with a brief description
Continued

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) 17 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 (http://www.sec.gov/rules/sro.shtml); or
- Send an email to rule-comments@ sec.gov. Please include File Number SR– NYSEAMER–2021–22 on the subject line.

Paper Comments

 Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090. All submissions should refer to File Number SR-NYSEAMER-2021-22. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (http://www.sec.gov/ rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE,

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.

Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSEAMER-2021-22 and should be submitted on or before May

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. 18

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–09441 Filed 5–4–21; 8:45 am] BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-91705; File No. SR-NYSE-2021-28]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Effective Date in Commentary .10 Under NYSE Rule 1210

April 29, 2021.

Pursuant to Section 19(b)(1) ¹ of the Securities Exchange Act of 1934 (the "Exchange Act") ² and Rule 19b–4 thereunder, ³ notice is hereby given that on April 19, 2021, New York Stock Exchange LLC ("NYSE" or the "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the 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 a rule change to extend the effective date in Commentary .10 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) under NYSE Rule 1210 (Registration

3 17 CFR 240.19b-4.

Requirements) applicable to member organizations, from April 30, 2021 to June 30, 2021. The Exchange does not anticipate providing any further extensions to the temporary relief identified in this proposed rule change beyond June 30, 2021. 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 these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to extend the effective date in Commentary .10 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) under NYSE Rule 1210 (Registration Requirements) applicable to member organizations,5 from April 30, 2021 to June 30, 2021. The proposed rule change would extend the 120-day period that certain individuals can function as a principal without having successfully passed an appropriate qualification examination through June 30, 2021, and would apply only to those individuals who were designated to function as a principal

^{17 15} U.S.C. 78s(b)(2)(B).

¹⁸ 17 CFR 200.30–3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

⁴ If due to unforeseen circumstances a further extension is necessary, the Exchange will submit a separate rule filing to further extend the temporary relief

 $^{^{\}rm 5}\,{\rm The\; term\; ``member\; organization''}$ means a registered broker or dealer (unless exempt pursuant to the Exchange Act), including sole proprietors partnerships, limited liability partnerships, corporations, and limited liability corporations, approved by the Exchange pursuant to NYSE Rule 311. A registered broker or dealer must also be approved by the Exchange and authorized to designate an associated natural person to effect transactions on the floor of the Exchange or any facility thereof. See NYSE Rule 2(b)(i). The term "member organization" also includes any registered broker or dealer which does not own a trading license and agrees to be regulated by the Exchange as a member organization and which the Exchange has agreed to regulate. See NYSE Rule 2(b)(ii).

prior to March 3, 2021. This proposed rule change is based on a filing recently submitted by the Financial Industry Regulatory Authority, Inc. ("FINRA") ⁶ and is intended to harmonize the Exchange's registration rules with those of FINRA so as to promote uniform standards across the securities industry.

In response to COVID–19 global pandemic, last year FINRA began providing temporary relief by way of frequently asked questions ("FAQs") ⁷ to address disruptions to the administration of FINRA qualification examinations caused by the pandemic that have significantly limited the ability of individuals to sit for examinations due to Prometric test center capacity issues.⁸

FINRA published the first FAQ on March 20, 2020, providing that individuals who were designated to function as principals under FINRA Rule 1210.04 9 prior to February 2, 2020, would be given until May 31, 2020, to pass the appropriate principal qualification examination. 10 FINRA revised the FAQ to extend the expiration of the temporary relief to pass the appropriate principal examination until June 30, 2020, and then until August 31, 2020.

On September 25, 2020, NYSE filed with the Commission a proposed rule change for immediate effectiveness to extend the temporary relief provided via the FAQ by adopting temporary Commentary .10 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) under NYSE Rule 1210 (Registration

Requirements). ¹¹ Pursuant to this rule filing, individuals who were designated prior to September 3, 2020, to function as a principal under NYSE Rule 1210.10 had until December 31, 2020, to pass the appropriate qualification examination. The Exchange thereafter filed a proposed rule change to extend the expiration date of the temporary relief from December 31, 2020, to April 30, 2021. ¹²

As mentioned in the prior filings, FINRA began providing, and then extended, temporary relief to address the interruptions in the administration of FINRA qualification examinations at Prometric test centers and the limited ability of individuals to sit for the examinations caused by the COVID-19 pandemic.¹³ The prior filings also noted that the pandemic could result in firms potentially experiencing significant disruptions to their normal business operations that may be exacerbated by being unable to keep principal positions filled. Specifically, the limitation of inperson activities and staff absenteeism as a result of the health and welfare concerns stemming from COVID-19 could result in firms having difficulty finding other qualified individuals to transition into that role or requiring them to reallocate employee time and resources away from other critical responsibilities at the firm.

While there are signs of improvement, the COVID-19 conditions necessitating the temporary relief persist and FINRA has determined that there is a continued need for this temporary relief beyond April 30, 2021. Although Prometric has resumed testing in many of its U.S. test centers, Prometric's safety practices mean that currently not all test centers are open, some of the open test centers are at limited capacity, and some open test centers are delivering only certain examinations that have been deemed essential by the local government.¹⁴ In addition, while certain states have started to ease COVID-19 restrictions on businesses and social activities, public health officials continue to emphasize the importance for individuals to keep

taking numerous steps to protect themselves and help slow the spread of the disease.¹⁵

Although the COVID-19 conditions necessitating the temporary relief persist, in the FINRA Filing, FINRA stated that an extension of the relief is necessary only until June 30, 2021, because FINRA recently expanded the availability of online examinations. Prior to this expansion, the ongoing effects of the pandemic made it impracticable for FINRA members to ensure that the individuals who they had designated to function in a principal capacity, as set forth in FINRA Rule 1210.04, could successfully sit for and pass an appropriate qualification examination within the 120-calendar day period required under the rule.16 Specifically, if the individual wanted to take a qualifying examination, they were required to accept the health risks associated with taking an in-person examination because those examinations were not available online. On February 24, 2021, however, FINRA adopted an interim accommodation request process to allow candidates to take additional FINRA examinations online, including the General Securities Principal ("Series 24") examination.¹⁷ Because the qualifying examination has been made available online only recently, FINRA is concerned that individuals who have been designated to function in a principal capacity may not have sufficient time to schedule, study for, and take the applicable examination before April 30, 2021, the date the temporary relief is set to expire.

These ongoing circumstances make it impracticable for member organizations to ensure that the individuals whom they have designated to function in a principal capacity, as set forth in NYSE Rule 1210.03, are able to successfully sit for and pass an appropriate qualification examination within the 120-calendar day period required under the rule, or to find other qualified staff to fill this position. Therefore, NYSE is proposing to extend the effective date of the temporary relief provided through SR-NYSE-2020-104 until June 30, 2021. The proposed rule change would apply only to those individuals who were designated to function as a principal prior to March 3, 2021. Any individuals designated to function as a principal on or after March 3, 2021, would need to successfully pass an appropriate

⁶ See Exchange Act Release No. 91506 (April 8, 2021) 86 FR 19671 (April 14, 2021) (SR–FINRA–2021–005) (the "FINRA Filing"). The Exchange notes that the FINRA Filing also provides temporary relief to individuals registered with FINRA as Operations Professionals under FINRA Rule 1220. The Exchange does not have a registration category for Operations Professionals and therefore, the Exchange is not proposing to adopt that aspect of the FINRA Filing.

 $^{^7\,}See\ https://www.finra.org/rules-guidance/keytopics/covid-19/faq#qe.$

⁸ At the outset of the COVID–19 pandemic, all FINRA qualification examinations were administered at test centers operated by Prometric. Based on the health and welfare concerns resulting from COVID–19, in March 2020 Prometric closed all of its test centers in the United States and Canada and began to slowly reopen some of them at limited capacity in May. Currently, Prometric has resumed testing in many of its United States and Canada test centers, at either full or limited occupancy, based on local and government mandates.

 $^{^{9}}$ NYSE Rule 1210.03 is the corresponding rule to FINRA Rule 1210.04.

¹⁰ FINRA Rule 1210.04 (Requirements for Registered Persons Functioning as Principals for a Limited Period) allows a member firm to designate certain individuals to function in a principal capacity for 120 calendar days before having to pass an appropriate principal qualification examination. NYSE Rule 1210.03 provides the same allowance to member organizations.

¹¹ See Exchange Act Release No. 90111 (October 7, 2020), 85 FR 65090 (October 14, 2020) (Notice of Filing and Immediate Effectiveness of SR-NYSE-2020-80).

¹² See Exchange Act Release No. 90753 (December 21, 2020), 85 FR 85779 (December 29, 2020) (Notice of Filing and Immediate Effectiveness of SR-NYSE-2020-104).

¹³ Information about the continued impact of COVID-19 on FINRA-administered examinations is available at https://www.finra.org/rules-guidance/key-topics/covid-19/exams.

¹⁴ Information from Prometric about its safety practices and the impact of COVID–19 on its operations is available at https://www.prometric.com/covid-19-update/corona-virus-update. See also supra note 13.

¹⁵ See, e.g., Centers for Disease Control and Prevention, How to Protect Yourself & Others, https://www.cdc.gov/coronavirus/2019-ncov/ prevent-getting-sick/prevention.html.

¹⁶ See supra note 13.

¹⁷ Id.

qualification examination within 120 days.

NYSE believes that this proposed continued extension of time is tailored to address the needs and constraints on a member organization's operations during the COVID-19 pandemic, without significantly compromising critical investor protection. The proposed extension of time will help to minimize the impact of COVID-19 on member organizations by providing continued flexibility so that member organizations can ensure that principal positions remain filled. The potential risks from the proposed extension of the 120-day period are mitigated by the member organization's continued requirement to supervise the activities of these designated individuals and ensure compliance with federal securities laws and regulations, as well as NYSE rules. NYSE has filed the proposed rule change for immediate effectiveness and has requested that the Commission waive the requirement that the proposed rule change not become operative for 30 days after the date of the filing, so NYSE can implement the proposed rule change immediately.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Exchange Act, 18 in general, and furthers the objectives of Section 6(b)(5), ¹⁹ 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 proposed rule change is intended to minimize the impact of COVID-19 on member organization operations by extending the 120-day period certain individuals may function as a principal without having successfully passed an appropriate qualification examination under NYSE Rule 1210.03 until June 30, 2021. The proposed rule change does not relieve member organizations from maintaining, under the circumstances, a reasonably designed system to supervise the activities of their associated persons to achieve compliance with applicable securities laws and regulations, and with applicable NYSE rules that directly serve investor protection. In a time when faced with unique challenges

resulting from the COVID-19 pandemic, NYSE believes that the proposed rule change is a sensible accommodation that will continue to afford member organizations the ability to ensure that critical positions are filled and client services maintained, while continuing to serve and promote the protection of investors and the public interest in this unique environment.

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 Exchange Act. As set forth in the prior filings, the proposed rule change is intended solely to extend temporary relief necessitated by the continued impacts of the COVID-19 pandemic and the related health and safety risks of conducting in-person activities. In its filing, FINRA noted that the proposed rule change is necessary to temporarily rebalance the attendant benefits and costs of the obligations under FINRA Rule 1210 in response to the impacts of the COVID-19 pandemic that would otherwise result if the temporary relief was to expire on April 30, 2021. The Exchange accordingly incorporates FINRA's abbreviated economic impact assessment by reference.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act ²⁰ and Rule 19b–4(f)(6) thereunder.²¹

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b–4(f)(6)(iii), the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative immediately upon filing. As noted above, the Exchange stated that the conditions necessitating the temporary relief continue to exist and the proposed extension of time will help minimize the impact of the COVID-19 outbreak on NYSE member organizations' operations by allowing them to keep principal positions filled and minimizing disruptions to client services and other critical responsibilities. Despite signs of improvement, the Exchange further stated that the ongoing extenuating circumstances of the COVID-19 pandemic make it impractical to ensure that individuals designated to act in these capacities are able to take and pass the appropriate qualification examination during the 120-calendar day period required under the rules.

The Exchange observed that, following a nationwide closure of all test centers earlier in the year, some test centers have re-opened, but are operating at limited capacity or are only delivering certain examinations that have been deemed essential by the local government.²² However, on February 24, 2021, FINRA began providing the General Securities Principal (Series 24) Examination online through an interim accommodation request process.²³ Prior to this change, if individuals wanted to take these qualifying examinations, they were required to accept the health risks associated with taking an in-person examination. Even with the expansion of online qualifications examinations, the Exchange stated that extending the expiration date of the relief set forth in SR-NYSE-2020-104 until June 30, 2021 is still needed. The Exchange stated that this temporary relief will provide flexibility to allow individuals who have been designated to function in a principal sufficient time to schedule, study for and take the applicable examination before the temporary relief expires. Notably, the Exchange stated

¹⁸ 15 U.S.C. 78f(b).

¹⁹ 15 U.S.C. 78f(b)(5).

²⁰ 15 U.S.C. 78s(b)(3)(A).

²¹ 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.

²² See supra notes 13 and 14. The Exchange states that Prometric has also had to close some reopened test centers due to incidents of COVID-19 cases.

²³ See supra note 13 (including the February 24, 2021 announcement of the interim accommodation process for candidates to take certain examinations, including the General Securities Principal (Series 24) Examination, online.)

that it does not anticipate providing any further extensions to the temporary amendments and that any individuals designated to function as a principal on or after March 3, 2021 will need to successfully pass an appropriate qualification examination within 120 days.

For these reasons, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest.²⁴ Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.²⁵

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (http://www.sec.gov/rules/sro.shtml); or
- Send an email to *rule-comments@* sec.gov. Please include File Number SR–NYSE–2021–28 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–2021–28. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use

only one method. The Commission will post all comments on the Commission's internet website (http://www.sec.gov/ rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSE-2021-28 and should be submitted on or before May 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. 26

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–09434 Filed 5–4–21; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-91706; File No. SR-NYSEAMER-2021-24]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Effective Date in Commentary .10 under NYSE American Rule 2.1210

April 29, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 19b–4 thereunder, notice is hereby given that on April 19, 2021, NYSE American LLC ("NYSE American" or the "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission")

the proposed rule change as described in Items I and II below, which Items have been prepared by the 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 a rule change to extend the effective date in Commentary .10 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) under NYSE American Rule 2.1210 (Registration Requirements) applicable to member organizations, Equity Trading Permit ("ETP") Holders and American Trading Permit ("ATP") Holders, from April 30, 2021 to June 30, 2021. The Exchange does not anticipate providing any further extensions to the temporary relief identified in this proposed rule change beyond June 30, 2021.4 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 these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to extend the effective date in Commentary .10 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) under NYSE American Rule 2.1210 (Registration Requirements) applicable to member organizations, ETP Holders and ATP

²⁴ As noted above by the Exchange, this proposal is an extension of temporary relief provided in SR–NYSE–2020–080 and SR–NYSE–2020–104 where the Exchange also requested and the Commission granted a waiver of the 30-day operative delay. See SR–NYSE–2020–80, 85 FR at 65092 and SR–NYSE–2020–104, 85 FR at 85781.

²⁵ For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

²⁶ 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.

⁴ If due to unforeseen circumstances a further extension is necessary, the Exchange will submit a separate rule filing to further extend the temporary relief.

Holders (collectively, "Members"),5 from April 30, 2021 to June 30, 2021. The proposed rule change would extend the 120-day period that certain individuals can function as a principal without having successfully passed an appropriate qualification examination through June 30, 2021, and would apply only to those individuals who were designated to function as a principal prior to March 3, 2021. This proposed rule change is based on a filing recently submitted by the FINRA 6 and is intended to harmonize the Exchange's registration rules with those of FINRA so as to promote uniform standards across the securities industry.

In response to COVID-19 global pandemic, last year FINRA began providing temporary relief by way of frequently asked questions ("FAQs") ⁷ to address disruptions to the

⁵The term "member organization" is defined in NYSE American Rule 24 (Office Rules) as "a partnership, corporation or such other entity as the Exchange may, by Rule, permit to become a member organization, and which meets the qualifications specified in the Rules." The term "member organization" is defined in NYSE American Rule 2(b)(i) (Equities Rules) as a registered broker or dealer (unless exempt pursuant to the Exchange Act that is a member of the Financial Industry Regulatory Authority, Inc. ("FINRA") or another registered securities exchange. Member organizations that transact business with public customers or conduct business on the Floor of the Exchange shall at all times be members of FINRA. A registered broker or dealer must also be approved by the Exchange and authorized to designate an associated natural person to effect transactions on the floor of the Exchange or any facility thereof. This term shall include a natural person so registered, approved and licensed who directly effects transactions on the floor of the Exchange or any facility thereof." The term "member organization" also includes any registered broker or dealer that is a member of FINRA or a registered securities exchange, consistent with the requirements of section 2(b)(i) of this Rule, which does not own a trading license and agrees to be regulated by the Exchange as a member organization and which the Exchange has agreed to regulate." See NYSE American Rule 2(a)(ii) (Equities Rules). The term "ETP Holder" means a member organization that has been issued an ETP. An ETP Holder will agree to be bound by the Rules of the Exchange, and by all applicable rules and regulations of the Securities and Exchange Commission. See Rule NYSE American 1.1E(n). References to "member organization" as used in Exchange rules include ATP Holders, which are registered brokers or dealers approved to effect transactions on the Exchange's options marketplace. Under the Exchange's rules, an ATP Holder has the status as a "member" of the Exchange as that term is defined in Section 3 of the Exchange Act. See NYSE American Rules 900.2NY(4) & (5)

administration of FINRA qualification examinations caused by the pandemic that have significantly limited the ability of individuals to sit for examinations due to Prometric test center capacity issues.⁸

FINRA published the first FAQ on March 20, 2020, providing that individuals who were designated to function as principals under FINRA Rule 1210.04 9 prior to February 2, 2020, would be given until May 31, 2020, to pass the appropriate principal qualification examination. 10 FINRA revised the FAQ to extend the expiration of the temporary relief to pass the appropriate principal examination until June 30, 2020, and then until August 31, 2020.

On September 25, 2020, NYSE American filed with the Commission a proposed rule change for immediate effectiveness to extend the temporary relief provided via the FAQ by adopting temporary Commentary .10 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) under NYSE American Rule 2.1210 (Registration Requirements).11 Pursuant to this rule filing, individuals who were designated prior to September 3, 2020, to function as a principal under NYSE American Rule 2.1210.10 had until December 31, 2020, to pass the appropriate qualification examination. The Exchange thereafter filed a proposed rule change to extend the expiration date of the temporary relief from December 31, 2020, to April 30, 2021.12

As mentioned in the prior filings, FINRA began providing, and then extended, temporary relief to address the interruptions in the administration

of FINRA qualification examinations at Prometric test centers and the limited ability of individuals to sit for the examinations caused by the COVID-19 pandemic.¹³ The prior filings also noted that the pandemic could result in firms potentially experiencing significant disruptions to their normal business operations that may be exacerbated by being unable to keep principal positions filled. Specifically, the limitation of inperson activities and staff absenteeism as a result of the health and welfare concerns stemming from COVID-19 could result in firms having difficulty finding other qualified individuals to transition into that role or requiring them to reallocate employee time and resources away from other critical responsibilities at the firm.

While there are signs of improvement, the COVID-19 conditions necessitating the temporary relief persist and FINRA has determined that there is a continued need for this temporary relief beyond April 30, 2021. Although Prometric has resumed testing in many of its U.S. test centers, Prometric's safety practices mean that currently not all test centers are open, some of the open test centers are at limited capacity, and some open test centers are delivering only certain examinations that have been deemed essential by the local government.¹⁴ In addition, while certain states have started to ease COVID-19 restrictions on businesses and social activities, public health officials continue to emphasize the importance for individuals to keep taking numerous steps to protect themselves and help slow the spread of the disease.15

Although the COVID—19 conditions necessitating the temporary relief persist, in the FINRA Filing, FINRA stated that an extension of the relief is necessary only until June 30, 2021, because FINRA recently expanded the availability of online examinations. Prior to this expansion, the ongoing effects of the pandemic made it impracticable for FINRA members to ensure that the individuals who they had designated to function in a principal capacity, as set forth in FINRA Rule 1210.04, could successfully sit for and pass an appropriate qualification

⁶ See Exchange Act Release No. 91506 (April 8, 2021) 86 FR 19671 (April 14, 2021) (SR-FINRA–2021–005) (the "FINRA Filing"). The Exchange notes that the FINRA Filing also provides temporary relief to individuals registered with FINRA as Operations Professionals under FINRA Rule 1220. The Exchange does not have a registration category for Operations Professionals and therefore, the Exchange is not proposing to adopt that aspect of the FINRA Filing.

 $^{^{7}}$ See https://www.finra.org/rules-guidance/keytopics/covid-19/faq#qe.

⁸ At the outset of the COVID–19 pandemic, all FINRA qualification examinations were administered at test centers operated by Prometric. Based on the health and welfare concerns resulting from COVID–19, in March 2020 Prometric closed all of its test centers in the United States and Canada and began to slowly reopen some of them at limited capacity in May. Currently, Prometric has resumed testing in many of its United States and Canada test centers, at either full or limited occupancy, based on local and government mandates.

⁹ NYSE American Rule 2.1210.03 is the corresponding rule to FINRA Rule 1210.04.

¹⁰ FINRA Rule 1210.04 (Requirements for Registered Persons Functioning as Principals for a Limited Period) allows a member firm to designate certain individuals to function in a principal capacity for 120 calendar days before having to pass an appropriate principal qualification examination. NYSE American Rule 2.1210.03 provides the same allowance to Members.

¹¹ See Exchange Act Release No. 90115 (October 7, 2020), 85 FR 64595 (October 13, 2020) (Notice of Filing and Immediate Effectiveness of SR-NYSEAMER-2020-71).

¹² See Exchange Act Release No. 90754 (December 21, 2020), 85 FR 85821 (December 29, 2020) (Notice of Filing and Immediate Effectiveness of SR-NYSEAMER-2020-85).

¹³ Information about the continued impact of COVID–19 on FINRA-administered examinations is available at https://www.finra.org/rules-guidance/key-topics/covid-19/exams.

¹⁴ Information from Prometric about its safety practices and the impact of COVID-19 on its operations is available at https://www.prometric.com/covid-19-update/corona-virus-update. See also supra note 13.

¹⁵ See, e.g., Centers for Disease Control and Prevention, How to Protect Yourself & Others, https://www.cdc.gov/coronavirus/2019-ncov/ prevent-getting-sick/prevention.html.

examination within the 120-calendar day period required under the rule.16 Specifically, if the individual wanted to take a qualifying examination, they were required to accept the health risks associated with taking an in-person examination because those examinations were not available online. On February 24, 2021, however, FINRA adopted an interim accommodation request process to allow candidates to take additional FINRA examinations online, including the General Securities Principal ("Series 24") examination. 17 Because the qualifying examination has been made available online only recently, FINRA is concerned that individuals who have been designated to function in a principal capacity may not have sufficient time to schedule, study for, and take the applicable examination before April 30, 2021, the date the temporary relief is set to expire.

These ongoing circumstances make it impracticable for Members to ensure that the individuals whom they have designated to function in a principal capacity, as set forth in NYSE American Rule 2.1210.03, are able to successfully sit for and pass an appropriate qualification examination within the 120-calendar day period required under the rule, or to find other qualified staff to fill this position. Therefore, NYSE American is proposing to extend the effective date of the temporary relief provided through SR-NYSEAMER-2020-85 until June 30, 2021. The proposed rule change would apply only to those individuals who were designated to function as a principal prior to March 3, 2021. Any individuals designated to function as a principal on or after March 3, 2021, would need to successfully pass an appropriate qualification examination within 120 davs.

NYSE American believes that this proposed continued extension of time is tailored to address the needs and constraints on a Member's operations during the COVID-19 pandemic, without significantly compromising critical investor protection. The proposed extension of time will help to minimize the impact of COVID-19 on Members by providing continued flexibility so that Members can ensure that principal positions remain filled. The potential risks from the proposed extension of the 120-day period are mitigated by the Member's continued requirement to supervise the activities of these designated individuals and ensure compliance with federal securities laws and regulations, as well

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Exchange Act, 18 in general, and furthers the objectives of Section 6(b)(5),19 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 proposed rule change is intended to minimize the impact of COVID-19 on Member operations by extending the 120-day period certain individuals may function as a principal without having successfully passed an appropriate qualification examination under NYSE American Rule 2.1210.03 until June 30, 2021. The proposed rule change does not relieve Members from maintaining, under the circumstances, a reasonably designed system to supervise the activities of their associated persons to achieve compliance with applicable securities laws and regulations, and with applicable NYSE American rules that directly serve investor protection. In a time when faced with unique challenges resulting from the COVID-19 pandemic, NYSE American believes that the proposed rule change is a sensible accommodation that will continue to afford Members the ability to ensure that critical positions are filled and client services maintained, while continuing to serve and promote the protection of investors and the public interest in this unique environment.

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 Exchange Act. As set forth in the prior filings, the proposed rule change is intended solely to extend temporary relief necessitated

by the continued impacts of the COVID-19 pandemic and the related health and safety risks of conducting in-person activities. In its filing, FINRA noted that the proposed rule change is necessary to temporarily rebalance the attendant benefits and costs of the obligations under FINRA Rule 1210 in response to the impacts of the COVID-19 pandemic that would otherwise result if the temporary relief was to expire on April 30, 2021. The Exchange accordingly incorporates FINRA's abbreviated economic impact assessment by reference.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the **Proposed Rule Change and Timing for Commission Action**

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act 20 and Rule 19b-4(f)(6) thereunder.21

A proposed rule change filed under Rule 19b-4(f)(6) normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b-4(f)(6)(iii), the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative immediately upon filing. As noted above, the Exchange stated that the conditions necessitating the temporary relief continue to exist and the proposed extension of time will help minimize the impact of the COVID-19 outbreak on NYSE American Members' operations by allowing them to keep principal positions filled and minimizing disruptions to client services and other critical

as NYSE American rules. NYSE American has filed the proposed rule change for immediate effectiveness and has requested that the Commission waive the requirement that the proposed rule change not become operative for 30 days after the date of the filing, so NYSE American can implement the proposed rule change immediately.

^{18 15} U.S.C. 78f(b).

^{19 15} U.S.C. 78f(b)(5).

²⁰ 15 U.S.C. 78s(b)(3)(A).

²¹ 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.

¹⁶ See supra note 13. 17 Id.

responsibilities. Despite signs of improvement, the Exchange further stated that the ongoing extenuating circumstances of the COVID–19 pandemic make it impractical to ensure that individuals designated to act in these capacities are able to take and pass the appropriate qualification examination during the 120-calendar day period required under the rules.

The Exchange observed that, following a nationwide closure of all test centers earlier in the year, some test centers have re-opened, but are operating at limited capacity or are only delivering certain examinations that have been deemed essential by the local government.22 However, on February 24, 2021, FINRA began providing the General Securities Principal (Series 24) Examination online through an interim accommodation request process.23 Prior to this change, if individuals wanted to take these qualifying examinations, they were required to accept the health risks associated with taking an in-person examination. Even with the expansion of online qualifications examinations, the Exchange stated that extending the expiration date of the relief set forth in SR-NYSEAMER-2020-85 until June 30, 2021 is still needed. The Exchange stated that this temporary relief will provide flexibility to allow individuals who have been designated to function in a principal sufficient time to schedule, study for and take the applicable examination before the temporary relief expires. Notably, the Exchange stated that it does not anticipate providing any further extensions to the temporary amendments and that any individuals designated to function as a principal on or after March 3, 2021 will need to successfully pass an appropriate qualification examination within 120 days.

For these reasons, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest.²⁴ Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.²⁵

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (http://www.sec.gov/rules/sro.shtml); or
- Send an email to *rule-comments@* sec.gov. Please include File Number SR–NYSEAMER–2021–24 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-NYSEAMER-2021-24. 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 (http://www.sec.gov/ rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official

business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSEAMER-2021-24 and should be submitted on or before May 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. 26

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–09435 Filed 5–4–21; 8:45 am] BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-91724; File No. SR-CboeEDGX-2021-021]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing of a Proposed Rule Change To Amend the Sixth Amended and Restated Bylaws of Cboe EDGX Exchange, Inc.'s Parent Corporation, Cboe Global Markets, Inc. To Implement Proxy Access

April 29, 2021.

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 April 16, 2021, Cboe EDGX Exchange, Inc. ("Exchange" or "EDGX") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGX Exchange, Inc. (the "Exchange" or "EDGX") is filing with the Securities and Exchange Commission (the "Commission") a proposed rule change with respect to amendments to the Sixth Amended and Restated Bylaws (the "CGM Bylaws") of

 $^{^{22}}$ See supra notes 13 and 14. The Exchange states that Prometric has also had to close some reopened test centers due to incidents of COVID–19 cases.

²³ See supra note 13 (including the February 24, 2021 announcement of the interim accommodation process for candidates to take certain examinations, including the General Securities Principal (Series 24) Examination, online).

²⁴ As noted above by the Exchange, this proposal is an extension of temporary relief provided in SR-NYSEAMER-2020-71 and SR-NYSEAMER-2020-85 where the Exchange also requested and the Commission granted a waiver of the 30-day operative delay. See SR-NYSEAMER-2020-71, 85 FR at 64597-98 and SR-NYSEAMER-2020-85, 85 FR at 85823-24.

²⁵ For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

²⁶ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

^{2 17} CFR 240.19b-4.

its parent corporation, Cboe Global Markets, Inc. ("Cboe" or "Corporation"). The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (http://markets.cboe.com/us/options/regulation/rule_filings/edgx/), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

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

Choe has received a stockholder proposal submitted pursuant to Rule 14a-8 under the Act 3 which requested that the CGM Board take steps to implement a "proxy access" bylaw provision. In general, proxy access bylaws allow a stockholder, or group of stockholders, who comply with certain requirements, to nominate candidates for service on a board and have those candidates included in a company's proxy materials. Such provisions have become common among S&P 500 companies.4 Choe has determined to take the stockholder's requested steps to implement proxy access. Accordingly, the Exchange now proposes to make these changes by adopting new Section 2.16 of the CGM Bylaws and making certain conforming changes to current Sections 2.10 and 2.11 of the CGM Bylaws, all of which are described further below.

In developing its proposal, Cboe generally tried to balance the relative weight of arguments for and against proxy access provisions. On the one hand, Cboe recognizes the significance

of this issue to some investors, who see proxy access as an important accountability mechanism that allows them to participate in board elections through the nomination of stockholder candidates that are presented in a company's proxy statement. On the other hand, Cboe's proposed proxy access provision includes certain procedural requirements that are designed to help ensure, among other things, that Cboe and its stockholders will have full and accurate information about nominating stockholders and their nominees and that such stockholders and nominees will comply with applicable laws, regulations and other requirements. Additionally, the Exchange notes the proposed terms are common among companies that have adopted proxy access. The Exchange also notes that the parent companies of other exchanges have adopted substantively similar proxy access provisions and the Exchange does not believe such provisions are materially different than the Exchange's proposal.⁵

The proposed rule change would add new Section 2.16 to the CGM Bylaws. Section 2.16 would permit a stockholder, or group of up to 20 stockholders, to nominate director nominees for the Cboe Board, so long as the stockholder(s) have owned at least three percent of Cboe's outstanding shares of capital stock continuously for at least three years. The director nominees would be included in Cboe's annual meeting proxy materials. The proposed provision would limit the number of proposed director nominees to the greater of (i) two or (ii) 20% of the number of Cboe directors in office (rounded down to the nearest whole number, but no less than two) provided that the stockholder(s) and nominee(s) satisfy the other conditions specified in the CGM Bylaws as described further below.

Proposed Section 2.16(a)

The Exchange first proposes to amend the CGM Bylaws to, as set forth in the first sentence of proposed Section 2.16(a), require the Corporation to include in its proxy statement, its form proxy and any ballot distributed at the stockholder meeting, the name of, and

certain Required Information 6 about, any person nominated for election (the "Stockholder Nominee") to the Board by a stockholder or group of stockholders (the "Eligible Stockholder") 7 that satisfies the requirements set forth in the proxy access provision of CGM Bylaws.8 Proposed Section 2.16(a) will also make clear that Cboe is able to solicit against any Stockholder Nominee or include in its proxy materials the Corporation's own statements or other information relating to any Eligible Stockholder or Stockholder Nominee, including any information provided to the Corporation pursuant to Section 2.16. This provision clarifies that just because Cboe must include a Stockholder Nominee in its proxy materials if the proxy access provisions are satisfied, Choe does not necessarily have to support that nominee.

Proposed Section 2.16(b)

Proposed Section 2.16(b) will provide that in order to utilize this provision, the Eligible Stockholder must expressly request at the time of providing a required notice to the Corporation of the proxy access nomination (the "Notice of Proxy Access Nomination") to have its nominee included in the Corporation's proxy materials. Proposed Section 2.16(b) also establishes the deadline for a timely Notice of Proxy Access Nomination. Specifically, such a notice must be delivered to the Cboe's Secretary at the principal executive offices of the Corporation not earlier than the open of business on the one hundred fiftieth (150th) day and not later than the close of business on the one hundred twentieth (120th) day prior to the first anniversary of the date that Choe first distributed its proxy statement to stockholders for the previous year's annual meeting of stockholders provided, however, that in the event the annual meeting is more than thirty (30) days before or after the anniversary date of the prior year's

³ See 17 CFR 240.14a-8, which requires companies that are subject to the federal proxy rules to include shareholder proposals in companies' proxy statements to shareholders, subject to certain procedural and substantive requirements.

⁴More than 75% of S&P 500 companies have adopted proxy access bylaw provisions.

⁵ See Securities Exchange Release No. 79357 (November 18, 2016) 81 FR 85283 (November 25, 2016) (SR-NASDAQ-2016-127; SR-BX-2016-051; SR-ISE-2016-22; SR-ISEGemini-2016-10; SR-ISEMercury-2016-16; SR-PHLX-2016-93; SR-BSECC-2016-001; SR-SCCP-2016-01). See also Securities Exchange Release No. 77782 (May 6, 2016) 81 FR 29600 (May 12, 2016) (SR-NYSE-2016-14; SR-NYSEArca-2016-25; SR-NYSEMKT-2016-20).

⁶The Required Information is the information provided to Cboe's Corporate Secretary about the Stockholder Nominee and the Eligible Stockholder that is required to be disclosed in the Corporation's proxy statement by the regulations promulgated under the Act, and if the Eligible Stockholder so elects, a written statement, not to exceed 500 words, in support of the Stockholder Nominee(s)' candidacy (the "Supporting Statement", as defined further below).

⁷ As used throughout the CGM Bylaws, the term "Eligible Stockholder" includes each member of a stockholder group that submits a proxy access nomination to the extent the context requires.

⁸When the Corporation includes proxy access nominees in the proxy materials, such individuals will be included in addition to any persons nominated for election by at or the direction of the Board to the Board or any committee thereof.

annual meeting, or if no annual meeting was held in the preceding year, to be timely, the Notice of Proxy Access Nomination must be received at the principal executive offices of the Corporation no earlier than one hundred fifty (150) days before such annual meeting and no later than the later of one hundred twenty (120) days before such annual meeting or the tenth (10th) day following the day on which public announcement (as defined in Section 2.11) of the date of such meeting is first made by the Corporation. Further Section 2.16 will provide that in no event shall any adjournment or postponement of an annual meeting or the announcement thereof commence a new time period (or extend any time period) for the giving of a Notice of Proxy Access Nomination as described above. Choe believes this notice period will provide stockholders an adequate window to submit nominees via proxy access, while also providing the Corporation adequate time to diligence a proxy access nominee before including them in the proxy statement for the next annual meeting of stockholders.

Proposed Section 2.16(c)

Proposed Section 2.16(c) specifies that the maximum number ("the Permitted Number") of Stockholder Nominees nominated by all Eligible Stockholders that will be included in Choe's proxy materials with respect to an annual meeting of stockholders shall not exceed the greater of two or 20% of the total number of directors in office (rounded down to the nearest whole number) as of the last day on which a Notice of Proxy Access Nomination may be delivered pursuant to and in accordance with the proxy access provision of the Bylaws (the "Final Proxy Access Nomination Date"). In the event that one or more vacancies for any reason occurs after the Final Proxy Access Nomination Date but before the date of the annual meeting and the Board resolves to reduce the size of the Board in connection therewith, the Permitted Number of Stockholder Nominees included in Cboe's proxy materials shall be calculated based on the number of directors in office as so reduced. In addition, the Permitted Number shall be reduced by (i) the number of individuals who will be included in the Corporation's proxy materials as director nominees recommended by the Board pursuant to an agreement, arrangement or other understanding with a stockholder or group of stockholders (other than any such agreement, arrangement or understanding entered into in

connection with an acquisition of stock from the Corporation by such stockholder or group of stockholders) and/or (ii) the number of directors in office as of the Final Proxy Access Nomination Date who were included in the Corporation's proxy materials as Stockholder Nominees for any of the two preceding annual meetings of stockholders (including any persons counted as Stockholder Nominees pursuant to the immediately succeeding sentence) and whose reelection at the upcoming annual meeting is being recommended by the Board. Any individual nominated by an Eligible Stockholder for inclusion in the proxy materials pursuant to the proxy access provision of the CGM Bylaws whom the Board decides to nominate as a nominee of the Board, and any individual nominated by an Eligible Stockholder for inclusion in the proxy materials pursuant to the proxy access provision but whose nomination is subsequently withdrawn, shall be counted as one of the Stockholder Nominees for purposes of determining when the Permitted Number of Stockholder Nominees has been reached. Any Eligible Stockholder submitting more than one Stockholder Nominee for inclusion in the proxy materials shall rank such Stockholder Nominees based on the order that the Eligible Stockholder desires such Stockholder Nominees to be selected for inclusion in the proxy statement in the event that the total number of Stockholder Nominees submitted by Eligible Stockholders pursuant to the proxy access provision exceeds the Permitted Number of nominees allowed. In the event that the number of Stockholder Nominees submitted by Eligible Stockholders pursuant to Section 2.16 exceeds the Permitted Number of nominees allowed, the highest ranking Stockholder Nominee who meets the requirements of the proxy access provision of the Bylaws from each Eligible Stockholder will be selected for inclusion in the proxy materials until the Permitted Number is reached, going in order of the amount (largest to smallest) of shares of Cboe's outstanding capital stock each Eligible Stockholder disclosed as owned in its respective Notice of Proxy Access Nomination submitted to Cboe. If the Permitted Number is not reached after the highest ranking Stockholder Nominee who meets the requirements of the proxy access provision of the Bylaws from each Eligible Stockholder has been selected, then the next highest ranking Stockholder Nominee who meets the requirements of Section 2.16 from each Eligible Stockholder will be

selected for inclusion in the Corporation's proxy materials, and this process will continue as many times as necessary, following the same order each time, until the Permitted Number is reached. Additionally, notwithstanding anything to the contrary contained in proposed Section 2.16, Cboe will not be required to include any Stockholder Nominees in its proxy materials pursuant to Section 2.16 for any meeting of stockholders for which the Secretary receives a notice (whether or not subsequently withdrawn) that the Eligible Stockholder or any other stockholder intends to nominate one or more persons for election to the Board pursuant to Section 2.11 of the CGM Bylaws. Choe believes it is reasonable to limit the Board seats available to proxy access nominees and to establish procedures for selecting candidates if the nominee limit is exceeded. The limitation on Board seats available to proxy access nominees ensures that proxy access cannot be used to take over the entire Board, which is not the stated purpose of proxy access campaigns. The procedures for selecting candidates if the nominee limit is exceeded establish clear and rational guidelines for an orderly nomination process to avoid the Corporation having to make arbitrary judgments among candidates.

Proposed Section 2.16(d)

Proposed Section 2.16(d) defines who may qualify as an "Eligible Stockholder". Particularly, an Eligible Stockholder is a stockholder or group of no more than 20 stockholders 9 that (i) has owned continuously for at least three years (the "Minimum Holding Period") a number of shares of capital stock of the Corporation that represents at least three percent of the outstanding shares of capital stock of the Corporation as of the date the Notice of Proxy Access Nomination is received (the "Required Shares"), (ii) continues to own the Required Shares through the date of the annual meeting and (iii) meets all other requirements of proposed Section 2.16. Choe believes it is reasonable to require each member of a nominating group to provide such information so that both the Corporation and its stockholders are fully informed about the entire group making the proxy

⁹ For this purpose, any two or more funds that are part of the same Qualifying Fund Group may be counted as one stockholder. A "Qualifying Fund Group" means two or more funds that are (i) under common management and investment control, (ii) under common management and funded primarily by the same employer or (iii) a "group of investment companies" as such term is defined in Section 12(d)(1)(G)(ii) of the Investment Corporation Act of 1940, as amended.

access nomination. As such, Section 2.16(d) further makes clear that whenever the Eligible Stockholder consists of a group of stockholders (including a group of funds that are part of the same Qualifying Fund Group), (i) each provision in Section 2.16 that requires the Eligible Stockholder to provide any written statements, representations, undertakings, agreements or other instruments or to meet any other conditions shall be deemed to require each stockholder (including each individual fund) that is a member of such group to provide such statements, representations, undertakings, agreements or other instruments and to meet such other conditions (except that the members of such group may aggregate the shares that each member has owned continuously for the Minimum Holding Period in order to meet the three percent ownership requirement of the "Required Shares" definition) and (ii) a breach of any obligation, agreement or representation under Section 2.16 by any member of such group shall be deemed a breach by the Eligible Stockholder. No stockholder may be a member of more than one group of stockholders constituting an Eligible Stockholder with respect to any annual meeting.

Proposed Section 2.16(e)

Proposed Section 2.16(e) clarifies, for the avoidance of doubt, how "ownership" will be defined for purposes of meeting the ownership requirements of the Required Shares. Specifically, an Eligible Stockholder shall be deemed to "own" only those outstanding shares of Cboe's capital stock as to which the stockholder possesses both: (i) The full voting and investment rights pertaining to the shares; and (ii) the full economic interest in (including the opportunity for profit from and risk of loss on) such shares; provided that the number of shares calculated in accordance with clauses (i) and (ii) shall not include any shares: That are (1) sold by such stockholder or any of its affiliates in any transaction that has not been settled or closed; (2) borrowed by such stockholder or any of its affiliates for any purposes or purchased by such stockholder or any of its affiliates pursuant to an agreement to resell; or (3) subject to any option, warrant, forward contract, swap, contract of sale, other derivative or similar instrument or agreement entered into by such stockholder or any of its affiliates, whether any such instrument or agreement is to be settled with shares or with cash based on the notional amount

or value of shares of Cboe's outstanding capital stock, in any such case which instrument or agreement has, or is intended to have, the purpose or effect of: (A) Reducing in any manner, to any extent or at any time in the future, such stockholder's or its affiliates' full right to vote or direct the voting of any such shares; and/or (B) hedging, offsetting or altering to any degree any gain or loss realized or realizable from maintaining the full economic ownership of such shares by such stockholder or its affiliates.

Further, a stockholder shall "own" shares held in the name of a nominee or other intermediary so long as the stockholder retains the right to instruct how the shares are voted with respect to the election of directors and possesses the full economic interest in the shares. A stockholder's ownership of shares shall be deemed to continue during any period in which (i) the stockholder has loaned such shares provided that the stockholder has the power to recall such loaned shares on five (5) business days' notice and includes in the Notice of Proxy Access Nomination an agreement that it will (1) recall such loaned shares upon being notified that any of its Stockholder Nominees will be included in the Corporation's proxy materials and (2) will hold such shares through the date of the annual meeting or (ii) the stockholder has delegated any voting power by means of a proxy, power of attorney or other instrument or arrangement which is revocable at any time by the stockholder. Section 2.16(e) also clarifies that the terms "owned," "owning" and other variations of the word "own" shall have correlative meanings. Whether outstanding shares of Cboe's capital stock are "owned" for these purposes shall be determined by the Board. For purposes of Section 2.16, the term "affiliate" or "affiliates" shall have the meaning ascribed thereto under the rules and regulations of the Act.¹⁰ An Eligible Stockholder shall include in its Notice of Proxy Access Nomination the number of shares it is deemed to own for the purposes of proposed Section 2.16. In proposing the Required Shares and the Minimum

Holding Period, Cboe seeks to ensure that the Eligible Stockholder has had a sufficient stake in the Corporation for a sufficient amount of time and is not pursuing a short-term agenda.

Proposed Section 2.16(f)

Proposed Section 2.16(f) sets forth the information that an Eligible Stockholder must provide to Cboe's Corporate Secretary in writing within the deadline discussed above in order to make a proxy access nomination. This information includes:

- A statement by the Eligible Stockholder (1) setting forth and certifying as to the number of shares it owns and has owned continuously for the Minimum Holding Period and (2) agreeing to continue to own the Required Shares through the date of the annual meeting:
- one or more written statements from the record holder of the Required Shares (and from each intermediary through which the Required Shares are or have been held during the Minimum Holding Period) verifying that, as of a date within seven calendar days prior to the date the Notice of Proxy Access Nomination is delivered to Cboe's Secretary at the principal executive offices of the Corporation, the Eligible Stockholder owns, and has owned continuously for the Minimum Holding Period, the Required Shares, and the Eligible Stockholder's agreement to provide, within five (5) business days after the record date for the annual meeting, written statements from the record holder and intermediaries verifying the Eligible Stockholder's continuous ownership of the Required Shares through the record date;
- a copy of the Schedule 14N that has been filed with the SEC as required by Rule 14a–18 under the Act; ¹¹
- the information, representations and agreements and other documents that are required to be set forth in or included with a stockholder's notice of nomination given pursuant to Section 2.11 of the CGM Bylaws;
- the written consent of each Stockholder Nominee to being named in the proxy statement as a nominee and to serving as a director if elected;
- a representation that the Eligible Stockholder:
- Acquired the Required Shares in the ordinary course of business and not with the intent to change or influence

¹⁰ Pursuant to Rule 12b–2 under the Act, "[a]n 'affiliate' of, or a person 'affiliated' with, a specified person, is a person that directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, the person specified." 17 CFR 240.12b–2. Further, "[t]he term 'control' (including the terms 'controlling,' 'controlled by' and 'under common control with') means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a person, whether through the ownership of voting securities, by contract, or otherwise." 17 CFR

¹¹ See 17 CFR 240.14n–101 and 17 CFR 240.14a–18, which generally require a Nominating Stockholder to provide notice to the Corporation of its intent to submit a proxy access nomination on a Schedule 14N and file that notice, including the required disclosure, with the Commission on the date first transmitted to the Corporation.

control of Cboe, and does not presently have such intent;

 has not nominated and will not nominate for election any individual as a director at the annual meeting, other than its Stockholder Nominee(s);

has not engaged and will not engage in, and has not and will not be a participant in another person's, "solicitation" within the meaning of Rule 14a–1(l) under the Act in support of the election of any individual as a director at the annual meeting, other than its Stockholder Nominee(s) or a nominee of the Board:

has not distributed and will not distribute to any stockholder of the Corporation any form of proxy for the annual meeting other than the form distributed by the Corporation;

has complied and will comply with all laws, rules and regulations applicable to solicitations and the use, if any, of soliciting material in connection with the annual meeting,

 has provided and will provide facts, statements and other information in all communications with Cboe and its stockholders that are or will be true and correct in all material respects and do not and will not omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

an undertaking that the Eligible

Stockholder agrees to

Assume all liability stemming from any legal or regulatory violation arising out of the Eligible Stockholder's communications with the stockholders of the Corporation or out of the information that the Eligible Stockholder provided to the Corporation;

indemnify and hold harmless the Corporation and each of its Directors, officers and employees individually against any liability, loss or damages in connection with any threatened or pending action, suit or proceeding, whether legal, administrative or investigative, against the Corporation or any of its Directors, officers or employees arising out of any nomination submitted by the Eligible Stockholder pursuant to this Section 2.16 or any solicitation or other activity in connection therewith; and

file with the Securities and Exchange Commission any solicitation or other communication with the stockholders of the Corporation relating to the meeting at which its Stockholder Nominee(s) will be nominated, regardless of whether any such filing is required under Regulation 14A of the Act or whether any exemption from

filing is available for such solicitation or other communication under Regulation 14A of the Act;

- in the case of a nomination by a group of stockholders that together is an Eligible Stockholder, the designation by all group members of one group member that is authorized to receive communications, notices and inquiries from the Corporation and to act on behalf of all members of the group with respect to all matters relating to the nomination under this Section 2.16 (including withdrawal of the nomination);
- in the case of a nomination by an Eligible Stockholder consisting of a group of stockholders in which two or more funds are intended to be treated as one stockholder for purposes of qualifying as an Eligible Stockholder, documentation reasonably satisfactory to the Corporation that demonstrates that the funds are part of the same Qualifying Fund Group; and
- a written representation and agreement by the Stockholder Nominee that such person:
- Will act as a representative of all of the stockholders of the Corporation while serving as a director;
- will provide facts, statements and other information in all communications with the Corporation and its stockholders that are or will be true and correct in all material respects (and shall not omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading);
- is not and will not become a party to (i) any compensatory, payment or other financial agreement, arrangement or understanding with any person or entity other than the Corporation in connection with service or action as a director of the Corporation that has not been disclosed to the Corporation, (ii) any Voting Commitment that has not been disclosed to the Corporation or (iii) any Voting Commitment 12 that could reasonably be expected to limit or interfere with the Stockholder Nominee's ability to comply, if elected as a director of the Corporation, with its fiduciary duties under applicable law;
- will abide by and comply with the CGM Bylaws, the Certificate of Incorporation and applicable policies of the Corporation including all applicable publicly disclosed corporate governance, conflict of interest,

confidentiality and stock ownership and trading policies and guidelines of the Corporation, as well as the applicable provisions of the rules and regulations of the Securities and Exchange Commission and any stock exchange applicable to the Corporation.

In proposing the informational requirements for the Eligible Stockholder, Cboe's goal is to gather sufficient information about the Eligible Stockholder for both itself and its stockholders. Among other things, this information is designed to help ensure that Choe is able to comply with its disclosure and other requirements under applicable law and that Choe, its Board and its stockholders are able to assess the proxy access nomination adequately.

Proposed Section 2.16(g)

Proposed Section 2.16(g) establishes additional information the Stockholder Nominee must provide. Particularly:

 The Stockholder Nominee(s) must submit all completed and signed questionnaires required of directors and officers of the Corporation;

 the Corporation may require any proposed Stockholder Nominee to furnish any information:

That may reasonably be requested by the Corporation to determine whether the Stockholder Nominee would be independent under Section 3.3 and otherwise qualifies as independent under the rules of the principal national securities exchange on which the outstanding capital stock of the Corporation is traded;

that could be material to a reasonable stockholder's understanding of the independence, or lack thereof, of such Stockholder Nominee;

 that would be required to satisfy the requirements for qualification of directors under applicable foreign

regulations; or

(that may reasonably be requested by the Corporation to determine the eligibility of such Stockholder Nominee to be included in the Corporation's proxy materials pursuant to this Section 2.16 or to serve as a director of the Corporation: and

• the Corporation may require the Eligible Stockholder to furnish any other information that may reasonably be requested by the Corporation to verify the Eligible Stockholder's continuous Ownership of the Required Shares for the Minimum Holding Period and through the date of the annual meeting.

Like the informational requirements for an Eligible Stockholder, which are set forth above, the informational requirements for the Stockholder

¹² A "Voting Commitment" is defined as any agreement, arrangement or understanding with any person or entity as to how the Stockholder Nominee would vote or act on any issue or question as a

Nominee ensure that both Cboe and its stockholders will have sufficient information about the Stockholder Nominee. Among other things, this information will ensure that Cboe is able to comply with its disclosure and other requirements under applicable law and that Cboe, its Board and its stockholders are able to assess the proxy access nomination adequately.

Proposed Section 2.16(h)

Proposed Section 2.16(h) provides that an Eligible Stockholder may provide, at its option, to the Secretary, at the time the Notice of Proxy Access Nomination is provided, a written statement, not to exceed 500 words, in support of its Stockholder Nominee(s) candidacy (a "Supporting Statement"). Only one Supporting Statement may be submitted by an Eligible Stockholder (including any group of stockholders together constituting an Eligible Stockholder) in support of its Stockholder Nominee(s). Notwithstanding anything to the contrary contained in Section 2.16, the Corporation may omit from its proxy materials any information or Supporting Statement (or portion thereof) that it, in good faith, believes is untrue in any material respect (or omits to state a material fact necessary in order to make the statements made, in light of the circumstances under which they are made, not misleading) or would violate any applicable law, rule or regulation. The Exchange notes proposed Section 2.16(h) allows Choe to comply with Rule 14a-9 under the Act 13 and to protect its stockholders from information that is materially untrue or that violates any law, rule or regulation.

Proposed Section 2.16(i)

Pursuant to proposed Section 2.16(i), each Eligible Stockholder or Stockholder Nominee must promptly notify Cboe's Corporate Secretary of any information or communications provided by the Eligible Stockholder or Stockholder Nominee, as the case may be, to Cboe or its stockholders that when provided was not, or thereafter ceases to be, true and correct in all material respects or omits a material fact necessary to make the statements made, in light of the circumstances under which they were made, not misleading and of the information that is required

to correct any such defect. An Eligible Stockholder shall also provide immediate notice to the Corporation if the Eligible Stockholder ceases to own any of the Required Shares prior to the date of the annual meeting. In addition, any person providing any information to the Corporation pursuant to Section 2.16(i) shall be required to update or supplement such information, if necessary, so that all such information shall be true and correct as of the (i) as of the record date for determining the stockholders entitled to receive notice of the meeting and (ii) as of the date that is ten (10) business days prior to the meeting (or any postponement, adjournment or recess thereof), and such update shall be received by the Secretary at the principal executive offices of the Corporation (A) not later than five (5) business days after the record date for determining the stockholders entitled to receive notice of such meeting (in the case of an update required to be made under clause (i)) and (B) not later than seven (7) business days prior to the date for the meeting, if practicable, or, if not practicable, on the first practicable date prior to the meeting or any adjournment, recess or postponement thereof (in the case of an update required to be made pursuant to clause (ii)).

This provision further makes clear that providing any such notification, update or supplement, shall not be deemed to cure any defect in any previously provided information or communications or limit the remedies available to the Corporation relating to such defect (including the right to omit a Stockholder Nominee from its proxy materials). This provision is intended to protect Cboe's stockholders by requiring an Eligible Stockholder or Stockholder Nominee to give Choe notice of information previously provided that is materially untrue. Choe may then decide what action to take with respect to such defect, which may include, as noted above, omitting the relevant Stockholder Nominee from its proxy materials.

Proposed Section 2.16(j)

Proposed Section 2.16(j) provides that Cboe shall not be required to include a Stockholder Nominee in its proxy materials for any meeting of stockholders under certain circumstances. In these situations, the proxy access nomination shall be disregarded and no vote on such Stockholder Nominee will occur, even if Cboe has received proxies in respect of the vote. These circumstances occur when the Stockholder Nominee:

- Would not be an independent director under Section 3.3, under the rules of the principal national securities exchange on which the outstanding capital stock of the Corporation is traded, any applicable rules of the Securities and Exchange Commission and any publicly disclosed standards used by the Board in determining and disclosing independence of the Corporation's directors, in each case as determined by the Board in its sole discretion;
- would not meet the audit committee independence requirements under the rules of the principal national securities exchange on which the outstanding capital stock of the Corporation is traded;
- if elected, intended to resign as a director of the Corporation prior to the end of the full term for which he or she is standing for election;
- is or has been subject to any statutory disqualification under Section 3(a)(39) of the Act;
- is or has been subject to disqualification under 17 CFR 1.63;
- if elected, would cause the Corporation to be in violation of these Bylaws, the Certificate of Incorporation, the rules of the principal national securities exchange on which the outstanding capital stock of the Corporation is traded, or any applicable law, rule or regulation;
- is or has been, within the past three years, an officer or director of a competitor, as defined for purposes of Section 8 of the Clayton Antitrust Act of 1914:
- is a named subject of a pending criminal proceeding (excluding traffic violations and other minor offenses) or has been convicted in such a criminal proceeding within the past 10 years;
- is subject to any order of the type specified in Rule 506(d) of Regulation D promulgated under the Securities Act of 1933, as amended;
- has provided any information to the Corporation or its stockholders that was untrue in any material respect or that omitted to state a material fact necessary to make the statements made, in light of the circumstances in which they were made, not misleading; or
- breaches or fails, or the Eligible Stockholder breaches or fails, to comply with its obligations pursuant to the CGM Bylaws, including, but not limited to, Section 2.16 and any agreement, representation or undertaking required by Section 2.16.

Choe believes these provisions will protect the Corporation and its stockholders by allowing it to exclude certain categories of objectionable

¹³ See 17 CFR 240.14a-9, which generally prohibits proxy solicitations that contain any statement which, at the time and in the light of the circumstances under which it is made, is false or misleading with respect to any material fact, or which omits to state any material fact necessary in order to make the statements therein not false or misleading.

Stockholder Nominees from the proxy statement.

Proposed Section 2.16(k)

Proposed Section 2.16(k) provides that notwithstanding anything to the contrary contained in the CGM Bylaws, if (i) a Stockholder Nominee and/or the applicable Eligible Stockholder breaches any of its agreements or representations or fails to comply with any of its obligations under this Section 2.16 or (ii) a Stockholder Nominee otherwise becomes ineligible for inclusion in the Corporation's proxy materials pursuant to this Section 2.16, or dies, becomes disabled or otherwise becomes ineligible or unavailable for election at the annual meeting, in each case as determined by the Board or the chairman of the meeting, (1) the Corporation may omit or, to the extent feasible, remove the information concerning such Stockholder Nominee and the related Supporting Statement from its proxy materials and/or otherwise communicate to its stockholders that such Stockholder Nominee will not be eligible for election at the annual meeting, (2) the Corporation shall not be required to include in its proxy materials any successor or replacement nominee proposed by the applicable Eligible Stockholder or any other Eligible Stockholder and (3) the chairman of the meeting shall declare such nomination to be invalid and such nomination shall be disregarded, notwithstanding that proxies in respect of such vote may have been received by the Corporation. Choe believes this provision protects the Corporation and its stockholders by providing the Board or the chairman of the stockholder meeting limited authority to disqualify a proxy access nominee when that nominee or the sponsoring stockholder(s) have breached an obligation under the proxy access provision.

Proposed Section 2.16(l)

Proposed Section 2.16(l) states that the following Stockholder Nominees who are included in the Corporation's proxy materials for a particular annual meeting of stockholders will be ineligible to be a Stockholder Nominee for the next two annual meetings: (i) Stockholder Nominee who withdraws from or becomes ineligible or unavailable for election at the annual meeting; or (ii) Stockholder Nominee who does not receive at least 25% of the votes cast in favor of such Stockholder Nominee's election. For the avoidance of doubt, Section 2.16(l) also clarifies that this provision shall not prevent any stockholder from nominating any

person to the Board pursuant to Section 2.11 of the CGM Bylaws. Section 2.16(l) will save the Corporation and its stockholders the time and expense of analyzing and addressing subsequent proxy access nominations regarding individuals who were included in the proxy materials for a particular annual meeting but ultimately did not stand for election or receive a substantial amount of votes. After the next two annual meetings, these Stockholder Nominees would again be eligible for nomination through the proxy access provisions of the Bylaws.

Proposed Section 2.16(m)

Proposed Section 2.16(m) provides that notwithstanding the provisions of proposed Section 2.16, if the Eligible Stockholder providing notice (or a qualified representative of the Eligible Stockholder) does not appear in person (including virtually, in the case of a meeting held solely by means of remote communication) at the stockholder meeting to present the nomination of such Stockholder Nominee, such proposed nomination shall not be presented by the Corporation and shall not be transacted, notwithstanding that proxies in respect of such vote may have been received by the Corporation. For purposes of this Section 2.16, to be considered a qualified representative of the Eligible Stockholder providing notice, a person must be a duly authorized officer, manager or partner of such stockholder or must be authorized by a writing executed by such stockholder or an electronic transmission delivered by such stockholder to act for such stockholder as proxy at the meeting and such writing or electronic transmission, or a reliable reproduction of the writing or electronic transmission, must be provided to the Corporation at least twenty-four (24) hours prior to the meeting.

Proposed Section 2.16(n)

In case there are matters involving a proxy access nomination that are open to interpretation, proposed Section 2.16(n) states that the Board (or any other person or body authorized by the Board) shall have exclusive power and authority to interpret the proxy access provisions of the Bylaws and make all determinations deemed necessary or advisable in connection with proposed Section 2.16 as to any person, facts or circumstances. In addition, all actions, interpretations and determinations of the Board (or any person or body authorized by the Board) with respect to the proxy access provisions shall be final, conclusive and binding on the

Corporation, the stockholders and all other parties. While Cboe has attempted to implement a clear, detailed and thorough proxy access provision, there may be matters about future proxy access nominations that are open to interpretation. In these cases, Cboe believes it is reasonable and necessary to designate an arbiter to make final decisions on these points and that the Board is best-suited to act as that arbiter.

Proposed Section 2.16(o)

For the avoidance of doubt, proposed Section 2.16(o) states that the proxy access provisions outlined in proposed Section 2.16 shall be the exclusive means for stockholders to include nominees in the Corporation's proxy materials. Stockholders may, of course, continue to propose nominees through other means, but the Board will have final authority to determine whether to include those nominees in the Corporation's proxy materials.

Revisions to Other Sections of the Bylaws

Choe also proposes to make conforming changes to Sections 2.10 and 2.11 to provide clarifications and prevent confusion. First, the Exchange proposes to add a reference to Section 2.11 and proposed Section 2.16 to clarify the exact bylaw provisions relating to stockholder nominees. Next, the Exchange proposes to amend Section 2.11. Section 2.11 currently describes the business that may be properly brought before an annual meeting of stockholders and the methods by which nominations of persons for election to the Board may be made at an annual meeting of stockholders. Choe proposes to add proxy access nominations (i.e., reference to Section 2.16) to the list of methods. Current Section 2.11(a)(i) also states, among other things, that compliance with Section 2.11 shall be the exclusive means for a stockholder to propose business or director nominations before an annual meeting stockholders. The Exchange proposes to clarify that Sections 2.11 and 2.16 are the exclusive means for a stockholder to make a director nomination.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act. 14 Specifically, the Exchange believes the proposed rule change is consistent with the Section

^{14 15} U.S.C. 78f(b).

6(b)(5) ¹⁵ requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

In light of a shareholder proposal received from a stockholder, Cboe is proposing changes to its Bylaws to implement proxy access. The Exchange believes that this filing furthers the objectives of Section 6(b)(5) of the Act because the proposed rule change would be consistent with and facilitate a governance and regulatory structure that 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 regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. Particularly, the Exchange believes that, by permitting an Eligible Stockholder of Cboe that meets the stated requirements to nominate directors and have its nominees included in Cboe's annual meeting proxy statement, the proposed rule change strengthens the corporate governance of the Exchange's ultimate parent company, which is beneficial to both investors and the public interest.

Additionally, the procedural requirements are designed to help protect investors by stating clearly and explicitly the procedures stockholders must follow in order to submit a proper proxy access nomination. The informational requirements are designed to enhance investor protection by helping to ensure among other things, that the Corporation and its stockholders have full and accurate information about nominating stockholders and their nominees and that such stockholders and nominees comply with applicable laws, regulations and other requirements. Moreover, as noted above, proxy access has become commonplace among companies and the Exchange believes its core provisions are common among companies that have adopted proxy

access, including the parent companies of other exchanges that have adopted similar proxy access provisions.¹⁶

Finally, the remaining changes to existing provisions of the CGM Bylaws are clarifying in nature, and they enhance investor protection and the public interest by preventing confusion with respect to the operation of the Bylaw provisions.

B. Self-Regulatory Organization's Statement on Burden on Competition

Because the proposed rule change relates to the governance of the Corporation and not to the operations of the Exchange, the Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not designed to address any competitive issue or have any impact on competition; rather, adoption of a proxy access bylaw by the Corporation is intended to enhance corporate governance and accountability to stockholders.

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

Within 45 days of the date of publication of this notice in the Federal Register or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission shall: (a) By order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (http://www.sec.gov/rules/sro.shtml); or
- Send an email to *rule-comments@ sec.gov*. Please include File Number SR–CboeEDGX–2021–021 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

Washington, DC 20549-1090. All submissions should refer to File Number SR-CboeEDGX-2021-021. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (http://www.sec.gov/ rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-CboeEDGX-2021-021 and should be submitted on or before May 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. 17

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–09444 Filed 5–4–21; 8:45 am]

BILLING CODE 8011-01-P

¹⁶ See Securities Exchange Release No. 79357 (November 18, 2016) 81 FR 85283 (November 25, 2016) (SR-NASDAQ-2016-127; SR-BX-2016-051; SR-ISE-2016-22; SR-ISEGemini-2016-10; SR-ISEMercury-2016-16; SR-PHLX-2016-93; SR-SECC-2016-001; SR-SCCP-2016-01). See also Securities Exchange Release No. 77782 (May 6, 2016) 81 FR 29600 (May 12, 2016) (SR-NYSE-2016-14; SR-NYSEArca-2016-25; SR-NYSEMKT-2016-21; SR-NYSEARCA-2016-25; SR-NYSEMKT-2016-21; SR-NYSEARCA-2016-25; SR-NYSEMKT-2016-21; SR-NYSEARCA-2016-25; SR-NYSEMKT-2016-21; SR-NYSEM

^{17 17} CFR 200.30-3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91728; File No. SR–CBOE– 2021–023]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing of a Proposed Rule Change To Amend the Sixth Amended and Restated Bylaws of Cboe Exchange, Inc.'s Parent Corporation, Cboe Global Markets, Inc. To Implement Proxy Access

April 29, 2021.

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 April 16, 2021, Cboe Exchange, Inc. ("Exchange" or "Cboe Options") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the "Exchange" or "Cboe Options") is filing with the Securities and Exchange Commission (the "Commission") a proposed rule change with respect to amendments to the Sixth Amended and Restated Bylaws (the "CGM Bylaws") of its parent corporation, Cboe Global Markets, Inc. ("Cboe" or "Corporation"). The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (http://www.cboe.com/AboutCBOE/CBOELegalRegulatory Home.aspx), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of

the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Cboe has received a stockholder proposal submitted pursuant to Rule 14a–8 under the Act ³ which requested that the CGM Board take steps to implement a "proxy access" bylaw provision. In general, proxy access bylaws allow a stockholder, or group of stockholders, who comply with certain requirements, to nominate candidates for service on a board and have those candidates included in a company's proxy materials. Such provisions have become common among S&P 500 companies.4 Choe has determined to take the stockholder's requested steps to implement proxy access. Accordingly, the Exchange now proposes to make these changes by adopting new Section 2.16 of the CGM Bylaws and making certain conforming changes to current Sections 2.10 and 2.11 of the CGM Bylaws, all of which are described further below.

In developing its proposal, Cboe generally tried to balance the relative weight of arguments for and against proxy access provisions. On the one hand, Cboe recognizes the significance of this issue to some investors, who see proxy access as an important accountability mechanism that allows them to participate in board elections through the nomination of stockholder candidates that are presented in a company's proxy statement. On the other hand, Cboe's proposed proxy access provision includes certain procedural requirements that are designed to help ensure, among other things, that Cboe and its stockholders will have full and accurate information about nominating stockholders and their nominees and that such stockholders and nominees will comply with applicable laws, regulations and other requirements. Additionally, the Exchange notes the proposed terms are common among companies that have adopted proxy access. The Exchange also notes that the parent companies of other exchanges have adopted substantively similar proxy access provisions and the Exchange does not

believe such provisions are materially different than the Exchange's proposal.⁵

The proposed rule change would add new Section 2.16 to the CGM Bylaws. Section 2.16 would permit a stockholder, or group of up to 20 stockholders, to nominate director nominees for the Cboe Board, so long as the stockholder(s) have owned at least three percent of Cboe's outstanding shares of capital stock continuously for at least three years. The director nominees would be included in Cboe's annual meeting proxy materials. The proposed provision would limit the number of proposed director nominees to the greater of (i) two or (ii) 20% of the number of Cboe directors in office (rounded down to the nearest whole number, but no less than two) provided that the stockholder(s) and nominee(s) satisfy the other conditions specified in the CGM Bylaws as described further below.

Proposed Section 2.16(a)

The Exchange first proposes to amend the CGM Bylaws to, as set forth in the first sentence of proposed Section 2.16(a), require the Corporation to include in its proxy statement, its form proxy and any ballot distributed at the stockholder meeting, the name of, and certain Required Information ⁶ about, any person nominated for election (the "Stockholder Nominee") to the Board by a stockholder or group of stockholders (the "Eligible Stockholder") 7 that satisfies the requirements set forth in the proxy access provision of CGM Bylaws.8 Proposed Section 2.16(a) will also make clear that Cboe is able to solicit against any Stockholder Nominee or include in

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See 17 CFR 240.14a–8, which requires companies that are subject to the federal proxy rules to include shareholder proposals in companies' proxy statements to shareholders, subject to certain procedural and substantive requirements.

 $^{^4}$ More than 75% of S&P 500 companies have adopted proxy access bylaw provisions.

 ⁵ See Securities Exchange Release No. 79357
 (November 18, 2016) 81 FR 85283 (November 25, 2016) (SR-NASDAQ-2016-127; SR-BX-2016-051; SR-ISE-2016-22; SR-ISEGemini-2016-10; SR-ISEMercury-2016-16; SR-PHLX-2016-93; SR-BSECC-2016-001; SR-SCCP-2016-01). See also Securities Exchange Release No. 77782 (May 6, 2016) 81 FR 29600 (May 12, 2016) (SR-NYSE-2016-14; SR-NYSEArca-2016-25; SR-NYSEMKT-2016-20].

⁶The Required Information is the information provided to Cboe's Corporate Secretary about the Stockholder Nominee and the Eligible Stockholder that is required to be disclosed in the Corporation's proxy statement by the regulations promulgated under the Act, and if the Eligible Stockholder so elects, a written statement, not to exceed 500 words, in support of the Stockholder Nominee(s)' candidacy (the "Supporting Statement", as defined further below).

⁷ As used throughout the CGM Bylaws, the term "Eligible Stockholder" includes each member of a stockholder group that submits a proxy access nomination to the extent the context requires.

⁸ When the Corporation includes proxy access nominees in the proxy materials, such individuals will be included in addition to any persons nominated for election by at or the direction of the Board to the Board or any committee thereof.

its proxy materials the Corporation's own statements or other information relating to any Eligible Stockholder or Stockholder Nominee, including any information provided to the Corporation pursuant to Section 2.16. This provision clarifies that just because Cboe must include a Stockholder Nominee in its proxy materials if the proxy access provisions are satisfied, Cboe does not necessarily have to support that nominee.

Proposed Section 2.16(b)

Proposed Section 2.16(b) will provide that in order to utilize this provision, the Eligible Stockholder must expressly request at the time of providing a required notice to the Corporation of the proxy access nomination (the "Notice of Proxy Access Nomination") to have its nominee included in the Corporation's proxy materials. Proposed Section 2.16(b) also establishes the deadline for a timely Notice of Proxy Access Nomination. Specifically, such a notice must be delivered to the Cboe's Secretary at the principal executive offices of the Corporation not earlier than the open of business on the one hundred fiftieth (150th) day and not later than the close of business on the one hundred twentieth (120th) day prior to the first anniversary of the date that Choe first distributed its proxy statement to stockholders for the previous year's annual meeting of stockholders provided, however, that in the event the annual meeting is more than thirty (30) days before or after the anniversary date of the prior year's annual meeting, or if no annual meeting was held in the preceding year, to be timely, the Notice of Proxy Access Nomination must be received at the principal executive offices of the Corporation no earlier than one hundred fifty (150) days before such annual meeting and no later than the later of one hundred twenty (120) days before such annual meeting or the tenth (10th) day following the day on which public announcement (as defined in Section 2.11) of the date of such meeting is first made by the Corporation. Further Section 2.16 will provide that in no event shall any adjournment or postponement of an annual meeting or the announcement thereof commence a new time period (or extend any time period) for the giving of a Notice of Proxy Access Nomination as described above. Choe believes this notice period will provide stockholders an adequate window to submit nominees via proxy access, while also providing the Corporation adequate time to diligence a proxy access nominee before including them in the proxy statement

for the next annual meeting of stockholders.

Proposed Section 2.16(c)

Proposed Section 2.16(c) specifies that the maximum number ("the Permitted Number") of Stockholder Nominees nominated by all Eligible Stockholders that will be included in Choe's proxy materials with respect to an annual meeting of stockholders shall not exceed the greater of two or 20% of the total number of directors in office (rounded down to the nearest whole number) as of the last day on which a Notice of Proxy Access Nomination may be delivered pursuant to and in accordance with the proxy access provision of the Bylaws (the "Final Proxy Access Nomination Date"). In the event that one or more vacancies for any reason occurs after the Final Proxy Access Nomination Date but before the date of the annual meeting and the Board resolves to reduce the size of the Board in connection therewith, the Permitted Number of Stockholder Nominees included in Choe's proxy materials shall be calculated based on the number of directors in office as so reduced. In addition, the Permitted Number shall be reduced by (i) the number of individuals who will be included in the Corporation's proxy materials as director nominees recommended by the Board pursuant to an agreement, arrangement or other understanding with a stockholder or group of stockholders (other than any such agreement, arrangement or understanding entered into in connection with an acquisition of stock from the Corporation by such stockholder or group of stockholders) and/or (ii) the number of directors in office as of the Final Proxy Access Nomination Date who were included in the Corporation's proxy materials as Stockholder Nominees for any of the two preceding annual meetings of stockholders (including any persons counted as Stockholder Nominees pursuant to the immediately succeeding sentence) and whose reelection at the upcoming annual meeting is being recommended by the Board. Any individual nominated by an Eligible Stockholder for inclusion in the proxy materials pursuant to the proxy access provision of the CGM Bylaws whom the Board decides to nominate as a nominee of the Board, and any individual nominated by an Eligible Stockholder for inclusion in the proxy materials pursuant to the proxy access provision but whose nomination is subsequently withdrawn, shall be counted as one of the Stockholder Nominees for purposes of determining when the Permitted

Number of Stockholder Nominees has been reached. Any Eligible Stockholder submitting more than one Stockholder Nominee for inclusion in the proxy materials shall rank such Stockholder Nominees based on the order that the Eligible Stockholder desires such Stockholder Nominees to be selected for inclusion in the proxy statement in the event that the total number of Stockholder Nominees submitted by Eligible Stockholders pursuant to the proxy access provision exceeds the Permitted Number of nominees allowed. In the event that the number of Stockholder Nominees submitted by Eligible Stockholders pursuant to Section 2.16 exceeds the Permitted Number of nominees allowed, the highest ranking Stockholder Nominee who meets the requirements of the proxy access provision of the Bylaws from each Eligible Stockholder will be selected for inclusion in the proxy materials until the Permitted Number is reached, going in order of the amount (largest to smallest) of shares of Cboe's outstanding capital stock each Eligible Stockholder disclosed as owned in its respective Notice of Proxy Access Nomination submitted to Cooe. If the Permitted Number is not reached after the highest ranking Stockholder Nominee who meets the requirements of the proxy access provision of the Bylaws from each Eligible Stockholder has been selected, then the next highest ranking Stockholder Nominee who meets the requirements of Section 2.16 from each Eligible Stockholder will be selected for inclusion in the Corporation's proxy materials, and this process will continue as many times as necessary, following the same order each time, until the Permitted Number is reached. Additionally, notwithstanding anything to the contrary contained in proposed Section 2.16, Choe will not be required to include any Stockholder Nominees in its proxy materials pursuant to Section 2.16 for any meeting of stockholders for which the Secretary receives a notice (whether or not subsequently withdrawn) that the Eligible Stockholder or any other stockholder intends to nominate one or more persons for election to the Board pursuant to Section 2.11 of the CGM Bylaws. Choe believes it is reasonable to limit the Board seats available to proxy access nominees and to establish procedures for selecting candidates if the nominee limit is exceeded. The limitation on Board seats available to proxy access nominees ensures that proxy access cannot be used to take over the entire Board, which is not the stated

purpose of proxy access campaigns. The procedures for selecting candidates if the nominee limit is exceeded establish clear and rational guidelines for an orderly nomination process to avoid the Corporation having to make arbitrary judgments among candidates.

Proposed Section 2.16(d)

Proposed Section 2.16(d) defines who may qualify as an "Eligible Stockholder". Particularly, an Eligible Stockholder is a stockholder or group of no more than 20 stockholders 9 that (i) has owned continuously for at least three years (the "Minimum Holding Period'') a number of shares of capital stock of the Corporation that represents at least three percent of the outstanding shares of capital stock of the Corporation as of the date the Notice of Proxy Access Nomination is received (the "Required Shares"), (ii) continues to own the Required Shares through the date of the annual meeting and (iii) meets all other requirements of proposed Section 2.16. Choe believes it is reasonable to require each member of a nominating group to provide such information so that both the Corporation and its stockholders are fully informed about the entire group making the proxy access nomination. As such, Section 2.16(d) further makes clear that whenever the Eligible Stockholder consists of a group of stockholders (including a group of funds that are part of the same Qualifying Fund Group), (i) each provision in Section 2.16 that requires the Eligible Stockholder to provide any written statements, representations, undertakings, agreements or other instruments or to meet any other conditions shall be deemed to require each stockholder (including each individual fund) that is a member of such group to provide such statements, representations, undertakings, agreements or other instruments and to meet such other conditions (except that the members of such group may aggregate the shares that each member has owned continuously for the Minimum Holding Period in order to meet the three percent ownership requirement of the "Required Shares" definition) and (ii) a breach of any obligation, agreement or representation under Section 2.16 by any member of such group shall be

deemed a breach by the Eligible Stockholder. No stockholder may be a member of more than one group of stockholders constituting an Eligible Stockholder with respect to any annual meeting.

Proposed Section 2.16(e)

Proposed Section 2.16(e) clarifies, for the avoidance of doubt, how "ownership" will be defined for purposes of meeting the ownership requirements of the Required Shares. Specifically, an Eligible Stockholder shall be deemed to "own" only those outstanding shares of Choe's capital stock as to which the stockholder possesses both: (i) The full voting and investment rights pertaining to the shares; and (ii) the full economic interest in (including the opportunity for profit from and risk of loss on) such shares; provided that the number of shares calculated in accordance with clauses (i) and (ii) shall not include any shares: That are (1) sold by such stockholder or any of its affiliates in any transaction that has not been settled or closed; (2) borrowed by such stockholder or any of its affiliates for any purposes or purchased by such stockholder or any of its affiliates pursuant to an agreement to resell; or (3) subject to any option, warrant, forward contract, swap, contract of sale, other derivative or similar instrument or agreement entered into by such stockholder or any of its affiliates, whether any such instrument or agreement is to be settled with shares or with cash based on the notional amount or value of shares of Cboe's outstanding capital stock, in any such case which instrument or agreement has, or is intended to have, the purpose or effect of: (A) Reducing in any manner, to any extent or at any time in the future, such stockholder's or its affiliates' full right to vote or direct the voting of any such shares; and/or (B) hedging, offsetting or altering to any degree any gain or loss realized or realizable from maintaining the full economic ownership of such shares by such stockholder or its affiliates.

Further, a stockholder shall "own" shares held in the name of a nominee or other intermediary so long as the stockholder retains the right to instruct how the shares are voted with respect to the election of directors and possesses the full economic interest in the shares. A stockholder's ownership of shares shall be deemed to continue during any period in which (i) the stockholder has loaned such shares provided that the stockholder has the power to recall such loaned shares on five (5) business days' notice and includes in the Notice of

Proxy Access Nomination an agreement that it will (1) recall such loaned shares upon being notified that any of its Stockholder Nominees will be included in the Corporation's proxy materials and (2) will hold such shares through the date of the annual meeting or (ii) the stockholder has delegated any voting power by means of a proxy, power of attorney or other instrument or arrangement which is revocable at any time by the stockholder. Section 2.16(e) also clarifies that the terms "owned," "owning" and other variations of the word "own" shall have correlative meanings. Whether outstanding shares of Cboe's capital stock are "owned" for these purposes shall be determined by the Board. For purposes of Section 2.16, the term "affiliate" or "affiliates" shall have the meaning ascribed thereto under the rules and regulations of the Act.¹⁰ An Eligible Stockholder shall include in its Notice of Proxy Access Nomination the number of shares it is deemed to own for the purposes of proposed Section 2.16. In proposing the Required Shares and the Minimum Holding Period, Choe seeks to ensure that the Eligible Stockholder has had a sufficient stake in the Corporation for a sufficient amount of time and is not pursuing a short-term agenda.

Proposed Section 2.16(f)

Proposed Section 2.16(f) sets forth the information that an Eligible Stockholder must provide to Cboe's Corporate Secretary in writing within the deadline discussed above in order to make a proxy access nomination. This information includes:

- A statement by the Eligible Stockholder (1) setting forth and certifying as to the number of shares it owns and has owned continuously for the Minimum Holding Period and (2) agreeing to continue to own the Required Shares through the date of the annual meeting;
- one or more written statements from the record holder of the Required Shares (and from each intermediary through which the Required Shares are or have been held during the Minimum Holding Period) verifying that, as of a

⁹ For this purpose, any two or more funds that are part of the same Qualifying Fund Group may be counted as one stockholder. A "Qualifying Fund Group" means two or more funds that are (i) under common management and investment control, (ii) under common management and funded primarily by the same employer or (iii) a "group of investment companies" as such term is defined in Section 12(d)(1)(G)(ii) of the Investment Corporation Act of 1940, as amended.

¹⁰ Pursuant to Rule 12b–2 under the Act, "[a]n 'affiliate' of, or a person 'affiliated' with, a specified person, is a person that directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, the person specified." 17 CFR 240.12b–2. Further, "[t]he term 'control' (including the terms 'controlling,' 'controlled by' and 'under common control with') means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a person, whether through the ownership of voting securities, by contract, or otherwise." 17 CFR 240.12b–2.

date within seven calendar days prior to the date the Notice of Proxy Access Nomination is delivered to Cboe's Secretary at the principal executive offices of the Corporation, the Eligible Stockholder owns, and has owned continuously for the Minimum Holding Period, the Required Shares, and the Eligible Stockholder's agreement to provide, within five (5) business days after the record date for the annual meeting, written statements from the record holder and intermediaries verifying the Eligible Stockholder's continuous ownership of the Required Shares through the record date;

• a copy of the Schedule 14N that has been filed with the SEC as required by Rule 14a–18 under the Act; ¹¹

• the information, representations and agreements and other documents that are required to be set forth in or included with a stockholder's notice of nomination given pursuant to Section 2.11 of the CGM Bylaws;

• the written consent of each Stockholder Nominee to being named in the proxy statement as a nominee and to serving as a director if elected;

• a representation that the Eligible Stockholder:

O Acquired the Required Shares in the ordinary course of business and not with the intent to change or influence control of Cboe, and does not presently have such intent;

• has not nominated and will not nominate for election any individual as a director at the annual meeting, other than its Stockholder Nominee(s);

has not engaged and will not engage in, and has not and will not be a participant in another person's, "solicitation" within the meaning of Rule 14a–1(l) under the Act in support of the election of any individual as a director at the annual meeting, other than its Stockholder Nominee(s) or a nominee of the Board;

 has not distributed and will not distribute to any stockholder of the Corporation any form of proxy for the annual meeting other than the form distributed by the Corporation;

 has complied and will comply with all laws, rules and regulations applicable to solicitations and the use, if any, of soliciting material in connection with the annual meeting, and

• has provided and will provide facts, statements and other information

in all communications with Cboe and its stockholders that are or will be true and correct in all material respects and do not and will not omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

• an undertaking that the Eligible Stockholder agrees to

assume all liability stemming from any legal or regulatory violation arising out of the Eligible Stockholder's communications with the stockholders of the Corporation or out of the information that the Eligible Stockholder provided to the Corporation;

o indemnify and hold harmless the Corporation and each of its Directors, officers and employees individually against any liability, loss or damages in connection with any threatened or pending action, suit or proceeding, whether legal, administrative or investigative, against the Corporation or any of its Directors, officers or employees arising out of any nomination submitted by the Eligible Stockholder pursuant to this Section 2.16 or any solicitation or other activity in connection therewith; and

of file with the Securities and Exchange Commission any solicitation or other communication with the stockholders of the Corporation relating to the meeting at which its Stockholder Nominee(s) will be nominated, regardless of whether any such filing is required under Regulation 14A of the Act or whether any exemption from filing is available for such solicitation or other communication under Regulation 14A of the Act;

• in the case of a nomination by a group of stockholders that together is an Eligible Stockholder, the designation by all group members of one group member that is authorized to receive communications, notices and inquiries from the Corporation and to act on behalf of all members of the group with respect to all matters relating to the nomination under this Section 2.16 (including withdrawal of the nomination);

• in the case of a nomination by an Eligible Stockholder consisting of a group of stockholders in which two or more funds are intended to be treated as one stockholder for purposes of qualifying as an Eligible Stockholder, documentation reasonably satisfactory to the Corporation that demonstrates that the funds are part of the same Qualifying Fund Group; and

• a written representation and agreement by the Stockholder Nominee that such person:

 Will act as a representative of all of the stockholders of the Corporation while serving as a director;

• will provide facts, statements and other information in all communications with the Corporation and its stockholders that are or will be true and correct in all material respects (and shall not omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading);

 is not and will not become a party to (i) any compensatory, payment or other financial agreement, arrangement or understanding with any person or entity other than the Corporation in connection with service or action as a director of the Corporation that has not been disclosed to the Corporation, (ii) any Voting Commitment that has not been disclosed to the Corporation or (iii) any Voting Commitment 12 that could reasonably be expected to limit or interfere with the Stockholder Nominee's ability to comply, if elected as a director of the Corporation, with its fiduciary duties under applicable law; and

o will abide by and comply with the CGM Bylaws, the Certificate of Incorporation and applicable policies of the Corporation including all applicable publicly disclosed corporate governance, conflict of interest, confidentiality and stock ownership and trading policies and guidelines of the Corporation, as well as the applicable provisions of the rules and regulations of the Securities and Exchange Commission and any stock exchange applicable to the Corporation.

In proposing the informational requirements for the Eligible Stockholder, Cboe's goal is to gather sufficient information about the Eligible Stockholder for both itself and its stockholders. Among other things, this information is designed to help ensure that Cboe is able to comply with its disclosure and other requirements under applicable law and that Cboe, its Board and its stockholders are able to assess the proxy access nomination adequately.

Proposed Section 2.16(g)

Proposed Section 2.16(g) establishes additional information the Stockholder Nominee must provide. Particularly:

 The Stockholder Nominee(s) must submit all completed and signed

¹¹ See 17 CFR 240.14n–101 and 17 CFR 240.14a–18, which generally require a Nominating Stockholder to provide notice to the Corporation of its intent to submit a proxy access nomination on a Schedule 14N and file that notice, including the required disclosure, with the Commission on the date first transmitted to the Corporation.

¹² A "Voting Commitment" is defined as any agreement, arrangement or understanding with any person or entity as to how the Stockholder Nominee would vote or act on any issue or question as a director.

questionnaires required of directors and officers of the Corporation;

- the Corporation may require any proposed Stockholder Nominee to furnish any information:
- O That may reasonably be requested by the Corporation to determine whether the Stockholder Nominee would be independent under Section 3.3 and otherwise qualifies as independent under the rules of the principal national securities exchange on which the outstanding capital stock of the Corporation is traded;

 that could be material to a reasonable stockholder's understanding of the independence, or lack thereof, of such Stockholder Nominee;

 that would be required to satisfy the requirements for qualification of directors under applicable foreign regulations; or

that may reasonably be requested by the Corporation to determine the eligibility of such Stockholder Nominee to be included in the Corporation's proxy materials pursuant to this Section 2.16 or to serve as a director of the Corporation; and

• the Corporation may require the Eligible Stockholder to furnish any other information that may reasonably be requested by the Corporation to verify the Eligible Stockholder's continuous Ownership of the Required Shares for the Minimum Holding Period and through the date of the annual meeting.

Like the informational requirements for an Eligible Stockholder, which are set forth above, the informational requirements for the Stockholder Nominee ensure that both Cboe and its stockholders will have sufficient information about the Stockholder Nominee. Among other things, this information will ensure that Cboe is able to comply with its disclosure and other requirements under applicable law and that Cboe, its Board and its stockholders are able to assess the proxy access nomination adequately.

Proposed Section 2.16(h)

Proposed Section 2.16(h) provides that an Eligible Stockholder may provide, at its option, to the Secretary, at the time the Notice of Proxy Access Nomination is provided, a written statement, not to exceed 500 words, in support of its Stockholder Nominee(s)' candidacy (a "Supporting Statement"). Only one Supporting Statement may be submitted by an Eligible Stockholder (including any group of stockholders together constituting an Eligible Stockholder) in support of its Stockholder Nominee(s). Notwithstanding anything to the

contrary contained in Section 2.16, the Corporation may omit from its proxy materials any information or Supporting Statement (or portion thereof) that it, in good faith, believes is untrue in any material respect (or omits to state a material fact necessary in order to make the statements made, in light of the circumstances under which they are made, not misleading) or would violate any applicable law, rule or regulation. The Exchange notes proposed Section 2.16(h) allows Choe to comply with Rule 14a-9 under the Act 13 and to protect its stockholders from information that is materially untrue or that violates any law, rule or regulation.

Proposed Section 2.16(i)

Pursuant to proposed Section 2.16(i), each Eligible Stockholder or Stockholder Nominee must promptly notify Choe's Corporate Secretary of any information or communications provided by the Eligible Stockholder or Stockholder Nominee, as the case may be, to Cboe or its stockholders that when provided was not, or thereafter ceases to be, true and correct in all material respects or omits a material fact necessary to make the statements made, in light of the circumstances under which they were made, not misleading and of the information that is required to correct any such defect. An Eligible Stockholder shall also provide immediate notice to the Corporation if the Eligible Stockholder ceases to own any of the Required Shares prior to the date of the annual meeting. In addition, any person providing any information to the Corporation pursuant to Section 2.16(i) shall be required to update or supplement such information, if necessary, so that all such information shall be true and correct as of the (i) as of the record date for determining the stockholders entitled to receive notice of the meeting and (ii) as of the date that is ten (10) business days prior to the meeting (or any postponement, adjournment or recess thereof), and such update shall be received by the Secretary at the principal executive offices of the Corporation (A) not later than five (5) business days after the record date for determining the stockholders entitled to receive notice of such meeting (in the case of an update required to be made under clause (i)) and (B) not later than seven (7) business

days prior to the date for the meeting, if practicable, or, if not practicable, on the first practicable date prior to the meeting or any adjournment, recess or postponement thereof (in the case of an update required to be made pursuant to clause (ii)).

This provision further makes clear that providing any such notification, update or supplement, shall not be deemed to cure any defect in any previously provided information or communications or limit the remedies available to the Corporation relating to such defect (including the right to omit a Stockholder Nominee from its proxy materials). This provision is intended to protect Cboe's stockholders by requiring an Eligible Stockholder or Stockholder Nominee to give Choe notice of information previously provided that is materially untrue. Choe may then decide what action to take with respect to such defect, which may include, as noted above, omitting the relevant Stockholder Nominee from its proxy materials.

Proposed Section 2.16(j)

Proposed Section 2.16(j) provides that Cboe shall not be required to include a Stockholder Nominee in its proxy materials for any meeting of stockholders under certain circumstances. In these situations, the proxy access nomination shall be disregarded and no vote on such Stockholder Nominee will occur, even if Cboe has received proxies in respect of the vote. These circumstances occur when the Stockholder Nominee:

- Would not be an independent director under Section 3.3, under the rules of the principal national securities exchange on which the outstanding capital stock of the Corporation is traded, any applicable rules of the Securities and Exchange Commission and any publicly disclosed standards used by the Board in determining and disclosing independence of the Corporation's directors, in each case as determined by the Board in its sole discretion;
- would not meet the audit committee independence requirements under the rules of the principal national securities exchange on which the outstanding capital stock of the Corporation is traded;
- if elected, intended to resign as a director of the Corporation prior to the end of the full term for which he or she is standing for election;
- is or has been subject to any statutory disqualification under Section 3(a)(39) of the Act;
- is or has been subject to disqualification under 17 CFR 1.63;

¹³ See 17 CFR 240.14a–9, which generally prohibits proxy solicitations that contain any statement which, at the time and in the light of the circumstances under which it is made, is false or misleading with respect to any material fact, or which omits to state any material fact necessary in order to make the statements therein not false or misleading.

- if elected, would cause the Corporation to be in violation of these Bylaws, the Certificate of Incorporation, the rules of the principal national securities exchange on which the outstanding capital stock of the Corporation is traded, or any applicable law, rule or regulation;
- is or has been, within the past three years, an officer or director of a competitor, as defined for purposes of Section 8 of the Clayton Antitrust Act of
- is a named subject of a pending criminal proceeding (excluding traffic violations and other minor offenses) or has been convicted in such a criminal proceeding within the past 10 years;

• is subject to any order of the type specified in Rule 506(d) of Regulation D promulgated under the Securities Act of

1933, as amended;

 has provided any information to the Corporation or its stockholders that was untrue in any material respect or that omitted to state a material fact necessary to make the statements made, in light of the circumstances in which they were made, not misleading; or

• breaches or fails, or the Eligible Stockholder breaches or fails, to comply with its obligations pursuant to the CGM Bylaws, including, but not limited to, Section 2.16 and any agreement, representation or undertaking required by Section 2.16.

Choe believes these provisions will protect the Corporation and its stockholders by allowing it to exclude certain categories of objectionable Stockholder Nominees from the proxy statement.

Proposed Section 2.16(k)

Proposed Section 2.16(k) provides that notwithstanding anything to the contrary contained in the CGM Bylaws, if (i) a Stockholder Nominee and/or the applicable Eligible Stockholder breaches any of its agreements or representations or fails to comply with any of its obligations under this Section 2.16 or (ii) a Stockholder Nominee otherwise becomes ineligible for inclusion in the Corporation's proxy materials pursuant to this Section 2.16, or dies, becomes disabled or otherwise becomes ineligible or unavailable for election at the annual meeting, in each case as determined by the Board or the chairman of the meeting, (1) the Corporation may omit or, to the extent feasible, remove the information concerning such Stockholder Nominee and the related Supporting Statement from its proxy materials and/or otherwise communicate to its stockholders that such Stockholder Nominee will not be eligible for election

at the annual meeting, (2) the Corporation shall not be required to include in its proxy materials any successor or replacement nominee proposed by the applicable Eligible Stockholder or any other Eligible Stockholder and (3) the chairman of the meeting shall declare such nomination to be invalid and such nomination shall be disregarded, notwithstanding that proxies in respect of such vote may have been received by the Corporation. Choe believes this provision protects the Corporation and its stockholders by providing the Board or the chairman of the stockholder meeting limited authority to disqualify a proxy access nominee when that nominee or the sponsoring stockholder(s) have breached an obligation under the proxy access provision.

Proposed Section 2.16(l)

Proposed Section 2.16(l) states that the following Stockholder Nominees who are included in the Corporation's proxy materials for a particular annual meeting of stockholders will be ineligible to be a Stockholder Nominee for the next two annual meetings: (i) Stockholder Nominee who withdraws from or becomes ineligible or unavailable for election at the annual meeting; or (ii) Stockholder Nominee who does not receive at least 25% of the votes cast in favor of such Stockholder Nominee's election. For the avoidance of doubt, Section 2.16(l) also clarifies that this provision shall not prevent any stockholder from nominating any person to the Board pursuant to Section 2.11 of the CGM Bylaws. Section 2.16(l) will save the Corporation and its stockholders the time and expense of analyzing and addressing subsequent proxy access nominations regarding individuals who were included in the proxy materials for a particular annual meeting but ultimately did not stand for election or receive a substantial amount of votes. After the next two annual meetings, these Stockholder Nominees would again be eligible for nomination through the proxy access provisions of the Bylaws.

Proposed Section 2.16(m)

Proposed Section 2.16(m) provides that notwithstanding the provisions of proposed Section 2.16, if the Eligible Stockholder providing notice (or a qualified representative of the Eligible Stockholder) does not appear in person (including virtually, in the case of a meeting held solely by means of remote communication) at the stockholder meeting to present the nomination of such Stockholder Nominee, such proposed nomination shall not be

presented by the Corporation and shall not be transacted, notwithstanding that proxies in respect of such vote may have been received by the Corporation. For purposes of this Section 2.16, to be considered a qualified representative of the Eligible Stockholder providing notice, a person must be a duly authorized officer, manager or partner of such stockholder or must be authorized by a writing executed by such stockholder or an electronic transmission delivered by such stockholder to act for such stockholder as proxy at the meeting and such writing or electronic transmission, or a reliable reproduction of the writing or electronic transmission, must be provided to the Corporation at least twenty-four (24) hours prior to the meeting.

Proposed Section 2.16(n)

In case there are matters involving a proxy access nomination that are open to interpretation, proposed Section 2.16(n) states that the Board (or any other person or body authorized by the Board) shall have exclusive power and authority to interpret the proxy access provisions of the Bylaws and make all determinations deemed necessary or advisable in connection with proposed Section 2.16 as to any person, facts or circumstances. In addition, all actions, interpretations and determinations of the Board (or any person or body authorized by the Board) with respect to the proxy access provisions shall be final, conclusive and binding on the Corporation, the stockholders and all other parties. While Cboe has attempted to implement a clear, detailed and thorough proxy access provision, there may be matters about future proxy access nominations that are open to interpretation. In these cases, Cboe believes it is reasonable and necessary to designate an arbiter to make final decisions on these points and that the Board is best-suited to act as that arbiter.

Proposed Section 2.16(o)

For the avoidance of doubt, proposed Section 2.16(o) states that the proxy access provisions outlined in proposed Section 2.16 shall be the exclusive means for stockholders to include nominees in the Corporation's proxy materials. Stockholders may, of course, continue to propose nominees through other means, but the Board will have final authority to determine whether to include those nominees in the Corporation's proxy materials.

Revisions to Other Sections of the Bylaws

Choe also proposes to make conforming changes to Sections 2.10 and 2.11 to provide clarifications and prevent confusion. First, the Exchange proposes to add a reference to Section 2.11 and proposed Section 2.16 to clarify the exact bylaw provisions relating to stockholder nominees. Next, the Exchange proposes to amend Section 2.11. Section 2.11 currently describes the business that may be properly brought before an annual meeting of stockholders and the methods by which nominations of persons for election to the Board may be made at an annual meeting of stockholders. Choe proposes to add proxy access nominations (i.e., reference to Section 2.16) to the list of methods. Current Section 2.11(a)(i) also states, among other things, that compliance with Section 2.11 shall be the exclusive means for a stockholder to propose business or director nominations before an annual meeting stockholders. The Exchange proposes to clarify that Sections 2.11 and 2.16 are the exclusive means for a stockholder to make a director nomination.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act. 14 Specifically, the Exchange believes the proposed rule change is consistent with the Section $6(b)(\bar{5})^{15}$ requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

In light of a shareholder proposal received from a stockholder, Cboe is proposing changes to its Bylaws to implement proxy access. The Exchange believes that this filing furthers the objectives of Section 6(b)(5) of the Act because the proposed rule change would be consistent with and facilitate a governance and regulatory structure that 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 regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. Particularly, the Exchange believes that, by permitting an Eligible Stockholder of Cboe that meets the stated requirements to nominate directors and have its nominees included in Cboe's annual meeting proxy statement, the proposed rule change strengthens the corporate governance of the Exchange's ultimate parent company, which is beneficial to both investors and the public interest.

Additionally, the procedural requirements are designed to help protect investors by stating clearly and explicitly the procedures stockholders must follow in order to submit a proper proxy access nomination. The informational requirements are designed to enhance investor protection by helping to ensure among other things, that the Corporation and its stockholders have full and accurate information about nominating stockholders and their nominees and that such stockholders and nominees comply with applicable laws, regulations and other requirements. Moreover, as noted above, proxy access has become commonplace among companies and the Exchange believes its core provisions are common among companies that have adopted proxy access, including the parent companies of other exchanges that have adopted similar proxy access provisions. 16

Finally, the remaining changes to existing provisions of the CGM Bylaws are clarifying in nature, and they enhance investor protection and the public interest by preventing confusion with respect to the operation of the Bylaw provisions.

B. Self-Regulatory Organization's Statement on Burden on Competition

Because the proposed rule change relates to the governance of the Corporation and not to the operations of the Exchange, the Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not designed to address any competitive issue or have any impact on competition; rather, adoption of a proxy access bylaw by the Corporation is intended to enhance corporate governance and accountability to stockholders.

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

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission shall: (a) By order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (http://www.sec.gov/rules/sro.shtml); or
- Send an email to *rule-comments@ sec.gov*. Please include File Number SR–CBOE–2021–023 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–CBOE–2021–023. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (http://www.sec.gov/rules/sro.shtml). Copies of the

^{14 15} U.S.C. 78f(b).

^{15 15} U.S.C. 78f(b)(5).

¹⁶ See Securities Exchange Release No. 79357
(November 18, 2016) 81 FR 85283
(November 25, 2016) (SR-NASDAQ-2016-127; SR-BX-2016-051; SR-ISE-2016-22; SR-ISEGemini-2016-10; SR-ISEMercury-2016-16; SR-PHLX-2016-93; SR-BSECC-2016-001; SR-SCCP-2016-01). See also Securities Exchange Release No. 77782
(May 6, 2016) 81 FR 29600
(May 12, 2016) (SR-NYSE-2016-14; SR-NYSEArca-2016-25; SR-NYSEMKT-2016-20).

submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-CBOE-2021-023 and should be submitted on or before May 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁷

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021-09447 Filed 5-4-21; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting; Date Change

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: 86 FR 23458, May 3, 2021.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: Thursday, May 6, 2021 at 2:00 p.m.

CHANGES IN THE MEETING: The Closed Meeting scheduled for Thursday, May 6, 2021 at 2:00 p.m., has been changed to Friday, May 7, 2021 at 1:00 p.m.

CONTACT PERSON FOR MORE INFORMATION:

For further information; please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

Dated: May 3, 2021.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2021–09552 Filed 5–3–21; 11:15 am] BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-91729; File No. SR-CboeBYX-2021-009]

Self-Regulatory Organizations; Cboe BYX Exchange, Inc.; Notice of Filing of a Proposed Rule Change To Amend the Sixth Amended and Restated Bylaws of Cboe BYX Exchange, Inc.'s Parent Corporation, Cboe Global Markets, Inc. To Implement Proxy Access

April 29, 2021.

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 April 16, 2021, Cboe BYX Exchange, Inc. ("Exchange" or "BYX") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BYX Exchange, Inc. (the "Exchange" or "BYX") is filing with the Securities and Exchange Commission (the "Commission") a proposed rule change with respect to amendments to the Sixth Amended and Restated Bylaws (the "CGM Bylaws") of its parent corporation, Cboe Global Markets, Inc. ("Cboe" or "Corporation"). The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (http://markets.cboe.com/us/equities/regulation/rule_filings/byx/), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of

the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Choe has received a stockholder proposal submitted pursuant to Rule 14a–8 under the Act ³ which requested that the CGM Board take steps to implement a "proxy access" bylaw provision. In general, proxy access bylaws allow a stockholder, or group of stockholders, who comply with certain requirements, to nominate candidates for service on a board and have those candidates included in a company's proxy materials. Such provisions have become common among S&P 500 companies.4 Choe has determined to take the stockholder's requested steps to implement proxy access. Accordingly, the Exchange now proposes to make these changes by adopting new Section 2.16 of the CGM Bylaws and making certain conforming changes to current Sections 2.10 and 2.11 of the CGM Bylaws, all of which are described further below.

In developing its proposal, Cboe generally tried to balance the relative weight of arguments for and against proxy access provisions. On the one hand, Cboe recognizes the significance of this issue to some investors, who see proxy access as an important accountability mechanism that allows them to participate in board elections through the nomination of stockholder candidates that are presented in a company's proxy statement. On the other hand, Cboe's proposed proxy access provision includes certain procedural requirements that are designed to help ensure, among other things, that Cboe and its stockholders will have full and accurate information about nominating stockholders and their nominees and that such stockholders and nominees will comply with applicable laws, regulations and other requirements. Additionally, the Exchange notes the proposed terms are common among companies that have adopted proxy access. The Exchange also notes that the parent companies of other exchanges have adopted substantively similar proxy access provisions and the Exchange does not

^{17 17} CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See 17 CFR 240.14a–8, which requires companies that are subject to the federal proxy rules to include shareholder proposals in companies' proxy statements to shareholders, subject to certain procedural and substantive requirements.

⁴More than 75% of S&P 500 companies have adopted proxy access bylaw provisions.

believe such provisions are materially different than the Exchange's proposal.⁵

The proposed rule change would add new Section 2.16 to the CGM Bylaws. Section 2.16 would permit a stockholder, or group of up to 20 stockholders, to nominate director nominees for the Cboe Board, so long as the stockholder(s) have owned at least three percent of Cboe's outstanding shares of capital stock continuously for at least three years. The director nominees would be included in Cboe's annual meeting proxy materials. The proposed provision would limit the number of proposed director nominees to the greater of (i) two or (ii) 20% of the number of Cboe directors in office (rounded down to the nearest whole number, but no less than two) provided that the stockholder(s) and nominee(s) satisfy the other conditions specified in the CGM Bylaws as described further below.

Proposed Section 2.16(a)

The Exchange first proposes to amend the CGM Bylaws to, as set forth in the first sentence of proposed Section 2.16(a), require the Corporation to include in its proxy statement, its form proxy and any ballot distributed at the stockholder meeting, the name of, and certain Required Information 6 about, any person nominated for election (the "Stockholder Nominee") to the Board by a stockholder or group of stockholders (the "Ĕligible Stockholder") 7 that satisfies the requirements set forth in the proxy access provision of CGM Bylaws.8 Proposed Section 2.16(a) will also make clear that Cboe is able to solicit against any Stockholder Nominee or include in

its proxy materials the Corporation's own statements or other information relating to any Eligible Stockholder or Stockholder Nominee, including any information provided to the Corporation pursuant to Section 2.16. This provision clarifies that just because Cboe must include a Stockholder Nominee in its proxy materials if the proxy access provisions are satisfied, Cboe does not necessarily have to support that nominee.

Proposed Section 2.16(b)

Proposed Section 2.16(b) will provide that in order to utilize this provision, the Eligible Stockholder must expressly request at the time of providing a required notice to the Corporation of the proxy access nomination (the "Notice of Proxy Access Nomination") to have its nominee included in the Corporation's proxy materials. Proposed Section 2.16(b) also establishes the deadline for a timely Notice of Proxy Access Nomination. Specifically, such a notice must be delivered to the Cboe's Secretary at the principal executive offices of the Corporation not earlier than the open of business on the one hundred fiftieth (150th) day and not later than the close of business on the one hundred twentieth (120th) day prior to the first anniversary of the date that Choe first distributed its proxy statement to stockholders for the previous year's annual meeting of stockholders provided, however, that in the event the annual meeting is more than thirty (30) days before or after the anniversary date of the prior year's annual meeting, or if no annual meeting was held in the preceding year, to be timely, the Notice of Proxy Access Nomination must be received at the principal executive offices of the Corporation no earlier than one hundred fifty (150) days before such annual meeting and no later than the later of one hundred twenty (120) days before such annual meeting or the tenth (10th) day following the day on which public announcement (as defined in Section 2.11) of the date of such meeting is first made by the Corporation. Further Section 2.16 will provide that in no event shall any adjournment or postponement of an annual meeting or the announcement thereof commence a new time period (or extend any time period) for the giving of a Notice of Proxy Access Nomination as described above. Choe believes this notice period will provide stockholders an adequate window to submit nominees via proxy access, while also providing the Corporation adequate time to diligence a proxy access nominee before including them in the proxy statement

for the next annual meeting of stockholders.

Proposed Section 2.16(c)

Proposed Section 2.16(c) specifies that the maximum number ("the Permitted Number") of Stockholder Nominees nominated by all Eligible Stockholders that will be included in Choe's proxy materials with respect to an annual meeting of stockholders shall not exceed the greater of two or 20% of the total number of directors in office (rounded down to the nearest whole number) as of the last day on which a Notice of Proxy Access Nomination may be delivered pursuant to and in accordance with the proxy access provision of the Bylaws (the "Final Proxy Access Nomination Date"). In the event that one or more vacancies for any reason occurs after the Final Proxy Access Nomination Date but before the date of the annual meeting and the Board resolves to reduce the size of the Board in connection therewith, the Permitted Number of Stockholder Nominees included in Choe's proxy materials shall be calculated based on the number of directors in office as so reduced. In addition, the Permitted Number shall be reduced by (i) the number of individuals who will be included in the Corporation's proxy materials as director nominees recommended by the Board pursuant to an agreement, arrangement or other understanding with a stockholder or group of stockholders (other than any such agreement, arrangement or understanding entered into in connection with an acquisition of stock from the Corporation by such stockholder or group of stockholders) and/or (ii) the number of directors in office as of the Final Proxy Access Nomination Date who were included in the Corporation's proxy materials as Stockholder Nominees for any of the two preceding annual meetings of stockholders (including any persons counted as Stockholder Nominees pursuant to the immediately succeeding sentence) and whose reelection at the upcoming annual meeting is being recommended by the Board. Any individual nominated by an Eligible Stockholder for inclusion in the proxy materials pursuant to the proxy access provision of the CGM Bylaws whom the Board decides to nominate as a nominee of the Board, and any individual nominated by an Eligible Stockholder for inclusion in the proxy materials pursuant to the proxy access provision but whose nomination is subsequently withdrawn, shall be counted as one of the Stockholder Nominees for purposes of determining when the Permitted

⁵ See Securities Exchange Release No. 79357
(November 18, 2016) 81 FR 85283
(November 25, 2016) (SR-NASDAQ-2016-127; SR-BX-2016-051; SR-ISE-2016-22; SR-ISEGemini-2016-10; SR-ISEMercury-2016-16; SR-PHLX-2016-93; SR-BSECC-2016-001; SR-SCCP-2016-01). See also Securities Exchange Release No. 77782
(May 6, 2016) 81 FR 29600
(May 12, 2016) (SR-NYSE-2016-14; SR-NYSEArca-2016-25; SR-NYSEMKT-2016-20).

⁶The Required Information is the information provided to Cboe's Corporate Secretary about the Stockholder Nominee and the Eligible Stockholder that is required to be disclosed in the Corporation's proxy statement by the regulations promulgated under the Act, and if the Eligible Stockholder so elects, a written statement, not to exceed 500 words, in support of the Stockholder Nominee(s)' candidacy (the "Supporting Statement", as defined further below).

⁷ As used throughout the CGM Bylaws, the term "Eligible Stockholder" includes each member of a stockholder group that submits a proxy access nomination to the extent the context requires.

⁸When the Corporation includes proxy access nominees in the proxy materials, such individuals will be included in addition to any persons nominated for election by at or the direction of the Board to the Board or any committee thereof.

Number of Stockholder Nominees has been reached. Any Eligible Stockholder submitting more than one Stockholder Nominee for inclusion in the proxy materials shall rank such Stockholder Nominees based on the order that the Eligible Stockholder desires such Stockholder Nominees to be selected for inclusion in the proxy statement in the event that the total number of Stockholder Nominees submitted by Eligible Stockholders pursuant to the proxy access provision exceeds the Permitted Number of nominees allowed. In the event that the number of Stockholder Nominees submitted by Eligible Stockholders pursuant to Section 2.16 exceeds the Permitted Number of nominees allowed, the highest ranking Stockholder Nominee who meets the requirements of the proxy access provision of the Bylaws from each Eligible Stockholder will be selected for inclusion in the proxy materials until the Permitted Number is reached, going in order of the amount (largest to smallest) of shares of Cboe's outstanding capital stock each Eligible Stockholder disclosed as owned in its respective Notice of Proxy Access Nomination submitted to Choe. If the Permitted Number is not reached after the highest ranking Stockholder Nominee who meets the requirements of the proxy access provision of the Bylaws from each Eligible Stockholder has been selected, then the next highest ranking Stockholder Nominee who meets the requirements of Section 2.16 from each Eligible Stockholder will be selected for inclusion in the Corporation's proxy materials, and this process will continue as many times as necessary, following the same order each time, until the Permitted Number is reached. Additionally, notwithstanding anything to the contrary contained in proposed Section 2.16, Choe will not be required to include any Stockholder Nominees in its proxy materials pursuant to Section 2.16 for any meeting of stockholders for which the Secretary receives a notice (whether or not subsequently withdrawn) that the Eligible Stockholder or any other stockholder intends to nominate one or more persons for election to the Board pursuant to Section 2.11 of the CGM Bylaws. Choe believes it is reasonable to limit the Board seats available to proxy access nominees and to establish procedures for selecting candidates if the nominee limit is exceeded. The limitation on Board seats available to proxy access nominees ensures that proxy access cannot be used to take over the entire Board, which is not the stated

purpose of proxy access campaigns. The procedures for selecting candidates if the nominee limit is exceeded establish clear and rational guidelines for an orderly nomination process to avoid the Corporation having to make arbitrary judgments among candidates.

Proposed Section 2.16(d)

Proposed Section 2.16(d) defines who may qualify as an "Eligible Stockholder". Particularly, an Eligible Stockholder is a stockholder or group of no more than 20 stockholders 9 that (i) has owned continuously for at least three years (the "Minimum Holding Period") a number of shares of capital stock of the Corporation that represents at least three percent of the outstanding shares of capital stock of the Corporation as of the date the Notice of Proxy Access Nomination is received (the "Required Shares"), (ii) continues to own the Required Shares through the date of the annual meeting and (iii) meets all other requirements of proposed Section 2.16. Choe believes it is reasonable to require each member of a nominating group to provide such information so that both the Corporation and its stockholders are fully informed about the entire group making the proxy access nomination. As such, Section 2.16(d) further makes clear that whenever the Eligible Stockholder consists of a group of stockholders (including a group of funds that are part of the same Qualifying Fund Group), (i) each provision in Section 2.16 that requires the Eligible Stockholder to provide any written statements, representations, undertakings, agreements or other instruments or to meet any other conditions shall be deemed to require each stockholder (including each individual fund) that is a member of such group to provide such statements, representations, undertakings, agreements or other instruments and to meet such other conditions (except that the members of such group may aggregate the shares that each member has owned continuously for the Minimum Holding Period in order to meet the three percent ownership requirement of the "Required Shares" definition) and (ii) a breach of any obligation, agreement or representation under Section 2.16 by any member of such group shall be

deemed a breach by the Eligible Stockholder. No stockholder may be a member of more than one group of stockholders constituting an Eligible Stockholder with respect to any annual meeting.

Proposed Section 2.16(e)

Proposed Section 2.16(e) clarifies, for the avoidance of doubt, how "ownership" will be defined for purposes of meeting the ownership requirements of the Required Shares. Specifically, an Eligible Stockholder shall be deemed to "own" only those outstanding shares of Choe's capital stock as to which the stockholder possesses both: (i) The full voting and investment rights pertaining to the shares; and (ii) the full economic interest in (including the opportunity for profit from and risk of loss on) such shares; provided that the number of shares calculated in accordance with clauses (i) and (ii) shall not include any shares: That are (1) sold by such stockholder or any of its affiliates in any transaction that has not been settled or closed; (2) borrowed by such stockholder or any of its affiliates for any purposes or purchased by such stockholder or any of its affiliates pursuant to an agreement to resell; or (3) subject to any option, warrant, forward contract, swap, contract of sale, other derivative or similar instrument or agreement entered into by such stockholder or any of its affiliates, whether any such instrument or agreement is to be settled with shares or with cash based on the notional amount or value of shares of Cboe's outstanding capital stock, in any such case which instrument or agreement has, or is intended to have, the purpose or effect of: (A) Reducing in any manner, to any extent or at any time in the future, such stockholder's or its affiliates' full right to vote or direct the voting of any such shares; and/or (B) hedging, offsetting or altering to any degree any gain or loss realized or realizable from maintaining the full economic ownership of such shares by such stockholder or its affiliates.

Further, a stockholder shall "own" shares held in the name of a nominee or other intermediary so long as the stockholder retains the right to instruct how the shares are voted with respect to the election of directors and possesses the full economic interest in the shares. A stockholder's ownership of shares shall be deemed to continue during any period in which (i) the stockholder has loaned such shares provided that the stockholder has the power to recall such loaned shares on five (5) business days' notice and includes in the Notice of

⁹For this purpose, any two or more funds that are part of the same Qualifying Fund Group may be counted as one stockholder. A "Qualifying Fund Group" means two or more funds that are (i) under common management and investment control, (ii) under common management and funded primarily by the same employer or (iii) a "group of investment companies" as such term is defined in Section 12(d)(1)(G)(ii) of the Investment Corporation Act of 1940, as amended.

Proxy Access Nomination an agreement that it will (1) recall such loaned shares upon being notified that any of its Stockholder Nominees will be included in the Corporation's proxy materials and (2) will hold such shares through the date of the annual meeting or (ii) the stockholder has delegated any voting power by means of a proxy, power of attorney or other instrument or arrangement which is revocable at any time by the stockholder. Section 2.16(e) also clarifies that the terms "owned," "owning" and other variations of the word "own" shall have correlative meanings. Whether outstanding shares of Cboe's capital stock are "owned" for these purposes shall be determined by the Board. For purposes of Section 2.16, the term "affiliate" or "affiliates" shall have the meaning ascribed thereto under the rules and regulations of the Act.¹⁰ An Eligible Stockholder shall include in its Notice of Proxy Access Nomination the number of shares it is deemed to own for the purposes of proposed Section 2.16. In proposing the Required Shares and the Minimum Holding Period, Choe seeks to ensure that the Eligible Stockholder has had a sufficient stake in the Corporation for a sufficient amount of time and is not pursuing a short-term agenda.

Proposed Section 2.16(f)

Proposed Section 2.16(f) sets forth the information that an Eligible Stockholder must provide to Cboe's Corporate Secretary in writing within the deadline discussed above in order to make a proxy access nomination. This information includes:

- A statement by the Eligible Stockholder (1) setting forth and certifying as to the number of shares it owns and has owned continuously for the Minimum Holding Period and (2) agreeing to continue to own the Required Shares through the date of the annual meeting;
- one or more written statements from the record holder of the Required Shares (and from each intermediary through which the Required Shares are or have been held during the Minimum Holding Period) verifying that, as of a

date within seven calendar days prior to the date the Notice of Proxy Access Nomination is delivered to Cboe's Secretary at the principal executive offices of the Corporation, the Eligible Stockholder owns, and has owned continuously for the Minimum Holding Period, the Required Shares, and the Eligible Stockholder's agreement to provide, within five (5) business days after the record date for the annual meeting, written statements from the record holder and intermediaries verifying the Eligible Stockholder's continuous ownership of the Required Shares through the record date;

- a copy of the Schedule 14N that has been filed with the SEC as required by Rule 14a-18 under the Act; 11
- the information, representations and agreements and other documents that are required to be set forth in or included with a stockholder's notice of nomination given pursuant to Section 2.11 of the CGM Bylaws;
- the written consent of each Stockholder Nominee to being named in the proxy statement as a nominee and to serving as a director if elected;
- a representation that the Eligible Stockholder:
- Acquired the Required Shares in the ordinary course of business and not with the intent to change or influence control of Cboe, and does not presently have such intent;
- has not nominated and will not nominate for election any individual as a director at the annual meeting, other than its Stockholder Nominee(s);
- has not engaged and will not engage in, and has not and will not be a participant in another person's, "solicitation" within the meaning of Rule 14a–1(l) under the Act in support of the election of any individual as a director at the annual meeting, other than its Stockholder Nominee(s) or a nominee of the Board;
- has not distributed and will not distribute to any stockholder of the Corporation any form of proxy for the annual meeting other than the form distributed by the Corporation;
- has complied and will comply with all laws, rules and regulations applicable to solicitations and the use, if any, of soliciting material in connection with the annual meeting,
- has provided and will provide facts, statements and other information

in all communications with Cboe and its stockholders that are or will be true and correct in all material respects and do not and will not omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

• an undertaking that the Eligible

Stockholder agrees to

 assume all liability stemming from any legal or regulatory violation arising out of the Eligible Stockholder's communications with the stockholders of the Corporation or out of the information that the Eligible Stockholder provided to the

Corporation;

- indemnify and hold harmless the Corporation and each of its Directors, officers and employees individually against any liability, loss or damages in connection with any threatened or pending action, suit or proceeding, whether legal, administrative or investigative, against the Corporation or any of its Directors, officers or employees arising out of any nomination submitted by the Eligible Stockholder pursuant to this Section 2.16 or any solicitation or other activity in connection therewith; and
- file with the Securities and Exchange Commission any solicitation or other communication with the stockholders of the Corporation relating to the meeting at which its Stockholder Nominee(s) will be nominated, regardless of whether any such filing is required under Regulation 14A of the Act or whether any exemption from filing is available for such solicitation or other communication under Regulation 14A of the Act;
- in the case of a nomination by a group of stockholders that together is an Eligible Stockholder, the designation by all group members of one group member that is authorized to receive communications, notices and inquiries from the Corporation and to act on behalf of all members of the group with respect to all matters relating to the nomination under this Section 2.16 (including withdrawal of the nomination):
- in the case of a nomination by an Eligible Stockholder consisting of a group of stockholders in which two or more funds are intended to be treated as one stockholder for purposes of qualifying as an Eligible Stockholder, documentation reasonably satisfactory to the Corporation that demonstrates that the funds are part of the same Qualifying Fund Group; and
- a written representation and agreement by the Stockholder Nominee that such person:

¹⁰ Pursuant to Rule 12b–2 under the Act, "[a]n 'affiliate' of, or a person 'affiliated' with, a specified person, is a person that directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, the person specified." 17 CFR 240.12b-2. Further, [t]he term 'control' (including the terms 'controlling,' 'controlled by' and 'under common control with') means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a person, whether through the ownership of voting securities, by contract, or otherwise." 17 CFR 240.12b-2.

 $^{^{11}\,}See$ 17 CFR 240.14n–101 and 17 CFR 240.14a– 18, which generally require a Nominating Stockholder to provide notice to the Corporation of its intent to submit a proxy access nomination on a Schedule 14N and file that notice, including the required disclosure, with the Commission on the date first transmitted to the Corporation.

- Will act as a representative of all of the stockholders of the Corporation while serving as a director;
- will provide facts, statements and other information in all communications with the Corporation and its stockholders that are or will be true and correct in all material respects (and shall not omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading);
- is not and will not become a party to (i) any compensatory, payment or other financial agreement, arrangement or understanding with any person or entity other than the Corporation in connection with service or action as a director of the Corporation that has not been disclosed to the Corporation, (ii) any Voting Commitment that has not been disclosed to the Corporation or (iii) any Voting Commitment 12 that could reasonably be expected to limit or interfere with the Stockholder Nominee's ability to comply, if elected as a director of the Corporation, with its fiduciary duties under applicable law; and
- o will abide by and comply with the CGM Bylaws, the Certificate of Incorporation and applicable policies of the Corporation including all applicable publicly disclosed corporate governance, conflict of interest, confidentiality and stock ownership and trading policies and guidelines of the Corporation, as well as the applicable provisions of the rules and regulations of the Securities and Exchange Commission and any stock exchange applicable to the Corporation.

In proposing the informational requirements for the Eligible Stockholder, Cboe's goal is to gather sufficient information about the Eligible Stockholder for both itself and its stockholders. Among other things, this information is designed to help ensure that Cboe is able to comply with its disclosure and other requirements under applicable law and that Cboe, its Board and its stockholders are able to assess the proxy access nomination adequately.

Proposed Section 2.16(g)

Proposed Section 2.16(g) establishes additional information the Stockholder Nominee must provide. Particularly:

• The Stockholder Nominee(s) must submit all completed and signed

questionnaires required of directors and officers of the Corporation;

 the Corporation may require any proposed Stockholder Nominee to furnish any information:

- O That may reasonably be requested by the Corporation to determine whether the Stockholder Nominee would be independent under Section 3.3 and otherwise qualifies as independent under the rules of the principal national securities exchange on which the outstanding capital stock of the Corporation is traded;
- that could be material to a reasonable stockholder's understanding of the independence, or lack thereof, of such Stockholder Nominee;
- that would be required to satisfy the requirements for qualification of directors under applicable foreign regulations; or
- o (that may reasonably be requested by the Corporation to determine the eligibility of such Stockholder Nominee to be included in the Corporation's proxy materials pursuant to this Section 2.16 or to serve as a director of the Corporation; and
- the Corporation may require the Eligible Stockholder to furnish any other information that may reasonably be requested by the Corporation to verify the Eligible Stockholder's continuous Ownership of the Required Shares for the Minimum Holding Period and through the date of the annual meeting.

Like the informational requirements for an Eligible Stockholder, which are set forth above, the informational requirements for the Stockholder Nominee ensure that both Cboe and its stockholders will have sufficient information about the Stockholder Nominee. Among other things, this information will ensure that Cboe is able to comply with its disclosure and other requirements under applicable law and that Cboe, its Board and its stockholders are able to assess the proxy access nomination adequately.

Proposed Section 2.16(h)

Proposed Section 2.16(h) provides that an Eligible Stockholder may provide, at its option, to the Secretary, at the time the Notice of Proxy Access Nomination is provided, a written statement, not to exceed 500 words, in support of its Stockholder Nominee(s)' candidacy (a "Supporting Statement"). Only one Supporting Statement may be submitted by an Eligible Stockholder (including any group of stockholders together constituting an Eligible Stockholder) in support of its Stockholder Nominee(s). Notwithstanding anything to the

contrary contained in Section 2.16, the Corporation may omit from its proxy materials any information or Supporting Statement (or portion thereof) that it, in good faith, believes is untrue in any material respect (or omits to state a material fact necessary in order to make the statements made, in light of the circumstances under which they are made, not misleading) or would violate any applicable law, rule or regulation. The Exchange notes proposed Section 2.16(h) allows Choe to comply with Rule 14a-9 under the Act 13 and to protect its stockholders from information that is materially untrue or that violates any law, rule or regulation.

Proposed Section 2.16(i)

Pursuant to proposed Section 2.16(i), each Eligible Stockholder or Stockholder Nominee must promptly notify Choe's Corporate Secretary of any information or communications provided by the Eligible Stockholder or Stockholder Nominee, as the case may be, to Cboe or its stockholders that when provided was not, or thereafter ceases to be, true and correct in all material respects or omits a material fact necessary to make the statements made, in light of the circumstances under which they were made, not misleading and of the information that is required to correct any such defect. An Eligible Stockholder shall also provide immediate notice to the Corporation if the Eligible Stockholder ceases to own any of the Required Shares prior to the date of the annual meeting. In addition, any person providing any information to the Corporation pursuant to Section 2.16(i) shall be required to update or supplement such information, if necessary, so that all such information shall be true and correct as of the (i) as of the record date for determining the stockholders entitled to receive notice of the meeting and (ii) as of the date that is ten (10) business days prior to the meeting (or any postponement, adjournment or recess thereof), and such update shall be received by the Secretary at the principal executive offices of the Corporation (A) not later than five (5) business days after the record date for determining the stockholders entitled to receive notice of such meeting (in the case of an update required to be made under clause (i)) and (B) not later than seven (7) business

¹² A "Voting Commitment" is defined as any agreement, arrangement or understanding with any person or entity as to how the Stockholder Nominee would vote or act on any issue or question as a

¹³ See 17 CFR 240.14a–9, which generally prohibits proxy solicitations that contain any statement which, at the time and in the light of the circumstances under which it is made, is false or misleading with respect to any material fact, or which omits to state any material fact necessary in order to make the statements therein not false or misleading.

days prior to the date for the meeting, if practicable, or, if not practicable, on the first practicable date prior to the meeting or any adjournment, recess or postponement thereof (in the case of an update required to be made pursuant to clause (ii)).

This provision further makes clear that providing any such notification, update or supplement, shall not be deemed to cure any defect in any previously provided information or communications or limit the remedies available to the Corporation relating to such defect (including the right to omit a Stockholder Nominee from its proxy materials). This provision is intended to protect Cboe's stockholders by requiring an Eligible Stockholder or Stockholder Nominee to give Choe notice of information previously provided that is materially untrue. Choe may then decide what action to take with respect to such defect, which may include, as noted above, omitting the relevant Stockholder Nominee from its proxy materials.

Proposed Section 2.16(j)

Proposed Section 2.16(j) provides that Cboe shall not be required to include a Stockholder Nominee in its proxy materials for any meeting of stockholders under certain circumstances. In these situations, the proxy access nomination shall be disregarded and no vote on such Stockholder Nominee will occur, even if Cboe has received proxies in respect of the vote. These circumstances occur when the Stockholder Nominee:

- Would not be an independent director under Section 3.3, under the rules of the principal national securities exchange on which the outstanding capital stock of the Corporation is traded, any applicable rules of the Securities and Exchange Commission and any publicly disclosed standards used by the Board in determining and disclosing independence of the Corporation's directors, in each case as determined by the Board in its sole discretion;
- would not meet the audit committee independence requirements under the rules of the principal national securities exchange on which the outstanding capital stock of the Corporation is traded;
- if elected, intended to resign as a director of the Corporation prior to the end of the full term for which he or she is standing for election;
- is or has been subject to any statutory disqualification under Section 3(a)(39) of the Act;
- is or has been subject to disqualification under 17 CFR 1.63;

- if elected, would cause the Corporation to be in violation of these Bylaws, the Certificate of Incorporation, the rules of the principal national securities exchange on which the outstanding capital stock of the Corporation is traded, or any applicable law, rule or regulation;
- is or has been, within the past three years, an officer or director of a competitor, as defined for purposes of Section 8 of the Clayton Antitrust Act of 1914.
- is a named subject of a pending criminal proceeding (excluding traffic violations and other minor offenses) or has been convicted in such a criminal proceeding within the past 10 years;
- is subject to any order of the type specified in Rule 506(d) of Regulation D promulgated under the Securities Act of 1933, as amended;
- has provided any information to the Corporation or its stockholders that was untrue in any material respect or that omitted to state a material fact necessary to make the statements made, in light of the circumstances in which they were made, not misleading; or
- breaches or fails, or the Eligible Stockholder breaches or fails, to comply with its obligations pursuant to the CGM Bylaws, including, but not limited to, Section 2.16 and any agreement, representation or undertaking required by Section 2.16.

Cboe believes these provisions will protect the Corporation and its stockholders by allowing it to exclude certain categories of objectionable Stockholder Nominees from the proxy statement.

Proposed Section 2.16(k)

Proposed Section 2.16(k) provides that notwithstanding anything to the contrary contained in the CGM Bylaws, if (i) a Stockholder Nominee and/or the applicable Eligible Stockholder breaches any of its agreements or representations or fails to comply with any of its obligations under this Section 2.16 or (ii) a Stockholder Nominee otherwise becomes ineligible for inclusion in the Corporation's proxy materials pursuant to this Section 2.16, or dies, becomes disabled or otherwise becomes ineligible or unavailable for election at the annual meeting, in each case as determined by the Board or the chairman of the meeting, (1) the Corporation may omit or, to the extent feasible, remove the information concerning such Stockholder Nominee and the related Supporting Statement from its proxy materials and/or otherwise communicate to its stockholders that such Stockholder Nominee will not be eligible for election

at the annual meeting, (2) the Corporation shall not be required to include in its proxy materials any successor or replacement nominee proposed by the applicable Eligible Stockholder or any other Eligible Stockholder and (3) the chairman of the meeting shall declare such nomination to be invalid and such nomination shall be disregarded, notwithstanding that proxies in respect of such vote may have been received by the Corporation. Choe believes this provision protects the Corporation and its stockholders by providing the Board or the chairman of the stockholder meeting limited authority to disqualify a proxy access nominee when that nominee or the sponsoring stockholder(s) have breached an obligation under the proxy access provision.

Proposed Section 2.16(l)

Proposed Section 2.16(l) states that the following Stockholder Nominees who are included in the Corporation's proxy materials for a particular annual meeting of stockholders will be ineligible to be a Stockholder Nominee for the next two annual meetings: (i) Stockholder Nominee who withdraws from or becomes ineligible or unavailable for election at the annual meeting; or (ii) Stockholder Nominee who does not receive at least 25% of the votes cast in favor of such Stockholder Nominee's election. For the avoidance of doubt, Section 2.16(l) also clarifies that this provision shall not prevent any stockholder from nominating any person to the Board pursuant to Section 2.11 of the CGM Bylaws. Section 2.16(l) will save the Corporation and its stockholders the time and expense of analyzing and addressing subsequent proxy access nominations regarding individuals who were included in the proxy materials for a particular annual meeting but ultimately did not stand for election or receive a substantial amount of votes. After the next two annual meetings, these Stockholder Nominees would again be eligible for nomination through the proxy access provisions of the Bylaws.

Proposed Section 2.16(m)

Proposed Section 2.16(m) provides that notwithstanding the provisions of proposed Section 2.16, if the Eligible Stockholder providing notice (or a qualified representative of the Eligible Stockholder) does not appear in person (including virtually, in the case of a meeting held solely by means of remote communication) at the stockholder meeting to present the nomination of such Stockholder Nominee, such proposed nomination shall not be

presented by the Corporation and shall not be transacted, notwithstanding that proxies in respect of such vote may have been received by the Corporation. For purposes of this Section 2.16, to be considered a qualified representative of the Eligible Stockholder providing notice, a person must be a duly authorized officer, manager or partner of such stockholder or must be authorized by a writing executed by such stockholder or an electronic transmission delivered by such stockholder to act for such stockholder as proxy at the meeting and such writing or electronic transmission, or a reliable reproduction of the writing or electronic transmission, must be provided to the Corporation at least twenty-four (24) hours prior to the meeting.

Proposed Section 2.16(n)

In case there are matters involving a proxy access nomination that are open to interpretation, proposed Section 2.16(n) states that the Board (or any other person or body authorized by the Board) shall have exclusive power and authority to interpret the proxy access provisions of the Bylaws and make all determinations deemed necessary or advisable in connection with proposed Section 2.16 as to any person, facts or circumstances. In addition, all actions, interpretations and determinations of the Board (or any person or body authorized by the Board) with respect to the proxy access provisions shall be final, conclusive and binding on the Corporation, the stockholders and all other parties. While Choe has attempted to implement a clear, detailed and thorough proxy access provision, there may be matters about future proxy access nominations that are open to interpretation. In these cases, Cboe believes it is reasonable and necessary to designate an arbiter to make final decisions on these points and that the Board is best-suited to act as that arbiter.

Proposed Section 2.16(o)

For the avoidance of doubt, proposed Section 2.16(o) states that the proxy access provisions outlined in proposed Section 2.16 shall be the exclusive means for stockholders to include nominees in the Corporation's proxy materials. Stockholders may, of course, continue to propose nominees through other means, but the Board will have final authority to determine whether to include those nominees in the Corporation's proxy materials.

Revisions to Other Sections of the Bylaws

Choe also proposes to make conforming changes to Sections 2.10 and 2.11 to provide clarifications and prevent confusion. First, the Exchange proposes to add a reference to Section 2.11 and proposed Section 2.16 to clarify the exact bylaw provisions relating to stockholder nominees. Next, the Exchange proposes to amend Section 2.11. Section 2.11 currently describes the business that may be properly brought before an annual meeting of stockholders and the methods by which nominations of persons for election to the Board may be made at an annual meeting of stockholders. Choe proposes to add proxy access nominations (i.e., reference to Section 2.16) to the list of methods. Current Section 2.11(a)(i) also states, among other things, that compliance with Section 2.11 shall be the exclusive means for a stockholder to propose business or director nominations before an annual meeting stockholders. The Exchange proposes to clarify that Sections 2.11 and 2.16 are the exclusive means for a stockholder to make a director nomination.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act. 14 Specifically. the Exchange believes the proposed rule change is consistent with the Section $6(b)(5)^{15}$ requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

In light of a shareholder proposal received from a stockholder, Cboe is proposing changes to its Bylaws to implement proxy access. The Exchange believes that this filing furthers the objectives of Section 6(b)(5) of the Act because the proposed rule change would be consistent with and facilitate a governance and regulatory structure that 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 regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. Particularly, the Exchange believes that, by permitting an Eligible Stockholder of Cboe that meets the stated requirements to nominate directors and have its nominees included in Cboe's annual meeting proxy statement, the proposed rule change strengthens the corporate governance of the Exchange's ultimate parent company, which is beneficial to both investors and the public interest.

Additionally, the procedural requirements are designed to help protect investors by stating clearly and explicitly the procedures stockholders must follow in order to submit a proper proxy access nomination. The informational requirements are designed to enhance investor protection by helping to ensure among other things, that the Corporation and its stockholders have full and accurate information about nominating stockholders and their nominees and that such stockholders and nominees comply with applicable laws, regulations and other requirements. Moreover, as noted above, proxy access has become commonplace among companies and the Exchange believes its core provisions are common among companies that have adopted proxy access, including the parent companies of other exchanges that have adopted similar proxy access provisions. 16

Finally, the remaining changes to existing provisions of the CGM Bylaws are clarifying in nature, and they enhance investor protection and the public interest by preventing confusion with respect to the operation of the Bylaw provisions.

B. Self-Regulatory Organization's Statement on Burden on Competition

Because the proposed rule change relates to the governance of the Corporation and not to the operations of the Exchange, the Exchange does not believe that the proposed rule change

^{14 15} U.S.C. 78f(b).

¹⁵ 15 U.S.C. 78f(b)(5).

¹⁶ See Securities Exchange Release No. 79357
(November 18, 2016) 81 FR 85283 (November 25, 2016) (SR-NASDAQ-2016-127; SR-BX-2016-051; SR-ISE-2016-22; SR-ISEGemini-2016-10; SR-ISEMercury-2016-16; SR-PHLX-2016-93; SR-BSECC-2016-001; SR-SCCP-2016-01). See also Securities Exchange Release No. 77782 (May 6, 2016) 81 FR 29600 (May 12, 2016) (SR-NYSE-2016-14; SR-NYSEArca-2016-25; SR-NYSEMKT-2016-20).

will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not designed to address any competitive issue or have any impact on competition; rather, adoption of a proxy access bylaw by the Corporation is intended to enhance corporate governance and accountability to stockholders.

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

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission shall: (a) By order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (http://www.sec.gov/rules/sro.shtml): or
- Send an email to *rule-comments@* sec.gov. Please include File Number SR–CboeBYX–2021–009 on the subject line.

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CboeBYX–2021–009. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (http://www.sec.gov/rules/sro.shtml). Copies of the

submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-CboeBYX-2021-009 and should be submitted on or before May 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. 17

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–09448 Filed 5–4–21; 8:45 am] BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91695; File No. SR– CboeBZX–2021–019]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To List and Trade Shares of the VanEck Bitcoin Trust Under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares

April 28, 2021

On March 1, 2021, Cboe BZX Exchange, Inc. ("BZX") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") and Rule 19b—4 thereunder, a proposed rule change to list and trade shares of the VanEck Bitcoin Trust under BZX Rule 14.11(e)(4), Commodity-Based Trust

Shares. The proposed rule change was published for comment in the **Federal Register** on March 19, 2021.³ The Commission has received comments on the proposed rule change.⁴

Section 19(b)(2) of the Act 5 provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is May 3, 2021. The Commission is extending this 45day time period.

The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change and the comments received. Accordingly, pursuant to Section 19(b)(2) of the Act,⁶ the Commission designates June 17, 2021, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR-CboeBZX–2021–019).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.

I. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021-09280 Filed 5-4-21; 8:45 am]

BILLING CODE 8011-01-P

^{17 17} CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 91326 (March 15, 2021), 86 FR 14987 (March 19, 2021).

⁴Comments received on the proposed rule change are available at: https://www.sec.gov/comments/sr-cboebzx-2021-019/srcboebzx2021019.htm.

⁵ 15 U.S.C. 78s(b)(2).

⁶ *Id*

⁷¹⁷ CFR 200.30-3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-91720; File No. SR-NSCC-2021-802]

Self-Regulatory Organizations; **National Securities Clearing** Corporation; Notice of Filing of and No Objection to Advance Notice Regarding the Renewal of a 364-Day Committed Revolving Line-of-Credit and Future Annual Renewals

April 29, 2021.

Pursuant to Section 806(e)(1) of Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act entitled the Payment, Clearing, and Settlement Supervision Act of 2010 ("Clearing Supervision Act") and Rule 19b–4(n)(1)(i) under the Securities Exchange Act of 1934 ("Act"), notice is hereby given that on April 8, 2021, National Securities Clearing Corporation ("NSCC") filed with the Securities and Exchange Commission ("Commission") the advance notice SR-NSCC-2021-802. The advance notice (hereinafter, the "Advance Notice") is described in Items I, II and III below, which Items have been prepared by the clearing agency. The Commission is publishing this notice to solicit comments on the Advance Notice from interested persons and providing notice that the Commission does not object to the Advance Notice.

I. Clearing Agency's Statement of the Terms of Substance of the Advance Notice

NSCC is filing this advance notice in order to (1) renew its 364-day committed revolving line-of-credit with a syndicate of commercial lenders ("Credit Facility"), as described below (hereinafter, "Current Renewal"), and (2) enter into future annual renewals of the Credit Facility on substantially similar terms and conditions as the Current Renewal without needing to file an advance notice, also described below (hereinafter, "Future Renewals").3

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Advance Notice

In its filing with the Commission, the clearing agency included statements concerning the purpose of and basis for the Advance Notice and discussed any comments it received on the Advance Notice. The text of these statements may

be examined at the places specified in Item IV below. The clearing agency has prepared summaries, set forth in sections A and B below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement on Comments on the Advance Notice Received From Members, Participants, or Others

NSCC has not solicited or received any written comments to this advance notice. NSCC will notify the Commission of any written comments are received by NSCC.

(B) Advance Notice Filed Pursuant to Section 806(e) of the Clearing Supervision Act

Description of the Proposal

NSCC is filing this advance notice in order to enter into (1) the Current Renewal and (2) Future Renewals, as described below.

Background. NSCC and DTC maintain the Credit Facility as part of their liquidity risk management regime. The Credit Facility provides for both NSCC and DTC as borrowers, with an aggregate commitment of \$1.9 billion for DTC and the amount of any excess aggregate commitment for NSCC. As borrowers, NSCC and DTC are not jointly and severally liable, and each lender to the Credit Facility has a ratable commitment to each borrower. NSCC and DTC have separate collateral to secure their separate borrowings.

The Credit Facility is renewed annually, and from 2013 through 2017, NSCC and DTC each filed an advance notice each year with the Commission, pursuant to Section 806(e)(1) of the Clearing Supervision Act 4 and Rule 19b-4(n)(1)(i) under the Exchange Act ⁵ as part of that renewal process.6

In 2017, NSCC and DTC proposed and the Commission did not object to allowing NSCC and DTC to renew the Credit Facility, subject to specific conditions ("Evergreen Provisions"), without filing advance notices with the Commission.⁷ The Commission found that because the Evergreen Provisions would ensure that future annual renewals of the Credit Facility would be

on substantially similar terms and conditions as the 2017 Credit Facility, to which the Commission did not object. associated advance notice filings would not be necessary.8 However, in the event that an annual renewal of the Credit Facility would not satisfy the Evergreen Provisions, such renewal would be subject to an advance notice filing.

Some of the Evergreen Provisions are specific to NSCC, some to DTC, and some to both.9 One of the NSCC specific Evergreen Provisions is that NSCC would not seek or accept for its portion of the Credit Facility an aggregate commitment amount 15 percent below the amount NSCC sought in 2017.¹⁰ In 2017, NSCC sought an aggregate commitment amount of \$12.1 billion for its portion of the Credit Facility, which established a 15 percent threshold amount of no less than \$10.285 billion.11 Because NSCC now seeks an aggregate commitment amount of no more than \$10.1 billion for its portion of the Credit Facility, which is below that 15 percent threshold, it is filing this advance notice with the Commission. 12 DTC need not file an advance notice for its renewal of the Credit Facility because DTC would continue to comply with the Evergreen Provisions applicable to it.13 The only Evergreen Provision to which the Current Renewal would not satisfy is the 15 percent minimum threshold amount applicable to NSCC.

Current Renewal. The terms and conditions of the Current Renewal would be specified in the Revolving Credit Agreement, to be dated as of May 4, 2021, among DTC, NSCC, the lenders party thereto, the primary administrative and collateral agent, and the backup administrative and collateral agent ("Renewal Agreement"). Such terms and conditions would be substantially the same as the terms and conditions of the existing credit agreement, dated as of May 5, 2020 ("Existing Agreement"), except that

^{1 12} U.S.C. 5465(e)(1).

² 17 CFR 240.19b-4(n)(1)(i).

³ Terms not defined herein are defined in the Rules and Procedures of NSCC ("Rules"), http:// www.dtcc.com/~/media/Files/Downloads/legal/ rules/nscc_rules.pdf.

^{4 12} U.S.C. 5465(e)(1).

^{5 17} CFR 240.19b-4(n)(1)(i).

⁶ Securities Exchange Act Release Nos. 69557 (May 10, 2013), 78 FR 28936 (May 16, 2013) (SR-NSCC-2013-803); 72131 (May 8, 2014), 79 FR 27654 (May 14, 2014) (SR-NSCC-2014-805); 74906 (May 7, 2015), 80 FR 27714 (May 14, 2015) (SR– NSCC–2015–801); 77750 (April 29, 2016), 81 FR 27181 (May 5, 2016) (SR-NSCC-2016-801); 80605 (May 5, 2017), 82 FR 21850 (May 10, 2017) (SR-NSCC-2017-802).

⁷ Securities Exchange Act Release No. 80605 (May 5, 2017), 82 FR 21850 (May 10, 2017) (SR-NSCC-2017-802) ("2017 Filing").

⁸ *Id*.

⁹ See id.

¹⁰ Id

¹¹ Id.

¹² NSCC is seeking a reduced commitment amount for a variety of reasons, including but not limited to NSCC's ability to obtain additional liquidity from the issuance of commercial paper and extendable notes (see Securities Exchange Act Release Nos. 75730 (August 19, 2015), 80 FR 51638 (August 25, 2015) (SR-NSCC-2015-802); 82676 (February 9, 2018), 83 FR 6912 (February 15, 2018) (SR–NSČC–2017–807)), as well as certain term debt (see Securities Exchange Act Release No. 88146 (February 7, 2020), 85 FR 8046 (February 12, 2020) (SR-NSCC-2019-802)) ("Liquidity Filings").

¹³ See 2017 Filing, supra note 7.

pricing ¹⁴ and the aggregate commitment amount for NSCC, as discussed above, is expected to change. The substantive terms of the Renewal Agreement are set forth in the Summary of Indicative Principal Terms and Conditions, dated March 22, 2021 ("Term Sheet"), which is not a public document but has been included as a confidential Exhibit 3 to this filing.

For the Current Renewal, NSCC and DTC are seeking an aggregate commitment amount of no more than \$12 billion for the entire Credit Facility, of which \$1.9 billion would be committed to DTC as borrower and any remainder to NSCC as borrower, as provided in the Existing Agreement. Although NSCC and DTC are seeking an aggregate commitment amount of no more than \$12 billion, the actual, final amount will depend on a number of factors, including the total commitment amount received from lenders (i.e., it is possible that the total aggregate commitments received is less than the \$12 billion sought); projected market volatility over the Credit Facility's 364day period ("Facility Period"); potential business initiatives over the Facility Period; projected availability of NSCC's other liquidity resources (i.e., liquidity available via NSCC's commercial paper, extendable notes, term debt, 15 Clearing Fund, and Supplemental Liquidity Deposit ("SLD") requirement 16) over the Facility Period; and NSCC and DTC's long-term liquidity strategy.

NSCC and DTC would continue not to be jointly and severally liable and each lender would have a ratable commitment to each borrower. DTC and NSCC would continue to provide separate collateral to secure their

respective borrowings.
Future Renewals. NSCC expects to continue to renew the Credit Facility annually on substantially similar terms and conditions as the Current Renewal. The terms and conditions of all Future Renewals would be specified in subsequent credit agreements among DTC, NSCC, the lenders party thereto, and the agents.

As has been standard practice for the Credit Facility renewals, in connection with all Future Renewals, changes would not be made to (a) the financial institution acting as the primary administrative agent; or (b) the

commitment period, which would continue to be 364 days.

However, as was established with the 2017 Filing,17 in connection with all Future Renewals, changes may be made to (1) the aggregate commitment amount being sought for NSCC, so long as such amount does not vary more than 15 percent above or below the aggregate commitment amount being sought by NSCC under the Current Renewal (i.e., \$10.1 billion), which equates to an amount of no more than \$11.615 billion and no less than \$8.585 billion; 18 (2) the syndicate, so long as all lenders party to Future Renewals are subject to the same credit review as those lenders party to the Current Renewal; 19 (3) pricing and collateral haircuts,20 so long as such terms are consistent with the then current market practice; or (4) representations, warranties, covenants, terms of events of default,21 and other agreement provisions, so long as any

¹⁹ Potential lenders to the Credit Facility are analyzed to determine whether the potential lender has an acceptable credit risk profile. Criteria assessed can include long-term credit ratings, credit default swap spreads, sovereign ratings (*i.e.*, the rating of the country of the ultimate parent), as applicable, and any other factors that may suggest a stronger or weaker credit risk profile, as necessary.

²⁰ "Collateral haircuts" with respect to the collateral for any borrowing under the Credit Facility refers to the schedule of percentages of market value, by type of collateral, determining the collateral value of that type of collateral, for purposes of securing a borrowing under the Credit Facility.

changes are immaterial to NSCC as a borrower and do not impair NSCC's ability to borrow under the Credit Facility. NSCC would not consider such changes as materially altering the terms and conditions of the Credit Facility.

So long as NSCC does not make changes to the terms described in items (a) and (b) above in any Future Renewal, and so long as any Future Renewal adheres to the conditions described in items (1) through (4) above (together with items (a) and (b) above, "Proposed Evergreen Provisions"), NSCC would consider such Future Renewal as being on substantially the same terms and conditions as the Current Renewal, such that NSCC proposes that it would not need to file an advance notice pursuant to Section 806(e)(1) of the Clearing Supervision Act 22 and Rule 19b-4(n)(1)(i) under the Exchange Act.²³ Except for the specific dollar amounts described above, the Proposed Evergreen Provisions are the same as the Evergreen Provisions applicable to NSCC in the 2017 Filing.²⁴
In the event that NSCC would have a

In the event that NSCC would have a Future Renewal that would not satisfy the Proposed Evergreen Provisions and, thus, would not be on terms and conditions that are substantially similar to the Current Renewal, such renewal would be subject to an advance notice filing by NSCC.

Expected Effect on Risks to the Clearing Agency, Its Participants and the Market

The Renewal Agreement and its substantially similar predecessor agreements have been in place since the introduction of same day funds settlement at NSCC. The Current Renewal and Future Renewals subject to the Proposed Evergreen Provisions ("Evergreen Renewals") would continue to promote the reduction of liquidity risk to NSCC, its Members, and the securities market in general because they would help NSCC maintain sufficient liquidity resources to timely meet its settlement obligations with a high degree of confidence.

Management of Identified Risks

NSCC requires same day liquidity resources to cover the failure-to-settle of its Member, or affiliated family of Members, with the largest aggregate liquidity exposure. If a Member defaults on its end-of-day net settlement obligation, NSCC may borrow under the Credit Facility to enable it, if necessary, to fund settlement among non-defaulting Members, including

^{14 &}quot;Pricing" of the Credit Facility refers to the charges and fees owed by the borrowers (i.e., NSCC and DTC) to the agents and lenders thereto with respect to the services performed by the agents, the commitment to lend, and the rate of interest applicable to any borrowing under the Credit Facility, among other such matters.

¹⁵ See Liquidity Filings, supra note 12.

¹⁶ Rule 4A (sic), Rules, *supra* note 3.

¹⁷ Supra note 7.

¹⁸ NSCC continues to believe that a difference of no more than 15 percent, either above or below the aggregate commitment amount being sought by NSCC under the Current Renewal, would not constitute a material change in the nature or level of risk presented by NSCC requiring an advance notice filing (see supra notes 1 and 2) because (i) the standing requirement that NSCC maintain, in short, sufficient liquidity to cover the default of the member family that would generate the largest aggregate payment obligation, in extreme but plausible market conditions (see Rule 17Ad-22(e)(7)(i) under the Exchange Act, discussed below); (ii) availability of liquidity via NSCC's other liquidity resources (see Liquidity Filings, supra note 12 and see Rule 4A (sic), Rules, supra note 3); and (iii) the average size of the commitments for NSCC in past Credit Facilities, which have ranged from a low of \$6.18 billion in 2011, to a high of \$13.47 billion in 2014, both of which predated NSCC's commercial paper and term-debt offerings (see Liquidity Filings, supra note 12), as well as the long-term establishment of NSCC's SLD requirement (Rule 4A (sic), Rules, supra note 3), which currently covers monthly options expiry periods but has been proposed to cover all business days (see Securities Exchange Act Release No. 91347 (March 18, 2021), 86 FR 15750 (March 24, 2021) (SR-NSCC-2021-801)). More recently, NSCC's Credit Facility commitment amounts have been \$12.05 (2018), \$12.05 (2019), and \$10.90 billion (2020).

²¹ "Events of default" under the Credit Facility refers to those events or conditions which trigger or constitute a default of the borrowers under the agreement (e.g., a breach of terms or conditions or a failure to perform an obligation).

^{22 12} U.S.C. 5465(e)(1).

²³ 17 CFR 240.19b-4(n)(1)(i).

²⁴ See 2017 Filing, supra note 7.

settlement of guaranteed trades due to settle. Any borrowing would be secured principally by (i) securities deposited by Members in NSCC's Clearing Fund 25 (i.e., the Eligible Clearing Fund Securities, as defined in the Rules, pledged by Members to NSCC in lieu of cash Clearing Fund deposits) and (ii) securities cleared through NSCC's Continuous Net Settlement System that were intended for delivery to the defaulting Member upon payment of its net settlement obligation.

In addition to the Credit Facility and the Clearing Fund, NSCC has diversified its liquidity resources through the issuance of commercial paper and extendable notes, as well as certain term debt, as noted above.26 Each of these liquidity resources are an integral part of NSCC's risk management structure, as they help provide NSCC with liquidity to complete end-of-day net funds

settlement.

Because the Renewal Agreement would preserve substantially similar terms and conditions to the Existing Agreement, and Evergreen Renewals would preserve substantially similar terms and conditions to the Renewal Agreement, NSCC believes that the Current Renewal and Evergreen Renewals would not otherwise affect or alter the management of risk at NSCC.

Consistency With the Clearing Supervision Act

The objectives and principles of Section 805(b) of the Clearing Supervision Act are to promote of robust risk management, promote safety and soundness, reduce systemic risks, and support the stability of the broader financial system.²⁷ As discussed below, NSCC believes that the changes proposed in this advance notice are consistent with those objectives and principles.

Promoting Robust Risk Management. NSCC believes that the changes proposed in this advance notice are consistent with promoting robust risk management, particularly management of liquidity risk presented to NSCC. Renewing and maintaining the Credit Facility in the manner proposed would preserve the diversity of liquidity resources available to NSCC to help resolve a Member default. Additionally, allowing Evergreen Renewals without

an additional advance notice would provide NSCC, its Members, and market participants with greater certainty regarding a key source of committed liquidity to meet NSCC's settlement obligations, thus mitigating NSCC's liquidity risk. Further, because the Proposed Evergreen Provisions would ensure that any Future Renewal would be substantially similar to the Current Renewal, NSCC believes that any such renewals would promote robust risk management by preserving the diversity in liquidity resources available to NSCC to help resolve a Member default in the same manner as the Current Renewal. As such, NSCC believes the proposed changes would promote robust risk management practices at NSCC, consistent with Section 805(b) of the Clearing Supervision Act.

Promoting Safety and Soundness. NSCC believes that the changes proposed in this advance notice are consistent with promoting safety and soundness. As described above, the Current Renewal would enable NSCC to maintain an additional liquidity resource in the event of a Member default. That resource promotes safety and soundness for Members and market participants because it would provide NSCC with readily available liquidity to help NSCC continue to meet its respective obligations in a timely fashion in the event of a Member default, thereby helping to contain losses and liquidity pressures from that default. Because the Proposed Evergreen Provisions would ensure that any Future Renewals would be substantially similar to the Current Renewal, even without NSCC filing an advance notice, such renewals also would promote safety and soundness for the same reasons. As such, NSCC believes the proposed changes would promote safety and soundness, consistent with Section 805(b) of the Clearing Supervision Act.

Reducing Systemic Risks and Supporting the Stability of the Broader Financial System. NSCC also believes that the proposed changes in this advance notice are consistent with reducing systemic risks and supporting the stability of the broader financial system. As mentioned above, allowing NSCC to enter the Current Renewal would enable NSCC, which has been designated a systemically important financial market utility,²⁸ to continue to maintain an additional liquidity resource that NSCC may access to help

manage a Member default. In addition, because the Proposed Evergreen Provisions would ensure that any Future Renewals entered into without filing an advance notice would be on substantially similar terms as the Current Renewal, such renewals also would enable NSCC to continue to maintain an additional liquidity to help manage a Member default. Moreover, allowing Evergreen Renewals would reduce the risk of gaps in availability of this liquidity resource, providing increased certainty and stability for NSCC, its Members, and market participants regarding the availability of this liquidity risk management resource on an ongoing basis. Accordingly, NSCC believes that the proposed changes would help reduce systemic risk at NSCC, which in turn helps support the stability of the broader financial system, consistent with Section 805(b) of the Clearing Supervision Act.

NSCC also believes that the changes proposed in this advance notice are consistent with the requirements of Rule 17Ad-22(e)(7)(i) and (ii) under the

Exchange Act.29

Rule 17Ad-22(e)(7)(i) requires a covered clearing agency, of which NSCC is one,30 to "establish, implement, maintain and enforce written policies and procedures reasonably designed to . . . [e]ffectively measure, monitor, and manage liquidity risk that arises in or is borne by the covered clearing agency, including measuring, monitoring, and managing its settlement and funding flows on an ongoing and timely basis, and its use of intraday liquidity by, at a minimum . . . [m]aintaining sufficient liquid resources at the minimum in all relevant currencies to effect same-day . . . settlement of payment obligations with a high degree of confidence under a wide range of foreseeable stress scenarios that includes, but is not limited to, the default of the participant family that would generate the largest aggregate payment of obligation for the covered clearing agency in extreme but plausible conditions." 31

As described above, the Current Renewal would continue to provide NSCC with a readily available liquidity resource, enabling NSCC to continue to meet its respective obligations in a timely fashion in the event of a Member default, thereby helping to contain losses and liquidity pressures from that default. Additionally, because the Proposed Evergreen Provisions would

²⁵ NSCC's Clearing Fund (which operates as its default fund) addresses potential exposure through a number of risk-based component charges calculated and assessed daily and includes additional liquidity deposits by certain Members pursuant to NSCC's Supplemental Liquidity Deposits rule. Rule 4(A), Rules, *supra* note 3.

²⁶ See Liquidity Filings, supra note 12.

^{27 12} U.S.C. 5464(b).

²⁸ The Financial Stability Oversight Council designated NSCC a systemically important financial market utility on July 18, 2012. See Financial Stability Oversight Council 2012 Annual Report, Appendix A, http://www.treasury.gov/initiatives. fsoc/Documents/2012%20Annual%20Report.pdf.

²⁹ 17 CFR 240.17Ad-22(e)(7)(i) and (ii).

 $^{^{30}\,\}text{NSCC}$ is a "covered clearing agency" as defined by Rule 17Ad-22(a)(5) under the Exchange Act. 17 CFR 240.17Ad-22(a)(5).

^{31 17} CFR 240.17Ad-22(e)(7)(i)

ensure that any Future Renewals would be substantially similar to the Current Renewal, such renewals also would provide NSCC with a readily available liquidity resource that would enable it to continue to meet its respective obligations in a timely fashion in the event of a Member default, thereby helping to contain losses and liquidity pressures from that default. Moreover, allowing NSCC to enter into Evergreen Renewals without filing an additional advance notice would reduce the risk of gaps in liquidity coverage and better enable NSCC to continually maintain sufficient liquidity resources. Therefore, the NSCC believes that the proposed changes in this advance notice are consistent with Rule 17Ad-22(e)(7)(i).

Rule 17Ad-22(e)(7)(ii) under the Exchange Act requires NSCC to "establish, implement, maintain and enforce written policies and procedures reasonably designed to . . . [e]ffectively measure, monitor, and manage liquidity risk that arises in or is borne by the covered clearing agency, including measuring, monitoring, and managing its settlement and funding flows on an ongoing and timely basis, and its use of intraday liquidity by, at a minimum . . . [h]olding qualifying liquid resources sufficient to meet the minimum liquidity resource requirement under [Rule 17Ad-22(e)(7)(i) described abovel in each relevant currency for which the covered clearing agency has payment obligations owed to clearing members." 32 Rule 17Ad-22(a)(14) under the Exchange Act defines "qualifying liquid resources" to include, among other things, lines of credit without material adverse change provisions, that are readily available and convertible into cash.33

As described above, the Current Renewal would permit NSCC to enter into a committed line of credit that is designed to help ensure that NSCC has sufficient, readily-available qualifying liquid resources to meet the cash settlement obligations of its largest family of affiliated Members. Similarly, because the Proposed Evergreen Provisions would ensure that any Future Renewals would be substantially similar to the Current Renewal, such renewals also would permit NSCC to enter into a committed line of credit that is designed to help ensure that NSCC has sufficient, readily-available qualifying liquid resources to meet the cash settlement obligations of its largest family of affiliated Members. Accordingly, NSCC believes that the changes proposed in this advance notice

Accelerated Commission Action Requested

Because the Term Sheet was not finalized until approximately six weeks prior to the expected effective date of the Current Renewal (which is standard practice), NSCC respectfully requests, as it has done previously,34 that the Commission, pursuant to Section 806(e)(1)(I) of the Clearing Supervision Act,35 notify NSCC that it has no objection to the proposed changes in this advance notice no later than April 26, 2021, which is five business days prior to the May 4, 2021 effective date of the Current Renewal. NSCC requests Commission action five business days in advance of the effective date in order to ensure that there is no period of time that NSCC operates without this essential liquidity resource, given its importance to NSCC risk management and protecting NSCC settlement.

III. Date of Effectiveness of the Advance Notice, and Timing for Commission Action

The proposed change may be implemented if the Commission does not object to the proposed change within 60 days of the later of (i) the date that the proposed change was filed with the Commission or (ii) the date that any additional information requested by the Commission is received. The clearing agency shall not implement the proposed change if the Commission has any objection to the proposed change.

The Commission may extend the period for review by an additional 60 days if the proposed change raises novel or complex issues, subject to the Commission providing the clearing agency with prompt written notice of the extension. A proposed change may be implemented in less than 60 days from the date the advance notice is filed, or the date further information requested by the Commission is received, if the Commission notifies the clearing agency in writing that it does not object to the proposed change and authorizes the clearing agency to implement the proposed change on an earlier date, subject to any conditions imposed by the Commission.

The clearing agency shall post notice on its website of proposed changes that are implemented.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and

arguments concerning the foregoing, including whether the Advance Notice is consistent with the Clearing Supervision Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (http://www.sec.gov/rules/sro.shtml); or
- Send an email to *rule-comments@* sec.gov. Please include File Number SR–NSCC–2021–802 on the subject line.

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR-NSCC-2021-802. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (http://www.sec.gov/ rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the Advance Notice that are filed with the Commission, and all written communications relating to the Advance Notice between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of NSCC and on DTCC's website (http://dtcc.com/legal/sec-rulefilings.aspx). All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NSCC-2021-802 and should be submitted on or before May 26, 2021.

V. Commission Findings and Notice of No Objection

Although the Clearing Supervision Act does not specify a standard of review for an advance notice, its stated purpose is instructive: to mitigate systemic risk in the financial system

are consistent with Rule 17Ad–22(e)(7)(ii).

³⁴ See supra note 6.

^{35 12} U.S.C. 5465(e)(1)(I).

³² 17 CFR 240.17Ad-22(e)(7)(ii).

³³ 17 CFR 240.17Ad-22(a)(14).

and promote financial stability by, among other things, promoting uniform risk management standards for systemically important financial market utilities and strengthening the liquidity of systemically important financial market utilities.36 Section 805(a)(2) of the Clearing Supervision Act 37 authorizes the Commission to prescribe risk management standards for the payment, clearing, and settlement activities of designated clearing entities and financial institutions engaged in designated activities for which it is the supervisory agency or the appropriate financial regulator. Section 805(b) of the Clearing Supervision Act 38 states that the objectives and principles for the risk management standards prescribed under Section 805(a) shall be to:

- Promote robust risk management;
- promote safety and soundness;
- reduce systemic risks; and

support the stability of the broader

financial system.39 The Commission has adopted risk management standards under Section 805(a)(2) of the Act 40 and Section 17A of the Act ("Rule 17Ad–22").41 The Rule 17Ad-22 requires registered clearing agencies to establish, implement, maintain, and enforce written policies and procedures that are reasonably designed to meet certain minimum requirements for their operations and risk management practices on an ongoing basis.42 Therefore, it is appropriate for the Commission to review changes proposed in advance notices against Rule 17Ad-22 and the objectives and principles of these risk management standards as described in Section 805(b) of the Clearing Supervision Act. 43 The Commission believes the proposal in the Advance Notice is consistent with the objectives and principles described in Section 805(b) of the Act,44 and in Rule17Ad-22, in particular, Rule 17Ad-22(e)(7)

A. Consistency With Section 805(b) of the Clearing Supervision Act

As discussed below, the Commission believes that the changes proposed in the Advance Notice are consistent with Section 805(b) of the Act because they (i) promote robust risk management; (ii) are consistent with promoting safety

under the Act.45

and soundness; and (iii) are consistent with reducing systemic risks and promoting the stability of the broader financial system.

The Commission believes that the changes proposed in the Advance Notice are consistent with promoting robust risk management, in particular management of liquidity risk presented by NSCC. Renewing the Credit Facility would allow NSCC to continue to maintain it as a liquidity resource that it may use to resolve a member default. NSCC proposes to renew the Credit Facility at a \$10.1 billion aggregate commitment, which is an amount less than the \$12.1 billion aggregate commitment amount authorized in 2017, and outside the range that the Commission approved in the 2017 Notice of No Objection. However, NSCC has diversified and expanded its liquidity resources since 2017. Specifically, NSCC has expanded the amount that is available through its commercial paper program to \$10 billion, and it has obtained authorization to issue certain term debt.46 Therefore, the proceeds of these issuances are available to NSCC as an additional, and increased, amount of default liquidity resources that were not available in 2017.47 In addition, NSCC continues to have access to its Clearing Fund, including any supplemental liquidity deposits thereto, as an additional liquidity resource.48 Therefore, the Commission believes that the current renewal of the Credit Facility would be consistent with robust risk management by allowing NSCC to continue to manage the liquidity risk presented to it.49

Moreover, allowing NSCC annually to renew the Credit Facility under certain specified circumstances without an additional advance notice, subject to the proposed Evergreen Provisions, would provide NSCC and market participants with greater certainty regarding a continuing source of committed liquidity to meet its settlement obligations and thus mitigate NSCC' liquidity risk. Further, because the proposed Evergreen Provisions would continue to ensure that any such annual renewals would be substantially similar to the currently proposed Credit Facility, the Commission believes that any such renewals would promote robust risk management by continuing to available liquidity resources that NSCC may use to resolve a member default in the same manner as the currently proposed Credit Facility. As such, the Commission believes that the proposal would promote robust risk management practices at NSCC, consistent with Section 805(b) of the Act.50

The Commission also believes that the changes proposed in the Advance Notice are consistent with promoting safety and soundness. As described above, the currently proposed Credit Facility would continue to provide NSCC with a key liquidity resource in the event of a member default. This liquidity would promote safety and soundness for members because it would provide NSCC with a readily available liquidity resource that would enable it to continue to meet its respective obligations in a timely fashion in the event of a member default, thereby helping to contain losses and liquidity pressures from that default. Because the Proposed Evergreen Provisions would ensure that any annual renewals implemented without filing an advance notice would be substantially similar to the currently proposed Credit Facility, any such annual renewals would promote safety and soundness for the same reasons. As such, the Commission believes it is consistent with promoting safety and soundness as contemplated in Section 805(b) of the Act.51

In addition, the Commission believes that the changes proposed in the Advance Notice are consistent with reducing systemic risks and promoting the stability of the broader financial system. As mentioned above, allowing NSCC to enter into the currently

^{36 12} U.S.C. 5461(b).

^{37 12} U.S.C. 5464(a)(2).

^{38 12} U.S.C. 5464(b).

³⁹ *Id*

^{40 12} U.S.C. 5464(a)(2). 41 See 17 CFR 240.17Ad-22.

⁴² Id

^{43 12} U.S.C. 5464(b).

⁴⁴ Id

^{45 17} CFR 240.17Ad-22(e)(7).

⁴⁶ See Liquidity Filings, supra note 12.

⁴⁷ As a result of these additional and increased liquidity resources, the Credit Facility has generally represented a smaller portion of NSCC's total liquid resources since 2017, while still continuing to help ensure that NSCC meets its regulatory liquidity risk management obligations, as discussed in Section III.B.2 below.

⁴⁸ NSCC has the ability to collect supplemental liquidity deposits from certain of its members whose activity presents particular liquidity needs for NSCC. See generally Rule 4(A) of NSCC's Rules, supra note 3 (as approved by the Commission in 2013, https://www.sec.gov/rules/sro/nscc/2013/34-70999.pdf). These deposits serve as another liquidity resource that NSCC may use in the event of a member default. Currently, NSCC's rules allow for the collection of such deposits only in connection with monthly options expiry periods.

⁴⁹NSCC seeks the authority to renew the Credit Facility at an aggregate commitment amount of no more than \$10.1 billion, meaning that NSCC potentially could renew the Credit Facility at some amount less than \$10.1 billion consistent with the proposed authority, in light of market conditions at the time of the renewal and NSCC's assessment of its liquidity needs. Regardless of the amount of the Credit Facility into which NSCC ultimately enters, NSCC remains subject to the same regulatory requirements with respect to its liquidity risk, as

discussed in Section V.B. below, and would have to meet those requirements using some other combination of available resources.

^{50 12} U.S.C. 5464(b).

⁵¹ *Id*.

proposed Credit Facility would enable NSCC, which has been designated a systemically important financial market utility,52 to continue to maintain an additional liquidity resource that NSCC may access to help manage a member default. In addition, because the proposed Evergreen Provisions would ensure that any annual renewals entered into without filing an advance notice would be on substantially similar terms to the currently proposed Credit Facility, such future renewals also would enable NSCC to maintain an additional liquidity resource that NSCC may access to help manage a member default. Moreover, allowing the annual renewal of the Credit Facility under the proposed Evergreen Provisions without filing an additional advance notice would reduce the risk of disruption in availability of this liquidity resource. Further, allowing renewal without an advance notice in these specific circumstances would also provide heightened certainty and stability for NSCC and market participants regarding the availability of this liquidity resource on an ongoing basis. Accordingly, the Commission believes that the proposal would help reduce the systemic risk of NSCC, which in turn would help support the stability of the broader financial system, consistent with Section 805(b) of the Act.53

B. Consistency With Rule 17Ad– 22(e)(7)(i) and (ii)

The Commission believes the changes proposed in the Advance Notice are consistent with Rules 17Ad–22(e)(7)(i) and (ii), each promulgated under the Exchange Act, ⁵⁴ for the reasons described below.

Rule 17Ad-22(e)(7)(i) under the Exchange Act requires that a covered clearing agency establish, implement, maintain and enforce written policies and procedures reasonably designed to maintain sufficient liquid resources at the minimum in all relevant currencies to effect same-day and, where appropriate, intraday and multiday settlement of payment obligations with a high degree of confidence under a wide range of foreseeable stress scenarios that includes, but is not limited to, the default of the participant family that would generate the largest aggregate payment obligation for the covered clearing agency in extreme but plausible market conditions.55 Rule 17Ad–22(e)(7)(ii) under the Act requires that a cover clearing agency establish,

implement, maintain and enforce written policies and procedures reasonably designed to hold qualifying liquid resources sufficient to meet the minimum liquidity resource requirement under Rule 17Ad—22(e)(7)(i) in each relevant currency for which the covered clearing agency has payment obligations owed to its clearing members.⁵⁶

As described above, the currently proposed Credit Facility renewal would provide NSCC with a readily available liquidity resource that would enable NSCC to continue to meet its obligations in a timely fashion in the event of a member default, thereby helping to contain losses and liquidity pressures from that default. Additionally, because the proposed Evergreen Provisions would ensure that any annual renewals would be substantially similar to the currently proposed Credit Facility, such future renewals would also continue to provide NSCC with a readily available liquidity resource that would enable it to continue to meet its respective obligations in a timely fashion in the event of a member default, thereby helping to contain losses and liquidity pressures from that default. Moreover, allowing NSCC annually to renew the Credit Facility pursuant to the proposed Evergreen Provisions without filing an additional advance notice would reduce the risk of gaps in liquidity coverage and better allow NSCC to continually maintain sufficient liquidity resources.

In addition, the currently proposed renewal of the Credit Facility would permit NSCC to maintain a single Credit Facility designed to help ensure that NSCC has sufficient, readily-available qualifying liquid resources to meet the cash settlement obligations of its largest family of affiliated members. Similarly, because the proposed Evergreen Provisions would ensure that any annual renewals would be substantially similar to the currently proposed renewal of the Credit Facility, such renewals also would permit NSCC to maintain a single Credit Facility designed to help ensure that NSCC has sufficient, readily-available qualifying liquid resources to meet the cash settlement obligations of their largest family of affiliated members. Therefore, the Commission believes that NSCC's proposal would support its ability to hold qualifying liquid resources sufficient to meet the minimum liquidity resource requirement under

Rule 17Ad–22(e)(7)(i),⁵⁷ as required by Rule 17Ad–22(e)(7)(ii).⁵⁸

Accordingly, the Commission believes that the current renewal would be consistent with Rule 17Ad–22(e)(7)(i) and (ii) under the Exchange Act.⁵⁹

VI. Conclusion

It is therefore noticed, pursuant to Section 806(e)(1)(I) of the Clearing Supervision Act,⁶⁰ that the Commission does not object to Advance Notice SR–NSCC–2021–802 and that NSCC be and hereby is *authorized* to implement the change as of the date of this notice.

By the Commission.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–09428 Filed 5–4–21; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91702; File No. SR– EMERALD–2021–15]

Self-Regulatory Organizations; MIAX Emerald, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Interpretation and Policy .13 (Temporary Extension of the Limited Period for Registered Persons To Function as Principals) to Exchange Rule 1900, Registration Requirements, To Extend the Expiration Date of the Temporary Amendment Set Forth in SR–EMERALD–2020–21 From April 30, 2021 to June 30, 2021

April 29, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act" or "Exchange Act") 1 and Rule 19b–4 thereunder, 2 notice is hereby given that on April 21, 2021, MIAX Emerald, LLC ("MIAX Emerald" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been substantially prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

⁵² See supra note 28.

^{53 12} U.S.C. 5464(b).

^{54 17} CFR 240.17Ad-22(e)(7)(i) and (ii).

^{55 17} CFR 240.17Ad-22(e)(7)(i).

⁵⁶ 17 CFR 240.17Ad–22(e)(7)(ii). For purposes of Rule 17Ad–22(e)(7)(ii), "qualifying liquid resources" are defined in Rule 17Ad–22(a)(14) as including, in part, cash held either at the central bank of issue or at creditworthy commercial banks. 17 CFR 240.17Ad–22(a)(14).

 $^{^{57}\,17}$ CFR 240.17Ad–22(e)(7)(i).

 $^{^{58}\,17}$ CFR 240.17Ad–22(e)(7)(ii).

⁵⁹ 17 CFR 240.17Ad-22(e)(7).

⁶⁰ 12 U.S.C. 5465(e)(1)(I).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Interpretation and Policy .13 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) to Exchange Rule 1900, Registration Requirements, to extend the expiration date of the temporary amendment set forth in SR–EMERALD–2020–21 from April 30, 2021 to June 30, 2021. The Exchange does not anticipate providing any further extensions to the temporary amendment identified in this proposed rule change beyond June 30, 2021.

The text of the proposed rule change is available on the Exchange's website at http://www.miaxoptions.com/rule-filings/emerald, at MIAX Emerald's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Interpretation and Policy .13 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) to Exchange Rule 1900, Registration Requirements, to extend the expiration date of the temporary amendment set forth in SR-EMERALD-2020-21 from April 30, 2021 to June 30, 2021. The proposed rule change would extend the 120-day period that certain individuals can function as principals without having successfully passed an appropriate qualification examination through June 30, 2021,3 and would apply only to

those individuals who were designated to function as principals prior to March 3, 2021. This proposed rule change is based on a filing recently submitted by the Financial Industry Regulatory Authority, Inc. ("FINRA") ⁴ and is intended to harmonize the Exchange's registration rules with those of FINRA so as to promote uniform standards across the securities industry.

In response to the COVID–19 global pandemic, last year FINRA began providing temporary relief by way of frequently asked questions ("FAQs") ⁵ to address disruptions to the administration of FINRA qualification examinations caused by the pandemic that have significantly limited the ability of individuals to sit for examinations due to Prometric test center capacity issues.⁶

FINRA published the first FAQ on March 20, 2020, providing that individuals who were designated to function as principals under FINRA Rule 1210.04 ⁷ prior to February 2, 2020, would be given until May 31, 2020, to pass the appropriate principal qualification examination.8 On May 19, 2020, FINRA extended the relief to pass the appropriate examination until June 30, 2020. On June 29, 2020, FINRA again extended the temporary relief providing that individuals who were designated to function as principals under FINRA Rule 1210.04 prior to May 4, 2020, would be given until August 31, 2020, to pass the appropriate principal qualification examination. On August

Rule 1220. The Exchange does not have a registration category for Operations Professionals and therefore, the Exchange is not proposing to adopt that aspect of the FINRA Filing. If the Exchange seeks to provide additional temporary relief from the rule requirement identified in this proposal beyond June 30, 2021, it will submit a separate rule filing to further extend the temporary extension of time.

28, 2020, FINRA filed with the Commission a proposed rule change for immediate effectiveness to extend the temporary relief provided via the two FAQs by adopting: (1) Temporary Supplementary Material .12 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) under FINRA Rule 1210 (Registration Requirements), and (2) temporary Supplementary Material .07 (Temporary Extension of the Limited Period for Persons to Function as Operations Professionals) under FINRA Rule 1220 (Registration Categories).9 Pursuant to this rule filing, individuals who were designated prior to September 3, 2020, to function as a principal under FINRA Rule 1210.04 would have until December 31, 2020, to pass the appropriate qualification examination.

Thereafter, on December 9, 2020, FINRA filed with the Commission a proposed rule change for immediate effectiveness to extend the limited period for registered persons to function as a principal through April 30, 2021.10 Pursuant to this rule filing, individuals who were designated prior to January 1, 2021 to function as a principal would have until April 30, 2021 to pass the appropriate qualifying examination. On December 28, 2020, the Exchange filed with the Commission a proposed rule change for immediate effectiveness to extend the limited period for registered persons to function as a principal through April 30, 2021.11

The Exchange continues to closely monitor the impact of the COVID–19 pandemic on Members, ¹² investors, and other stakeholders. The Exchange initially provided temporary relief to address the interruptions in the administration of FINRA qualification examinations at Prometric test centers and the limited ability of individuals to sit for the examinations caused by the COVID–19 pandemic. ¹³ As mentioned in the FINRA Filing (SR–FINRA–2021–005), FINRA noted that the pandemic could result in firms potentially

³ See Exchange Act Release No. 91506 (April 8, 2021) 86 FR 19671 (April 14, 2021) (SR–FINRA–2021–005) (the "FINRA Filing"). The Exchange notes that the FINRA Filing also provides temporarily relief to individuals registered with FINRA as Operations Professionals under FINRA

⁴ See id.

 $^{^5}$ See https://www.finra.org/rules-guidance/keytopics/covid-19/faq#qe.

⁶At the outset of the COVID–19 pandemic, all FINRA qualification examinations were administered at test centers operated by Prometric. Based on the health and welfare concerns resulting from COVID–19, in March 2020 Prometric closed all of its test centers in the United States and Canada and began to slowly reopen some of them at limited capacity in May. Currently, Prometric has resumed testing in many of its United States and Canada test centers, at either full or limited occupancy, based on local and government mandates.

⁷ Exchange Rule 1900, Interpretation and Policy .04, is the corresponding rule to FINRA Rule 1210.04

⁸ FINRA Rule 1210.04 (Requirements for Registered Persons Functioning as Principals for a Limited Period) allows a FINRA-member firm to designate certain individuals to function in a principal capacity for 120 calendar days before having to pass an appropriate principal qualification examination. Exchange Rule 1900, Interpretation and Policy .04, provides the same allowance to Exchange Members.

⁹ See Exchange Act Release No. 89732 (September 1, 2020), 85 FR 55535 (September 8, 2020) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2020–026).

¹⁰ See Exchange Act Release No. 90617 (December 9, 2020), 85 FR 81258 (December 15, 2020) (SR-FINRA-2020-043).

¹¹ See Exchange Act Release No. 90829 (December 28, 2020), 86 FR 636 (December 30, 2020) (SR–EMERALD–2020–21).

¹² The term "Member" means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed "members" under the Exchange Act. See Exchange Rule 100.

¹³ Information about the continued impact of COVID–19 on FINRA-administered examinations is available at https://www.finra.org/rules-guidance/key-topics/covid-19/exams.

experiencing significant disruptions to their normal business operations that may be exacerbated by being unable to keep principal positions filled. Specifically, FINRA noted that the limitation of in-person activities and staff absenteeism as a result of the health and welfare concerns stemming from COVID–19 could result in firms having difficulty finding other qualified individuals to transition into those roles or requiring them to reallocate employee time and resources away from other critical responsibilities at the firm's organization.

While there are signs of improvement, the COVID-19 conditions necessitating the temporary relief persist and the Exchange has determined that there is a continued need for this temporary relief beyond April 30, 2021. Although Prometric has resumed testing in many of its U.S. test centers, Prometric's safety practices mean that currently not all test centers are open, some of the open test centers are at limited capacity, and some open test centers are delivering only certain examinations that have been deemed essential by the local government.14 In addition, while certain states have started to ease COVID-19 restrictions on businesses and social activities, public health officials continue to emphasize the importance for individuals to keep taking numerous steps to protect themselves and help slow the spread of the disease. 15

Although the COVID–19 conditions necessitating the temporary relief persist, the Exchange believes that an extension of the relief is necessary only until June 30, 2021, because FINRA recently expanded the availability of online examinations. Prior to this expansion, the ongoing effects of the pandemic made it impracticable for Members to ensure that the individuals who they had designated to function in a principal capacity, as set forth in Exchange Rule 1900, Interpretation and Policy .04, could successfully sit for and pass an appropriate qualification examination within the 120-calendar day period required under the rules.16 Specifically, if the individual wanted to take a qualifying examination, they were required to accept the health risks associated with taking an in-person examination because those

examinations were not available online. On February 24, 2021, however, FINRA adopted an interim accommodation request process to allow candidates to take additional FINRA examinations online, including the General Securities Principal ("Series 24") and Operations Professional ("Series 99") examinations. 17 Because the Series 24 qualifying examination has been made available online only recently, the Exchange is concerned that individuals who have been designated to function in a principal capacity may not have sufficient time to schedule, study for, and take the applicable examination before April 30, 2021, the date the temporary amendment is set to expire. Therefore, the Exchange proposes to extend the expiration date of the temporary amendment set forth in Exchange Rule 1900, Interpretation and Policy .13, from April 30, 2021 until June 30, 2021. The proposed rule change would apply only to those individuals who have been designated to function as a principal prior to March 3, 2021. As noted above, the Exchange does not anticipate providing any further extensions to the temporary amendment and any individuals designated to function as a principal on or after March 3, 2021, will need to successfully pass an appropriate qualification examination within 120 days.

The Exchange believes that this proposed continued extension of time is tailored to address the needs and constraints on a Member's operations during the COVID-19 pandemic, without significantly compromising critical investor protection. The proposed extension of time will help to minimize the impact of COVID-19 on Members by providing continued flexibility so that Members can ensure that principal positions remain filled. The potential risks from the proposed extension of the 120-day period are mitigated by a Member's continued requirement to supervise the activities of these designated individuals and ensure compliance with federal securities laws and regulations, as well as Exchange and FINRA rules.

The Exchange has filed the proposed rule change for immediate effectiveness and has requested that the Commission waive the requirement that the proposed rule change not become operative for 30 days after the date of the filing, so the Exchange can implement the proposed rule change immediately.

The Exchange believes that its proposed rule change is consistent with Section 6(b) of the Act 18 in general, and furthers the objectives of Section 6(b)(5) of the Act 19 in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

The proposed rule change is intended to minimize the impact of COVID-19 on Member operations by further extending the 120-day period certain individuals may function as a principal without having successfully passed an appropriate qualification examination under Exchange Rule 1900, Interpretation and Policy .04, until June 30, 2021. The proposed rule change does not relieve Members from maintaining, under the circumstances, a reasonably designed system to supervise the activities of their associated persons to achieve compliance with applicable securities laws and regulations, and with applicable Exchange and FINRA rules that directly serve investor protection. In a time when faced with unique challenges resulting from the COVID-19 pandemic, the Exchange believes that the proposed rule change is a sensible accommodation that will continue to afford Members the ability to ensure that critical positions are filled and client services maintained, while continuing to serve and promote the protection of investors and the public interest in this unique environment.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is intended to provide temporary relief given the impacts of the COVID-19 pandemic crisis and to also maintain consistency with the rules of other self-regulatory organizations ("SROs") with respect to the registration requirements applicable to Members and their registered personnel. In that regard, the Exchange believes that any burden on competition would be clearly outweighed by providing Members with temporary

¹⁴ Information from Prometric about its safety practices and the impact of COVID-19 on its operations is available at https:// www.prometric.com/corona-virusupdate. See also supra note 13.

¹⁵ See, e.g., Centers for Disease Control and Prevention, How to Protect Yourself & Others, https://www.cdc.gov/coronavirus/2019-ncov/ prevent-gettingsick/prevention.html.

¹⁶ See supra note 13.

^{2.} Statutory Basis

¹⁸ 15 U.S.C. 78f(b).

¹⁹ 15 U.S.C. 78f(b)(5).

relief in this unique environment while also ensuring clear and consistent requirements applicable across SROs and mitigating any risk of SROs implementing different standards in these important areas. In its filings, FINRA provides an abbreviated economic impact assessment maintaining that the changes are necessary to temporarily rebalance the attendant benefits and costs of the obligations under FINRA Rule 1210 in response to the impacts of the COVID-19 pandemic that is equally applicable to the changes the Exchange proposes.20 The Exchange accordingly incorporates FINRA's abbreviated economic impact assessment by reference.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act ²¹ and Rule 19b–4(f)(6) thereunder.²²

A proposed rule change filed under Rule 19b-4(f)(6) normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b-4(f)(6)(iii), the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative immediately upon filing. As noted above, the Exchange stated that the conditions necessitating the temporary relief continue to exist and the proposed extension of time will help minimize the impact of the COVID-19

outbreak on Members' operations by allowing them to keep principal positions filled and minimizing disruptions to client services and other critical responsibilities. Despite signs of improvement, the Exchange further stated that the ongoing extenuating circumstances of the COVID–19 pandemic make it impractical to ensure that individuals designated to act in a principal capacity are able to take and pass the appropriate qualification examination during the 120-calendar day period required under the rules.

The Exchange observed that, following a nationwide closure of all test centers earlier in the year, some test centers have re-opened, but are operating at limited capacity or are only delivering certain examinations that have been deemed essential by the local government.²³ However, on February 24, 2021, FINRA began providing the General Securities Principal (Series 24) Examination online through an interim accommodation request process.²⁴ Prior to this change, if individuals wanted to take these qualifying examinations, they were required to accept the health risks associated with taking an in-person examination. Even with the expansion of online qualifications examinations, the Exchange stated that extending the expiration date of the relief set forth in SR-EMERALD-2020-21 until June 30, 2021 is still needed. The Exchange stated that this temporary relief will provide flexibility to allow individuals who have been designated to function as a principal sufficient time to schedule, study for and take the applicable examination before the temporary relief expires. Notably, the Exchange stated that it does not anticipate providing any further extensions to the temporary amendment and that any individuals designated to function as a principal on or after March 3, 2021 will need to successfully pass an appropriate qualification examination within 120

For these reasons, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest.²⁵ Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.²⁶

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (http://www.sec.gov/rules/sro.shtml); or
- Send an email to *rule-comments@* sec.gov. Please include File Number SR-EMERALD-2021-15 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–EMERALD–2021–15. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (http://www.sec.gov/ rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official

 ²⁰ See supra notes 3 and 10; see also Exchange
 Act Release No. 89732 (September 1, 2020), 85 FR
 55535 (September 8, 2020) (SR-FINRA-2020-26).
 ²¹ 15 U.S.C. 78s(b)(3)(A).

^{22 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.

 $^{^{23}}$ See supra notes 13 and 14. The Exchange notes that Prometric has also had to close some reopened test centers due to incidents of COVID–19 cases.

²⁴ See supra note 13 (including the February 24, 2021 announcement of the interim accommodation process for candidates to take certain examinations, including the General Securities Principal (Series 24) Examination, online.)

²⁵ As noted above by the Exchange, this proposal is an extension of temporary relief provided in SR–EMERALD–2020–21 where the Exchange also requested and the Commission granted a waiver of the 30-day operative delay. See SR–EMERALD–2020–21, 86 FR at 639.

²⁶ For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. *See* 15 U.S.C.

business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-EMERALD-2021-15 and should be submitted on or before May 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. 27

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–09432 Filed 5–4–21; 8:45 am] BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-91725; File No. SR-CboeEDGA-2021-009]

Self-Regulatory Organizations; Cboe EDGA Exchange, Inc.; Notice of Filing of a Proposed Rule Change To Amend the Sixth Amended and Restated Bylaws of Cboe EDGA Exchange, Inc.'s Parent Corporation, Cboe Global Markets, Inc. To Implement Proxy Access

April 29, 2021.

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 April 16, 2021, Cboe EDGA Exchange, Inc. ("Exchange" or "EDGA") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGA Exchange, Inc. (the "Exchange" or "EDGA") is filing with the Securities and Exchange Commission (the "Commission") a proposed rule change with respect to amendments to the Sixth Amended and Restated Bylaws (the "CGM Bylaws") of

its parent corporation, Cboe Global Markets, Inc. ("Cboe" or "Corporation"). The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (http://markets.cboe.com/us/equities/regulation/rule_filings/edga/), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Choe has received a stockholder proposal submitted pursuant to Rule 14a–8 under the Act ³ which requested that the CGM Board take steps to implement a "proxy access" bylaw provision. In general, proxy access bylaws allow a stockholder, or group of stockholders, who comply with certain requirements, to nominate candidates for service on a board and have those candidates included in a company's proxy materials. Such provisions have become common among S&P 500 companies.4 Choe has determined to take the stockholder's requested steps to implement proxy access. Accordingly, the Exchange now proposes to make these changes by adopting new Section 2.16 of the CGM Bylaws and making certain conforming changes to current Sections 2.10 and 2.11 of the CGM Bylaws, all of which are described further below.

In developing its proposal, Cboe generally tried to balance the relative weight of arguments for and against proxy access provisions. On the one hand, Cboe recognizes the significance

of this issue to some investors, who see proxy access as an important accountability mechanism that allows them to participate in board elections through the nomination of stockholder candidates that are presented in a company's proxy statement. On the other hand, Cboe's proposed proxy access provision includes certain procedural requirements that are designed to help ensure, among other things, that Cboe and its stockholders will have full and accurate information about nominating stockholders and their nominees and that such stockholders and nominees will comply with applicable laws, regulations and other requirements. Additionally, the Exchange notes the proposed terms are common among companies that have adopted proxy access. The Exchange also notes that the parent companies of other exchanges have adopted substantively similar proxy access provisions and the Exchange does not believe such provisions are materially different than the Exchange's proposal.⁵

The proposed rule change would add new Section 2.16 to the CGM Bylaws. Section 2.16 would permit a stockholder, or group of up to 20 stockholders, to nominate director nominees for the Cboe Board, so long as the stockholder(s) have owned at least three percent of Cboe's outstanding shares of capital stock continuously for at least three years. The director nominees would be included in Cboe's annual meeting proxy materials. The proposed provision would limit the number of proposed director nominees to the greater of (i) two or (ii) 20% of the number of Cboe directors in office (rounded down to the nearest whole number, but no less than two) provided that the stockholder(s) and nominee(s) satisfy the other conditions specified in the CGM Bylaws as described further below.

Proposed Section 2.16(a)

The Exchange first proposes to amend the CGM Bylaws to, as set forth in the first sentence of proposed Section 2.16(a), require the Corporation to include in its proxy statement, its form proxy and any ballot distributed at the stockholder meeting, the name of, and

^{27 17} CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See 17 CFR 240.14a–8, which requires companies that are subject to the federal proxy rules to include shareholder proposals in companies' proxy statements to shareholders, subject to certain procedural and substantive requirements.

⁴More than 75% of S&P 500 companies have adopted proxy access bylaw provisions.

⁵ See Securities Exchange Release No. 79357 (November 18, 2016) 81 FR 85283 (November 25, 2016) (SR-NASDAQ-2016-127; SR-BX-2016-051; SR-ISE-2016-22; SR-ISEGemini-2016-10; SR-ISEMercury-2016-16; SR-PHLX-2016-93; SR-BSECC-2016-001; SR-SCCP-2016-01). See also Securities Exchange Release No. 77782 (May 6, 2016) 81 FR 29600 (May 12, 2016) (SR-NYSE-2016-14; SR-NYSEArca-2016-25; SR-NYSEMKT-2016-20).

certain Required Information 6 about, any person nominated for election (the "Stockholder Nominee") to the Board by a stockholder or group of stockholders (the "Eligible Stockholder") 7 that satisfies the requirements set forth in the proxy access provision of CGM Bylaws.8 Proposed Section 2.16(a) will also make clear that Cboe is able to solicit against any Stockholder Nominee or include in its proxy materials the Corporation's own statements or other information relating to any Eligible Stockholder or Stockholder Nominee, including any information provided to the Corporation pursuant to Section 2.16. This provision clarifies that just because Cboe must include a Stockholder Nominee in its proxy materials if the proxy access provisions are satisfied, Choe does not necessarily have to support that nominee.

Proposed Section 2.16(b)

Proposed Section 2.16(b) will provide that in order to utilize this provision, the Eligible Stockholder must expressly request at the time of providing a required notice to the Corporation of the proxy access nomination (the "Notice of Proxy Access Nomination") to have its nominee included in the Corporation's proxy materials. Proposed Section 2.16(b) also establishes the deadline for a timely Notice of Proxy Access Nomination. Specifically, such a notice must be delivered to the Cboe's Secretary at the principal executive offices of the Corporation not earlier than the open of business on the one hundred fiftieth (150th) day and not later than the close of business on the one hundred twentieth (120th) day prior to the first anniversary of the date that Choe first distributed its proxy statement to stockholders for the previous year's annual meeting of stockholders provided, however, that in the event the annual meeting is more than thirty (30) days before or after the anniversary date of the prior year's

annual meeting, or if no annual meeting was held in the preceding year, to be timely, the Notice of Proxy Access Nomination must be received at the principal executive offices of the Corporation no earlier than one hundred fifty (150) days before such annual meeting and no later than the later of one hundred twenty (120) days before such annual meeting or the tenth (10th) day following the day on which public announcement (as defined in Section 2.11) of the date of such meeting is first made by the Corporation. Further Section 2.16 will provide that in no event shall any adjournment or postponement of an annual meeting or the announcement thereof commence a new time period (or extend any time period) for the giving of a Notice of Proxy Access Nomination as described above. Choe believes this notice period will provide stockholders an adequate window to submit nominees via proxy access, while also providing the Corporation adequate time to diligence a proxy access nominee before including them in the proxy statement for the next annual meeting of stockholders.

Proposed Section 2.16(c)

Proposed Section 2.16(c) specifies that the maximum number ("the Permitted Number") of Stockholder Nominees nominated by all Eligible Stockholders that will be included in Choe's proxy materials with respect to an annual meeting of stockholders shall not exceed the greater of two or 20% of the total number of directors in office (rounded down to the nearest whole number) as of the last day on which a Notice of Proxy Access Nomination may be delivered pursuant to and in accordance with the proxy access provision of the Bylaws (the "Final Proxy Access Nomination Date"). In the event that one or more vacancies for any reason occurs after the Final Proxy Access Nomination Date but before the date of the annual meeting and the Board resolves to reduce the size of the Board in connection therewith, the Permitted Number of Stockholder Nominees included in Cboe's proxy materials shall be calculated based on the number of directors in office as so reduced. In addition, the Permitted Number shall be reduced by (i) the number of individuals who will be included in the Corporation's proxy materials as director nominees recommended by the Board pursuant to an agreement, arrangement or other understanding with a stockholder or group of stockholders (other than any such agreement, arrangement or understanding entered into in

connection with an acquisition of stock from the Corporation by such stockholder or group of stockholders) and/or (ii) the number of directors in office as of the Final Proxy Access Nomination Date who were included in the Corporation's proxy materials as Stockholder Nominees for any of the two preceding annual meetings of stockholders (including any persons counted as Stockholder Nominees pursuant to the immediately succeeding sentence) and whose reelection at the upcoming annual meeting is being recommended by the Board. Any individual nominated by an Eligible Stockholder for inclusion in the proxy materials pursuant to the proxy access provision of the CGM Bylaws whom the Board decides to nominate as a nominee of the Board, and any individual nominated by an Eligible Stockholder for inclusion in the proxy materials pursuant to the proxy access provision but whose nomination is subsequently withdrawn, shall be counted as one of the Stockholder Nominees for purposes of determining when the Permitted Number of Stockholder Nominees has been reached. Any Eligible Stockholder submitting more than one Stockholder Nominee for inclusion in the proxy materials shall rank such Stockholder Nominees based on the order that the Eligible Stockholder desires such Stockholder Nominees to be selected for inclusion in the proxy statement in the event that the total number of Stockholder Nominees submitted by Eligible Stockholders pursuant to the proxy access provision exceeds the Permitted Number of nominees allowed. In the event that the number of Stockholder Nominees submitted by Eligible Stockholders pursuant to Section 2.16 exceeds the Permitted Number of nominees allowed, the highest ranking Stockholder Nominee who meets the requirements of the proxy access provision of the Bylaws from each Eligible Stockholder will be selected for inclusion in the proxy materials until the Permitted Number is reached, going in order of the amount (largest to smallest) of shares of Cboe's outstanding capital stock each Eligible Stockholder disclosed as owned in its respective Notice of Proxy Access Nomination submitted to Cboe. If the Permitted Number is not reached after the highest ranking Stockholder Nominee who meets the requirements of the proxy access provision of the Bylaws from each Eligible Stockholder has been selected, then the next highest ranking Stockholder Nominee who meets the requirements of Section 2.16 from each Eligible Stockholder will be

⁶The Required Information is the information provided to Cboe's Corporate Secretary about the Stockholder Nominee and the Eligible Stockholder that is required to be disclosed in the Corporation's proxy statement by the regulations promulgated under the Act, and if the Eligible Stockholder so elects, a written statement, not to exceed 500 words, in support of the Stockholder Nominee(s)' candidacy (the "Supporting Statement", as defined further below).

⁷ As used throughout the CGM Bylaws, the term "Eligible Stockholder" includes each member of a stockholder group that submits a proxy access nomination to the extent the context requires.

⁸ When the Corporation includes proxy access nominees in the proxy materials, such individuals will be included in addition to any persons nominated for election by at or the direction of the Board to the Board or any committee thereof.

selected for inclusion in the Corporation's proxy materials, and this process will continue as many times as necessary, following the same order each time, until the Permitted Number is reached. Additionally, notwithstanding anything to the contrary contained in proposed Section 2.16, Cboe will not be required to include any Stockholder Nominees in its proxy materials pursuant to Section 2.16 for any meeting of stockholders for which the Secretary receives a notice (whether or not subsequently withdrawn) that the Eligible Stockholder or any other stockholder intends to nominate one or more persons for election to the Board pursuant to Section 2.11 of the CGM Bylaws. Choe believes it is reasonable to limit the Board seats available to proxy access nominees and to establish procedures for selecting candidates if the nominee limit is exceeded. The limitation on Board seats available to proxy access nominees ensures that proxy access cannot be used to take over the entire Board, which is not the stated purpose of proxy access campaigns. The procedures for selecting candidates if the nominee limit is exceeded establish clear and rational guidelines for an orderly nomination process to avoid the Corporation having to make arbitrary judgments among candidates.

Proposed Section 2.16(d)

Proposed Section 2.16(d) defines who may qualify as an "Eligible Stockholder". Particularly, an Eligible Stockholder is a stockholder or group of no more than 20 stockholders 9 that (i) has owned continuously for at least three years (the "Minimum Holding Period") a number of shares of capital stock of the Corporation that represents at least three percent of the outstanding shares of capital stock of the Corporation as of the date the Notice of Proxy Access Nomination is received (the "Required Shares"), (ii) continues to own the Required Shares through the date of the annual meeting and (iii) meets all other requirements of proposed Section 2.16. Choe believes it is reasonable to require each member of a nominating group to provide such information so that both the Corporation and its stockholders are fully informed about the entire group making the proxy

access nomination. As such, Section 2.16(d) further makes clear that whenever the Eligible Stockholder consists of a group of stockholders (including a group of funds that are part of the same Qualifying Fund Group), (i) each provision in Section 2.16 that requires the Eligible Stockholder to provide any written statements, representations, undertakings, agreements or other instruments or to meet any other conditions shall be deemed to require each stockholder (including each individual fund) that is a member of such group to provide such statements, representations, undertakings, agreements or other instruments and to meet such other conditions (except that the members of such group may aggregate the shares that each member has owned continuously for the Minimum Holding Period in order to meet the three percent ownership requirement of the "Required Shares" definition) and (ii) a breach of any obligation, agreement or representation under Section 2.16 by any member of such group shall be deemed a breach by the Eligible Stockholder. No stockholder may be a member of more than one group of stockholders constituting an Eligible Stockholder with respect to any annual meeting.

Proposed Section 2.16(e)

Proposed Section 2.16(e) clarifies, for the avoidance of doubt, how ''ownership'' will be defined for purposes of meeting the ownership requirements of the Required Shares. Specifically, an Eligible Stockholder shall be deemed to "own" only those outstanding shares of Cboe's capital stock as to which the stockholder possesses both: (i) The full voting and investment rights pertaining to the shares; and (ii) the full economic interest in (including the opportunity for profit from and risk of loss on) such shares; provided that the number of shares calculated in accordance with clauses (i) and (ii) shall not include any shares: That are (1) sold by such stockholder or any of its affiliates in any transaction that has not been settled or closed; (2) borrowed by such stockholder or any of its affiliates for any purposes or purchased by such stockholder or any of its affiliates pursuant to an agreement to resell; or (3) subject to any option, warrant, forward contract, swap, contract of sale, other derivative or similar instrument or agreement entered into by such stockholder or any of its affiliates, whether any such instrument or agreement is to be settled with shares or with cash based on the notional amount

or value of shares of Cboe's outstanding capital stock, in any such case which instrument or agreement has, or is intended to have, the purpose or effect of: (A) Reducing in any manner, to any extent or at any time in the future, such stockholder's or its affiliates' full right to vote or direct the voting of any such shares; and/or (B) hedging, offsetting or altering to any degree any gain or loss realized or realizable from maintaining the full economic ownership of such shares by such stockholder or its affiliates.

Further, a stockholder shall "own" shares held in the name of a nominee or other intermediary so long as the stockholder retains the right to instruct how the shares are voted with respect to the election of directors and possesses the full economic interest in the shares. A stockholder's ownership of shares shall be deemed to continue during any period in which (i) the stockholder has loaned such shares provided that the stockholder has the power to recall such loaned shares on five (5) business days' notice and includes in the Notice of Proxy Access Nomination an agreement that it will (1) recall such loaned shares upon being notified that any of its Stockholder Nominees will be included in the Corporation's proxy materials and (2) will hold such shares through the date of the annual meeting or (ii) the stockholder has delegated any voting power by means of a proxy, power of attorney or other instrument or arrangement which is revocable at any time by the stockholder. Section 2.16(e) also clarifies that the terms "owned," "owning" and other variations of the word "own" shall have correlative meanings. Whether outstanding shares of Cboe's capital stock are "owned" for these purposes shall be determined by the Board. For purposes of Section 2.16, the term "affiliate" or "affiliates" shall have the meaning ascribed thereto under the rules and regulations of the Act.¹⁰ An Eligible Stockholder shall include in its Notice of Proxy Access Nomination the number of shares it is deemed to own for the purposes of proposed Section 2.16. In proposing the Required Shares and the Minimum

⁹ For this purpose, any two or more funds that are part of the same Qualifying Fund Group may be counted as one stockholder. A "Qualifying Fund Group" means two or more funds that are (i) under common management and investment control, (ii) under common management and funded primarily by the same employer or (iii) a "group of investment companies" as such term is defined in Section 12(d)(1)(G)(ii) of the Investment Corporation Act of 1940, as amended.

¹⁰ Pursuant to Rule 12b–2 under the Act, "[a]n 'affiliate' of, or a person 'affiliated' with, a specified person, is a person that directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, the person specified." 17 CFR 240.12b–2. Further, "[t]he term 'control' (including the terms 'controlling,' 'controlled by' and 'under common control with') means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a person, whether through the ownership of voting securities, by contract, or otherwise." 17 CFR 240.12b–2.

Holding Period, Choe seeks to ensure that the Eligible Stockholder has had a sufficient stake in the Corporation for a sufficient amount of time and is not pursuing a short-term agenda.

Proposed Section 2.16(f)

Proposed Section 2.16(f) sets forth the information that an Eligible Stockholder must provide to Cboe's Corporate Secretary in writing within the deadline discussed above in order to make a proxy access nomination. This information includes:

- A statement by the Eligible Stockholder (1) setting forth and certifying as to the number of shares it owns and has owned continuously for the Minimum Holding Period and (2) agreeing to continue to own the Required Shares through the date of the annual meeting;
- one or more written statements from the record holder of the Required Shares (and from each intermediary through which the Required Shares are or have been held during the Minimum Holding Period) verifying that, as of a date within seven calendar days prior to the date the Notice of Proxy Access Nomination is delivered to Cboe's Secretary at the principal executive offices of the Corporation, the Eligible Stockholder owns, and has owned continuously for the Minimum Holding Period, the Required Shares, and the Eligible Stockholder's agreement to provide, within five (5) business days after the record date for the annual meeting, written statements from the record holder and intermediaries verifying the Eligible Stockholder's continuous ownership of the Required Shares through the record date:
- a copy of the Schedule 14N that has been filed with the SEC as required by Rule 14a–18 under the Act; ¹¹
- the information, representations and agreements and other documents that are required to be set forth in or included with a stockholder's notice of nomination given pursuant to Section 2.11 of the CGM Bylaws;
- the written consent of each Stockholder Nominee to being named in the proxy statement as a nominee and to serving as a director if elected;
- a representation that the Eligible Stockholder:
- Acquired the Required Shares in the ordinary course of business and not with the intent to change or influence

control of Choe, and does not presently have such intent;

- has not nominated and will not nominate for election any individual as a director at the annual meeting, other than its Stockholder Nominee(s);
- has not engaged and will not engage in, and has not and will not be a participant in another person's, "solicitation" within the meaning of Rule 14a–1(l) under the Act in support of the election of any individual as a director at the annual meeting, other than its Stockholder Nominee(s) or a nominee of the Board:
- has not distributed and will not distribute to any stockholder of the Corporation any form of proxy for the annual meeting other than the form distributed by the Corporation;
- has complied and will comply with all laws, rules and regulations applicable to solicitations and the use, if any, of soliciting material in connection with the annual meeting, and
- has provided and will provide facts, statements and other information in all communications with Cboe and its stockholders that are or will be true and correct in all material respects and do not and will not omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;
- an undertaking that the Eligible Stockholder agrees to
- assume all liability stemming from any legal or regulatory violation arising out of the Eligible Stockholder's communications with the stockholders of the Corporation or out of the information that the Eligible Stockholder provided to the Corporation;
- of indemnify and hold harmless the Corporation and each of its Directors, officers and employees individually against any liability, loss or damages in connection with any threatened or pending action, suit or proceeding, whether legal, administrative or investigative, against the Corporation or any of its Directors, officers or employees arising out of any nomination submitted by the Eligible Stockholder pursuant to this Section 2.16 or any solicitation or other activity in connection therewith; and
- of file with the Securities and Exchange Commission any solicitation or other communication with the stockholders of the Corporation relating to the meeting at which its Stockholder Nominee(s) will be nominated, regardless of whether any such filing is required under Regulation 14A of the Act or whether any exemption from

- filing is available for such solicitation or other communication under Regulation 14A of the Act;
- in the case of a nomination by a group of stockholders that together is an Eligible Stockholder, the designation by all group members of one group member that is authorized to receive communications, notices and inquiries from the Corporation and to act on behalf of all members of the group with respect to all matters relating to the nomination under this Section 2.16 (including withdrawal of the nomination);
- in the case of a nomination by an Eligible Stockholder consisting of a group of stockholders in which two or more funds are intended to be treated as one stockholder for purposes of qualifying as an Eligible Stockholder, documentation reasonably satisfactory to the Corporation that demonstrates that the funds are part of the same Qualifying Fund Group; and
- a written representation and agreement by the Stockholder Nominee that such person:
- Will act as a representative of all of the stockholders of the Corporation while serving as a director;
- will provide facts, statements and other information in all communications with the Corporation and its stockholders that are or will be true and correct in all material respects (and shall not omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading);
- is not and will not become a party to (i) any compensatory, payment or other financial agreement, arrangement or understanding with any person or entity other than the Corporation in connection with service or action as a director of the Corporation that has not been disclosed to the Corporation, (ii) any Voting Commitment that has not been disclosed to the Corporation or (iii) any Voting Commitment 12 that could reasonably be expected to limit or interfere with the Stockholder Nominee's ability to comply, if elected as a director of the Corporation, with its fiduciary duties under applicable law;
- will abide by and comply with the CGM Bylaws, the Certificate of Incorporation and applicable policies of the Corporation including all applicable publicly disclosed corporate governance, conflict of interest,

¹¹ See 17 CFR 240.14n–101 and 17 CFR 240.14a–18, which generally require a Nominating Stockholder to provide notice to the Corporation of its intent to submit a proxy access nomination on a Schedule 14N and file that notice, including the required disclosure, with the Commission on the date first transmitted to the Corporation.

 $^{^{12}\,\}mathrm{A}$ "Voting Commitment" is defined as any agreement, arrangement or understanding with any person or entity as to how the Stockholder Nominee would vote or act on any issue or question as a director.

confidentiality and stock ownership and trading policies and guidelines of the Corporation, as well as the applicable provisions of the rules and regulations of the Securities and Exchange Commission and any stock exchange applicable to the Corporation.

In proposing the informational requirements for the Eligible Stockholder, Cboe's goal is to gather sufficient information about the Eligible Stockholder for both itself and its stockholders. Among other things, this information is designed to help ensure that Cboe is able to comply with its disclosure and other requirements under applicable law and that Cboe, its Board and its stockholders are able to assess the proxy access nomination adequately.

Proposed Section 2.16(g)

Proposed Section 2.16(g) establishes additional information the Stockholder Nominee must provide. Particularly:

- The Stockholder Nominee(s) must submit all completed and signed questionnaires required of directors and officers of the Corporation;
- the Corporation may require any proposed Stockholder Nominee to furnish any information:
- O That may reasonably be requested by the Corporation to determine whether the Stockholder Nominee would be independent under Section 3.3 and otherwise qualifies as independent under the rules of the principal national securities exchange on which the outstanding capital stock of the Corporation is traded;
- that could be material to a reasonable stockholder's understanding of the independence, or lack thereof, of such Stockholder Nominee;
- that would be required to satisfy the requirements for qualification of directors under applicable foreign regulations; or
- (that may reasonably be requested by the Corporation to determine the eligibility of such Stockholder Nominee to be included in the Corporation's proxy materials pursuant to this Section 2.16 or to serve as a director of the Corporation; and
- the Corporation may require the Eligible Stockholder to furnish any other information that may reasonably be requested by the Corporation to verify the Eligible Stockholder's continuous Ownership of the Required Shares for the Minimum Holding Period and through the date of the annual meeting.

Like the informational requirements for an Eligible Stockholder, which are set forth above, the informational requirements for the Stockholder Nominee ensure that both Cboe and its stockholders will have sufficient information about the Stockholder Nominee. Among other things, this information will ensure that Cboe is able to comply with its disclosure and other requirements under applicable law and that Cboe, its Board and its stockholders are able to assess the proxy access nomination adequately.

Proposed Section 2.16(h)

Proposed Section 2.16(h) provides that an Eligible Stockholder may provide, at its option, to the Secretary, at the time the Notice of Proxy Access Nomination is provided, a written statement, not to exceed 500 words, in support of its Stockholder Nominee(s)' candidacy (a "Supporting Statement"). Only one Supporting Statement may be submitted by an Eligible Stockholder (including any group of stockholders together constituting an Eligible Stockholder) in support of its Stockholder Nominee(s). Notwithstanding anything to the contrary contained in Section 2.16, the Corporation may omit from its proxy materials any information or Supporting Statement (or portion thereof) that it, in good faith, believes is untrue in any material respect (or omits to state a material fact necessary in order to make the statements made, in light of the circumstances under which they are made, not misleading) or would violate any applicable law, rule or regulation. The Exchange notes proposed Section 2.16(h) allows Choe to comply with Rule 14a-9 under the Act 13 and to protect its stockholders from information that is materially untrue or that violates any law, rule or regulation.

Proposed Section 2.16(i)

Pursuant to proposed Section 2.16(i), each Eligible Stockholder or Stockholder Nominee must promptly notify Cboe's Corporate Secretary of any information or communications provided by the Eligible Stockholder or Stockholder Nominee, as the case may be, to Cboe or its stockholders that when provided was not, or thereafter ceases to be, true and correct in all material respects or omits a material fact necessary to make the statements made, in light of the circumstances under which they were made, not misleading and of the information that is required

to correct any such defect. An Eligible Stockholder shall also provide immediate notice to the Corporation if the Eligible Stockholder ceases to own any of the Required Shares prior to the date of the annual meeting. In addition, any person providing any information to the Corporation pursuant to Section 2.16(i) shall be required to update or supplement such information, if necessary, so that all such information shall be true and correct as of the (i) as of the record date for determining the stockholders entitled to receive notice of the meeting and (ii) as of the date that is ten (10) business days prior to the meeting (or any postponement, adjournment or recess thereof), and such update shall be received by the Secretary at the principal executive offices of the Corporation (A) not later than five (5) business days after the record date for determining the stockholders entitled to receive notice of such meeting (in the case of an update required to be made under clause (i)) and (B) not later than seven (7) business days prior to the date for the meeting, if practicable, or, if not practicable, on the first practicable date prior to the meeting or any adjournment, recess or postponement thereof (in the case of an update required to be made pursuant to clause (ii)).

This provision further makes clear that providing any such notification, update or supplement, shall not be deemed to cure any defect in any previously provided information or communications or limit the remedies available to the Corporation relating to such defect (including the right to omit a Stockholder Nominee from its proxy materials). This provision is intended to protect Cboe's stockholders by requiring an Eligible Stockholder or Stockholder Nominee to give Choe notice of information previously provided that is materially untrue. Choe may then decide what action to take with respect to such defect, which may include, as noted above, omitting the relevant Stockholder Nominee from its proxy materials.

Proposed Section 2.16(j)

Proposed Section 2.16(j) provides that Cboe shall not be required to include a Stockholder Nominee in its proxy materials for any meeting of stockholders under certain circumstances. In these situations, the proxy access nomination shall be disregarded and no vote on such Stockholder Nominee will occur, even if Cboe has received proxies in respect of the vote. These circumstances occur when the Stockholder Nominee:

¹³ See 17 CFR 240.14a-9, which generally prohibits proxy solicitations that contain any statement which, at the time and in the light of the circumstances under which it is made, is false or misleading with respect to any material fact, or which omits to state any material fact necessary in order to make the statements therein not false or misleading.

- Would not be an independent director under Section 3.3, under the rules of the principal national securities exchange on which the outstanding capital stock of the Corporation is traded, any applicable rules of the Securities and Exchange Commission and any publicly disclosed standards used by the Board in determining and disclosing independence of the Corporation's directors, in each case as determined by the Board in its sole discretion;
- would not meet the audit committee independence requirements under the rules of the principal national securities exchange on which the outstanding capital stock of the Corporation is traded;
- if elected, intended to resign as a director of the Corporation prior to the end of the full term for which he or she is standing for election;
- is or has been subject to any statutory disqualification under Section 3(a)(39) of the Act;
- is or has been subject to disqualification under 17 CFR 1.63;
- if elected, would cause the Corporation to be in violation of these Bylaws, the Certificate of Incorporation, the rules of the principal national securities exchange on which the outstanding capital stock of the Corporation is traded, or any applicable law, rule or regulation;
- is or has been, within the past three years, an officer or director of a competitor, as defined for purposes of Section 8 of the Clayton Antitrust Act of 1914;
- is a named subject of a pending criminal proceeding (excluding traffic violations and other minor offenses) or has been convicted in such a criminal proceeding within the past 10 years;
- is subject to any order of the type specified in Rule 506(d) of Regulation D promulgated under the Securities Act of 1933, as amended;
- has provided any information to the Corporation or its stockholders that was untrue in any material respect or that omitted to state a material fact necessary to make the statements made, in light of the circumstances in which they were made, not misleading; or
- breaches or fails, or the Eligible Stockholder breaches or fails, to comply with its obligations pursuant to the CGM Bylaws, including, but not limited to, Section 2.16 and any agreement, representation or undertaking required by Section 2.16.

Choe believes these provisions will protect the Corporation and its stockholders by allowing it to exclude certain categories of objectionable Stockholder Nominees from the proxy statement.

Proposed Section 2.16(k)

Proposed Section 2.16(k) provides that notwithstanding anything to the contrary contained in the CGM Bylaws, if (i) a Stockholder Nominee and/or the applicable Eligible Stockholder breaches any of its agreements or representations or fails to comply with any of its obligations under this Section 2.16 or (ii) a Stockholder Nominee otherwise becomes ineligible for inclusion in the Corporation's proxy materials pursuant to this Section 2.16, or dies, becomes disabled or otherwise becomes ineligible or unavailable for election at the annual meeting, in each case as determined by the Board or the chairman of the meeting, (1) the Corporation may omit or, to the extent feasible, remove the information concerning such Stockholder Nominee and the related Supporting Statement from its proxy materials and/or otherwise communicate to its stockholders that such Stockholder Nominee will not be eligible for election at the annual meeting, (2) the Corporation shall not be required to include in its proxy materials any successor or replacement nominee proposed by the applicable Eligible Stockholder or any other Eligible Stockholder and (3) the chairman of the meeting shall declare such nomination to be invalid and such nomination shall be disregarded, notwithstanding that proxies in respect of such vote may have been received by the Corporation. Choe believes this provision protects the Corporation and its stockholders by providing the Board or the chairman of the stockholder meeting limited authority to disqualify a proxy access nominee when that nominee or the sponsoring stockholder(s) have breached an obligation under the proxy access provision.

Proposed Section 2.16(l)

Proposed Section 2.16(1) states that the following Stockholder Nominees who are included in the Corporation's proxy materials for a particular annual meeting of stockholders will be ineligible to be a Stockholder Nominee for the next two annual meetings: (i) Stockholder Nominee who withdraws from or becomes ineligible or unavailable for election at the annual meeting; or (ii) Stockholder Nominee who does not receive at least 25% of the votes cast in favor of such Stockholder Nominee's election. For the avoidance of doubt, Section 2.16(l) also clarifies that this provision shall not prevent any stockholder from nominating any

person to the Board pursuant to Section 2.11 of the CGM Bylaws. Section 2.16(l) will save the Corporation and its stockholders the time and expense of analyzing and addressing subsequent proxy access nominations regarding individuals who were included in the proxy materials for a particular annual meeting but ultimately did not stand for election or receive a substantial amount of votes. After the next two annual meetings, these Stockholder Nominees would again be eligible for nomination through the proxy access provisions of the Bylaws.

Proposed Section 2.16(m)

Proposed Section 2.16(m) provides that notwithstanding the provisions of proposed Section 2.16, if the Eligible Stockholder providing notice (or a qualified representative of the Eligible Stockholder) does not appear in person (including virtually, in the case of a meeting held solely by means of remote communication) at the stockholder meeting to present the nomination of such Stockholder Nominee, such proposed nomination shall not be presented by the Corporation and shall not be transacted, notwithstanding that proxies in respect of such vote may have been received by the Corporation. For purposes of this Section 2.16, to be considered a qualified representative of the Eligible Stockholder providing notice, a person must be a duly authorized officer, manager or partner of such stockholder or must be authorized by a writing executed by such stockholder or an electronic transmission delivered by such stockholder to act for such stockholder as proxy at the meeting and such writing or electronic transmission, or a reliable reproduction of the writing or electronic transmission, must be provided to the Corporation at least twenty-four (24) hours prior to the meeting.

Proposed Section 2.16(n)

In case there are matters involving a proxy access nomination that are open to interpretation, proposed Section 2.16(n) states that the Board (or any other person or body authorized by the Board) shall have exclusive power and authority to interpret the proxy access provisions of the Bylaws and make all determinations deemed necessary or advisable in connection with proposed Section 2.16 as to any person, facts or circumstances. In addition, all actions, interpretations and determinations of the Board (or any person or body authorized by the Board) with respect to the proxy access provisions shall be final, conclusive and binding on the

Corporation, the stockholders and all other parties. While Cboe has attempted to implement a clear, detailed and thorough proxy access provision, there may be matters about future proxy access nominations that are open to interpretation. In these cases, Cboe believes it is reasonable and necessary to designate an arbiter to make final decisions on these points and that the Board is best-suited to act as that arbiter.

Proposed Section 2.16(o)

For the avoidance of doubt, proposed Section 2.16(o) states that the proxy access provisions outlined in proposed Section 2.16 shall be the exclusive means for stockholders to include nominees in the Corporation's proxy materials. Stockholders may, of course, continue to propose nominees through other means, but the Board will have final authority to determine whether to include those nominees in the Corporation's proxy materials.

Revisions to Other Sections of the Bylaws

Choe also proposes to make conforming changes to Sections 2.10 and 2.11 to provide clarifications and prevent confusion. First, the Exchange proposes to add a reference to Section 2.11 and proposed Section 2.16 to clarify the exact bylaw provisions relating to stockholder nominees. Next, the Exchange proposes to amend Section 2.11. Section 2.11 currently describes the business that may be properly brought before an annual meeting of stockholders and the methods by which nominations of persons for election to the Board may be made at an annual meeting of stockholders. Choe proposes to add proxy access nominations (i.e., reference to Section 2.16) to the list of methods. Current Section 2.11(a)(i) also states, among other things, that compliance with Section 2.11 shall be the exclusive means for a stockholder to propose business or director nominations before an annual meeting stockholders. The Exchange proposes to clarify that Sections 2.11 and 2.16 are the exclusive means for a stockholder to make a director nomination.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act. 14 Specifically, the Exchange believes the proposed rule change is consistent with the Section

6(b)(5) ¹⁵ requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

In light of a shareholder proposal received from a stockholder, Cboe is proposing changes to its Bylaws to implement proxy access. The Exchange believes that this filing furthers the objectives of Section 6(b)(5) of the Act because the proposed rule change would be consistent with and facilitate a governance and regulatory structure that 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 regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. Particularly, the Exchange believes that, by permitting an Eligible Stockholder of Cboe that meets the stated requirements to nominate directors and have its nominees included in Cboe's annual meeting proxy statement, the proposed rule change strengthens the corporate governance of the Exchange's ultimate parent company, which is beneficial to both investors and the public interest.

Additionally, the procedural requirements are designed to help protect investors by stating clearly and explicitly the procedures stockholders must follow in order to submit a proper proxy access nomination. The informational requirements are designed to enhance investor protection by helping to ensure among other things, that the Corporation and its stockholders have full and accurate information about nominating stockholders and their nominees and that such stockholders and nominees comply with applicable laws, regulations and other requirements. Moreover, as noted above, proxy access has become commonplace among companies and the Exchange believes its core provisions are common among companies that have adopted proxy

access, including the parent companies of other exchanges that have adopted similar proxy access provisions.¹⁶

Finally, the remaining changes to existing provisions of the CGM Bylaws are clarifying in nature, and they enhance investor protection and the public interest by preventing confusion with respect to the operation of the Bylaw provisions.

B. Self-Regulatory Organization's Statement on Burden on Competition

Because the proposed rule change relates to the governance of the Corporation and not to the operations of the Exchange, the Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not designed to address any competitive issue or have any impact on competition; rather, adoption of a proxy access bylaw by the Corporation is intended to enhance corporate governance and accountability to stockholders.

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

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission shall: (a) by order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule

¹⁶ See Securities Exchange Release No. 79357
(November 18, 2016) 81 FR 85283
(November 25, 2016) (SR-NASDAQ-2016-127; SR-BX-2016-051; SR-ISE-2016-22; SR-ISEGemini-2016-10; SR-ISEMercury-2016-16; SR-PHLX-2016-93; SR-BSECC-2016-001; SR-SCCP-2016-01). See also
Securities Exchange Release No. 77782
(May 6, 2016) 81 FR 29600
(May 12, 2016) (SR-NYSE-2016-14; SR-NYSEArca-2016-25; SR-NYSEMKT-2016-20)

change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (http://www.sec.gov/rules/sro.shtml); or
- Send an email to rule-comments@ sec.gov. Please include File Number SR-CboeEDGA-2021-009 on the subject line.

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090. All submissions should refer to File Number SR-CboeEDGA-2021-009. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (http://www.sec.gov/ rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-CboeEDGA-2021-009 and should be submitted on or before May 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. 17

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–09445 Filed 5–4–21; 8:45 am] BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91727; File No. SR– CboeBZX–2021–028]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing of a Proposed Rule Change To Amend the Sixth Amended and Restated Bylaws of Cboe BZX Exchange, Inc.'s Parent Corporation, Cboe Global Markets, Inc. To Implement Proxy Access

April 29, 2021.

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 April 16, 2021, Cboe BZX Exchange, Inc. ("Exchange" or "BZX") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BZX Exchange, Inc. (the "Exchange" or "BZX") is filing with the Securities and Exchange Commission (the "Commission") a proposed rule change with respect to amendments to the Sixth Amended and Restated Bylaws (the "CGM Bylaws") of its parent corporation, Cboe Global Markets, Inc. ("Cboe" or "Corporation"). The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (http://markets.cboe.com/us/equities/regulation/rule_filings/bzx/), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of

the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Choe has received a stockholder proposal submitted pursuant to Rule 14a-8 under the Act ³ which requested that the CGM Board take steps to implement a "proxy access" bylaw provision. In general, proxy access bylaws allow a stockholder, or group of stockholders, who comply with certain requirements, to nominate candidates for service on a board and have those candidates included in a company's proxy materials. Such provisions have become common among S&P 500 companies.4 Choe has determined to take the stockholder's requested steps to implement proxy access. Accordingly, the Exchange now proposes to make these changes by adopting new Section 2.16 of the CGM Bylaws and making certain conforming changes to current Sections 2.10 and 2.11 of the CGM Bylaws, all of which are described further below.

In developing its proposal, Cboe generally tried to balance the relative weight of arguments for and against proxy access provisions. On the one hand, Cboe recognizes the significance of this issue to some investors, who see proxy access as an important accountability mechanism that allows them to participate in board elections through the nomination of stockholder candidates that are presented in a company's proxy statement. On the other hand, Cboe's proposed proxy access provision includes certain procedural requirements that are designed to help ensure, among other things, that Cboe and its stockholders will have full and accurate information about nominating stockholders and their nominees and that such stockholders and nominees will comply with applicable laws, regulations and other requirements. Additionally, the Exchange notes the proposed terms are common among companies that have adopted proxy access. The Exchange also notes that the parent companies of other exchanges have adopted substantively similar proxy access provisions and the Exchange does not

^{17 17} CFR 200.30–3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See 17 CFR 240.14a-8, which requires companies that are subject to the federal proxy rules to include shareholder proposals in companies' proxy statements to shareholders, subject to certain procedural and substantive requirements.

 $^{^4}$ More than 75% of S&P 500 companies have adopted proxy access bylaw provisions.

believe such provisions are materially different than the Exchange's proposal.⁵

The proposed rule change would add new Section 2.16 to the CGM Bylaws. Section 2.16 would permit a stockholder, or group of up to 20 stockholders, to nominate director nominees for the Cboe Board, so long as the stockholder(s) have owned at least three percent of Cboe's outstanding shares of capital stock continuously for at least three years. The director nominees would be included in Cboe's annual meeting proxy materials. The proposed provision would limit the number of proposed director nominees to the greater of (i) two or (ii) 20% of the number of Cboe directors in office (rounded down to the nearest whole number, but no less than two) provided that the stockholder(s) and nominee(s) satisfy the other conditions specified in the CGM Bylaws as described further below.

Proposed Section 2.16(a)

The Exchange first proposes to amend the CGM Bylaws to, as set forth in the first sentence of proposed Section 2.16(a), require the Corporation to include in its proxy statement, its form proxy and any ballot distributed at the stockholder meeting, the name of, and certain Required Information 6 about, any person nominated for election (the "Stockholder Nominee") to the Board by a stockholder or group of stockholders (the "Ĕligible Stockholder") 7 that satisfies the requirements set forth in the proxy access provision of CGM Bylaws.8 Proposed Section 2.16(a) will also make clear that Cboe is able to solicit against any Stockholder Nominee or include in

its proxy materials the Corporation's own statements or other information relating to any Eligible Stockholder or Stockholder Nominee, including any information provided to the Corporation pursuant to Section 2.16. This provision clarifies that just because Cboe must include a Stockholder Nominee in its proxy materials if the proxy access provisions are satisfied, Cboe does not necessarily have to support that nominee.

Proposed Section 2.16(b)

Proposed Section 2.16(b) will provide that in order to utilize this provision, the Eligible Stockholder must expressly request at the time of providing a required notice to the Corporation of the proxy access nomination (the "Notice of Proxy Access Nomination") to have its nominee included in the Corporation's proxy materials. Proposed Section 2.16(b) also establishes the deadline for a timely Notice of Proxy Access Nomination. Specifically, such a notice must be delivered to the Cboe's Secretary at the principal executive offices of the Corporation not earlier than the open of business on the one hundred fiftieth (150th) day and not later than the close of business on the one hundred twentieth (120th) day prior to the first anniversary of the date that Choe first distributed its proxy statement to stockholders for the previous year's annual meeting of stockholders provided, however, that in the event the annual meeting is more than thirty (30) days before or after the anniversary date of the prior year's annual meeting, or if no annual meeting was held in the preceding year, to be timely, the Notice of Proxy Access Nomination must be received at the principal executive offices of the Corporation no earlier than one hundred fifty (150) days before such annual meeting and no later than the later of one hundred twenty (120) days before such annual meeting or the tenth (10th) day following the day on which public announcement (as defined in Section 2.11) of the date of such meeting is first made by the Corporation. Further Section 2.16 will provide that in no event shall any adjournment or postponement of an annual meeting or the announcement thereof commence a new time period (or extend any time period) for the giving of a Notice of Proxy Access Nomination as described above. Choe believes this notice period will provide stockholders an adequate window to submit nominees via proxy access, while also providing the Corporation adequate time to diligence a proxy access nominee before including them in the proxy statement

for the next annual meeting of stockholders.

Proposed Section 2.16(c)

Proposed Section 2.16(c) specifies that the maximum number ("the Permitted Number") of Stockholder Nominees nominated by all Eligible Stockholders that will be included in Choe's proxy materials with respect to an annual meeting of stockholders shall not exceed the greater of two or 20% of the total number of directors in office (rounded down to the nearest whole number) as of the last day on which a Notice of Proxy Access Nomination may be delivered pursuant to and in accordance with the proxy access provision of the Bylaws (the "Final Proxy Access Nomination Date"). In the event that one or more vacancies for any reason occurs after the Final Proxy Access Nomination Date but before the date of the annual meeting and the Board resolves to reduce the size of the Board in connection therewith, the Permitted Number of Stockholder Nominees included in Choe's proxy materials shall be calculated based on the number of directors in office as so reduced. In addition, the Permitted Number shall be reduced by (i) the number of individuals who will be included in the Corporation's proxy materials as director nominees recommended by the Board pursuant to an agreement, arrangement or other understanding with a stockholder or group of stockholders (other than any such agreement, arrangement or understanding entered into in connection with an acquisition of stock from the Corporation by such stockholder or group of stockholders) and/or (ii) the number of directors in office as of the Final Proxy Access Nomination Date who were included in the Corporation's proxy materials as Stockholder Nominees for any of the two preceding annual meetings of stockholders (including any persons counted as Stockholder Nominees pursuant to the immediately succeeding sentence) and whose reelection at the upcoming annual meeting is being recommended by the Board. Any individual nominated by an Eligible Stockholder for inclusion in the proxy materials pursuant to the proxy access provision of the CGM Bylaws whom the Board decides to nominate as a nominee of the Board, and any individual nominated by an Eligible Stockholder for inclusion in the proxy materials pursuant to the proxy access provision but whose nomination is subsequently withdrawn, shall be counted as one of the Stockholder Nominees for purposes of determining when the Permitted

⁵ See Securities Exchange Release No. 79357 (November 18, 2016) 81 FR 85283 (November 25, 2016) (SR-NASDAQ-2016-127; SR-BX-2016-051; SR-ISE-2016-22; SR-ISEGemini-2016-10; SR-ISEMercury-2016-16; SR-PHLX-2016-93; SR-BSECC-2016-001; SR-SCCP-2016-01). See also Securities Exchange Release No. 77782 (May 6, 2016) 81 FR 29600 (May 12, 2016) (SR-NYSE-2016-14; SR-NYSEArca-2016-25; SR-NYSEMKT-2016-20).

⁶The Required Information is the information provided to Cboe's Corporate Secretary about the Stockholder Nominee and the Eligible Stockholder that is required to be disclosed in the Corporation's proxy statement by the regulations promulgated under the Act, and if the Eligible Stockholder so elects, a written statement, not to exceed 500 words, in support of the Stockholder Nominee(s)' candidacy (the "Supporting Statement", as defined further below).

⁷ As used throughout the CGM Bylaws, the term "Eligible Stockholder" includes each member of a stockholder group that submits a proxy access nomination to the extent the context requires.

⁸When the Corporation includes proxy access nominees in the proxy materials, such individuals will be included in addition to any persons nominated for election by at or the direction of the Board to the Board or any committee thereof.

Number of Stockholder Nominees has been reached. Any Eligible Stockholder submitting more than one Stockholder Nominee for inclusion in the proxy materials shall rank such Stockholder Nominees based on the order that the Eligible Stockholder desires such Stockholder Nominees to be selected for inclusion in the proxy statement in the event that the total number of Stockholder Nominees submitted by Eligible Stockholders pursuant to the proxy access provision exceeds the Permitted Number of nominees allowed. In the event that the number of Stockholder Nominees submitted by Eligible Stockholders pursuant to Section 2.16 exceeds the Permitted Number of nominees allowed, the highest ranking Stockholder Nominee who meets the requirements of the proxy access provision of the Bylaws from each Eligible Stockholder will be selected for inclusion in the proxy materials until the Permitted Number is reached, going in order of the amount (largest to smallest) of shares of Cboe's outstanding capital stock each Eligible Stockholder disclosed as owned in its respective Notice of Proxy Access Nomination submitted to Choe. If the Permitted Number is not reached after the highest ranking Stockholder Nominee who meets the requirements of the proxy access provision of the Bylaws from each Eligible Stockholder has been selected, then the next highest ranking Stockholder Nominee who meets the requirements of Section 2.16 from each Eligible Stockholder will be selected for inclusion in the Corporation's proxy materials, and this process will continue as many times as necessary, following the same order each time, until the Permitted Number is reached. Additionally, notwithstanding anything to the contrary contained in proposed Section 2.16, Choe will not be required to include any Stockholder Nominees in its proxy materials pursuant to Section 2.16 for any meeting of stockholders for which the Secretary receives a notice (whether or not subsequently withdrawn) that the Eligible Stockholder or any other stockholder intends to nominate one or more persons for election to the Board pursuant to Section 2.11 of the CGM Bylaws. Choe believes it is reasonable to limit the Board seats available to proxy access nominees and to establish procedures for selecting candidates if the nominee limit is exceeded. The limitation on Board seats available to proxy access nominees ensures that proxy access cannot be used to take over the entire Board, which is not the stated

purpose of proxy access campaigns. The procedures for selecting candidates if the nominee limit is exceeded establish clear and rational guidelines for an orderly nomination process to avoid the Corporation having to make arbitrary judgments among candidates.

Proposed Section 2.16(d)

Proposed Section 2.16(d) defines who may qualify as an "Eligible Stockholder". Particularly, an Eligible Stockholder is a stockholder or group of no more than 20 stockholders 9 that (i) has owned continuously for at least three years (the "Minimum Holding Period") a number of shares of capital stock of the Corporation that represents at least three percent of the outstanding shares of capital stock of the Corporation as of the date the Notice of Proxy Access Nomination is received (the "Required Shares"), (ii) continues to own the Required Shares through the date of the annual meeting and (iii) meets all other requirements of proposed Section 2.16. Choe believes it is reasonable to require each member of a nominating group to provide such information so that both the Corporation and its stockholders are fully informed about the entire group making the proxy access nomination. As such, Section 2.16(d) further makes clear that whenever the Eligible Stockholder consists of a group of stockholders (including a group of funds that are part of the same Qualifying Fund Group), (i) each provision in Section 2.16 that requires the Eligible Stockholder to provide any written statements, representations, undertakings, agreements or other instruments or to meet any other conditions shall be deemed to require each stockholder (including each individual fund) that is a member of such group to provide such statements, representations, undertakings, agreements or other instruments and to meet such other conditions (except that the members of such group may aggregate the shares that each member has owned continuously for the Minimum Holding Period in order to meet the three percent ownership requirement of the "Required Shares" definition) and (ii) a breach of any obligation, agreement or representation under Section 2.16 by any member of such group shall be

deemed a breach by the Eligible Stockholder. No stockholder may be a member of more than one group of stockholders constituting an Eligible Stockholder with respect to any annual meeting.

Proposed Section 2.16(e)

Proposed Section 2.16(e) clarifies, for the avoidance of doubt, how "ownership" will be defined for purposes of meeting the ownership requirements of the Required Shares. Specifically, an Eligible Stockholder shall be deemed to "own" only those outstanding shares of Choe's capital stock as to which the stockholder possesses both: (i) The full voting and investment rights pertaining to the shares; and (ii) the full economic interest in (including the opportunity for profit from and risk of loss on) such shares; provided that the number of shares calculated in accordance with clauses (i) and (ii) shall not include any shares: That are (1) sold by such stockholder or any of its affiliates in any transaction that has not been settled or closed; (2) borrowed by such stockholder or any of its affiliates for any purposes or purchased by such stockholder or any of its affiliates pursuant to an agreement to resell; or (3) subject to any option, warrant, forward contract, swap, contract of sale, other derivative or similar instrument or agreement entered into by such stockholder or any of its affiliates, whether any such instrument or agreement is to be settled with shares or with cash based on the notional amount or value of shares of Cboe's outstanding capital stock, in any such case which instrument or agreement has, or is intended to have, the purpose or effect of: (A) Reducing in any manner, to any extent or at any time in the future, such stockholder's or its affiliates' full right to vote or direct the voting of any such shares; and/or (B) hedging, offsetting or altering to any degree any gain or loss realized or realizable from maintaining the full economic ownership of such shares by such stockholder or its affiliates.

Further, a stockholder shall "own" shares held in the name of a nominee or other intermediary so long as the stockholder retains the right to instruct how the shares are voted with respect to the election of directors and possesses the full economic interest in the shares. A stockholder's ownership of shares shall be deemed to continue during any period in which (i) the stockholder has loaned such shares provided that the stockholder has the power to recall such loaned shares on five (5) business days' notice and includes in the Notice of

⁹For this purpose, any two or more funds that are part of the same Qualifying Fund Group may be counted as one stockholder. A "Qualifying Fund Group" means two or more funds that are (i) under common management and investment control, (ii) under common management and funded primarily by the same employer or (iii) a "group of investment companies" as such term is defined in Section 12(d)(1)(G)(ii) of the Investment Corporation Act of 1940, as amended.

Proxy Access Nomination an agreement that it will (1) recall such loaned shares upon being notified that any of its Stockholder Nominees will be included in the Corporation's proxy materials and (2) will hold such shares through the date of the annual meeting or (ii) the stockholder has delegated any voting power by means of a proxy, power of attorney or other instrument or arrangement which is revocable at any time by the stockholder. Section 2.16(e) also clarifies that the terms "owned," "owning" and other variations of the word "own" shall have correlative meanings. Whether outstanding shares of Cboe's capital stock are "owned" for these purposes shall be determined by the Board. For purposes of Section 2.16, the term "affiliate" or "affiliates" shall have the meaning ascribed thereto under the rules and regulations of the Act.¹⁰ An Eligible Stockholder shall include in its Notice of Proxy Access Nomination the number of shares it is deemed to own for the purposes of proposed Section 2.16. In proposing the Required Shares and the Minimum Holding Period, Choe seeks to ensure that the Eligible Stockholder has had a sufficient stake in the Corporation for a sufficient amount of time and is not pursuing a short-term agenda.

Proposed Section 2.16(f)

Proposed Section 2.16(f) sets forth the information that an Eligible Stockholder must provide to Cboe's Corporate Secretary in writing within the deadline discussed above in order to make a proxy access nomination. This information includes:

- A statement by the Eligible Stockholder (1) setting forth and certifying as to the number of shares it owns and has owned continuously for the Minimum Holding Period and (2) agreeing to continue to own the Required Shares through the date of the annual meeting;
- one or more written statements from the record holder of the Required Shares (and from each intermediary through which the Required Shares are or have been held during the Minimum Holding Period) verifying that, as of a

date within seven calendar days prior to the date the Notice of Proxy Access Nomination is delivered to Cboe's Secretary at the principal executive offices of the Corporation, the Eligible Stockholder owns, and has owned continuously for the Minimum Holding Period, the Required Shares, and the Eligible Stockholder's agreement to provide, within five (5) business days after the record date for the annual meeting, written statements from the record holder and intermediaries verifying the Eligible Stockholder's continuous ownership of the Required Shares through the record date;

- a copy of the Schedule 14N that has been filed with the SEC as required by Rule 14a–18 under the Act; ¹¹
- the information, representations and agreements and other documents that are required to be set forth in or included with a stockholder's notice of nomination given pursuant to Section 2.11 of the CGM Bylaws;
- the written consent of each Stockholder Nominee to being named in the proxy statement as a nominee and to serving as a director if elected;
- a representation that the Eligible Stockholder:
- Acquired the Required Shares in the ordinary course of business and not with the intent to change or influence control of Cboe, and does not presently have such intent;
- has not nominated and will not nominate for election any individual as a director at the annual meeting, other than its Stockholder Nominee(s);
- has not engaged and will not engage in, and has not and will not be a participant in another person's, "solicitation" within the meaning of Rule 14a-1(l) under the Act in support of the election of any individual as a director at the annual meeting, other than its Stockholder Nominee(s) or a nominee of the Board;
- has not distributed and will not distribute to any stockholder of the Corporation any form of proxy for the annual meeting other than the form distributed by the Corporation;
- has complied and will comply with all laws, rules and regulations applicable to solicitations and the use, if any, of soliciting material in connection with the annual meeting, and
- has provided and will provide facts, statements and other information

in all communications with Cboe and its stockholders that are or will be true and correct in all material respects and do not and will not omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

• an undertaking that the Eligible

Stockholder agrees to

 assume all liability stemming from any legal or regulatory violation arising out of the Eligible Stockholder's communications with the stockholders of the Corporation or out of the information that the Eligible Stockholder provided to the Corporation;

- o indemnify and hold harmless the Corporation and each of its Directors, officers and employees individually against any liability, loss or damages in connection with any threatened or pending action, suit or proceeding, whether legal, administrative or investigative, against the Corporation or any of its Directors, officers or employees arising out of any nomination submitted by the Eligible Stockholder pursuant to this Section 2.16 or any solicitation or other activity in connection therewith; and
- of file with the Securities and
 Exchange Commission any solicitation
 or other communication with the
 stockholders of the Corporation relating
 to the meeting at which its Stockholder
 Nominee(s) will be nominated,
 regardless of whether any such filing is
 required under Regulation 14A of the
 Act or whether any exemption from
 filing is available for such solicitation or
 other communication under Regulation
 14A of the Act;
- in the case of a nomination by a group of stockholders that together is an Eligible Stockholder, the designation by all group members of one group member that is authorized to receive communications, notices and inquiries from the Corporation and to act on behalf of all members of the group with respect to all matters relating to the nomination under this Section 2.16 (including withdrawal of the nomination);
- in the case of a nomination by an Eligible Stockholder consisting of a group of stockholders in which two or more funds are intended to be treated as one stockholder for purposes of qualifying as an Eligible Stockholder, documentation reasonably satisfactory to the Corporation that demonstrates that the funds are part of the same Qualifying Fund Group; and

• a written representation and agreement by the Stockholder Nominee that such person:

¹⁰ Pursuant to Rule 12b–2 under the Act, "[a]n 'affiliate' of, or a person 'affiliated' with, a specified person, is a person that directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, the person specified." 17 CFR 240.12b–2. Further, "[t]he term 'control' (including the terms 'controlling,' 'controlled by' and 'under common control with') means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a person, whether through the ownership of voting securities, by contract, or otherwise." 17 CFR 240.12b–2.

¹¹ See 17 CFR 240.14n–101 and 17 CFR 240.14a–18, which generally require a Nominating Stockholder to provide notice to the Corporation of its intent to submit a proxy access nomination on a Schedule 14N and file that notice, including the required disclosure, with the Commission on the date first transmitted to the Corporation.

- Will act as a representative of all of the stockholders of the Corporation while serving as a director;
- will provide facts, statements and other information in all communications with the Corporation and its stockholders that are or will be true and correct in all material respects (and shall not omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading);
- is not and will not become a party to (i) any compensatory, payment or other financial agreement, arrangement or understanding with any person or entity other than the Corporation in connection with service or action as a director of the Corporation that has not been disclosed to the Corporation, (ii) any Voting Commitment that has not been disclosed to the Corporation or (iii) any Voting Commitment 12 that could reasonably be expected to limit or interfere with the Stockholder Nominee's ability to comply, if elected as a director of the Corporation, with its fiduciary duties under applicable law; and
- o will abide by and comply with the CGM Bylaws, the Certificate of Incorporation and applicable policies of the Corporation including all applicable publicly disclosed corporate governance, conflict of interest, confidentiality and stock ownership and trading policies and guidelines of the Corporation, as well as the applicable provisions of the rules and regulations of the Securities and Exchange Commission and any stock exchange applicable to the Corporation.

In proposing the informational requirements for the Eligible Stockholder, Cboe's goal is to gather sufficient information about the Eligible Stockholder for both itself and its stockholders. Among other things, this information is designed to help ensure that Cboe is able to comply with its disclosure and other requirements under applicable law and that Cboe, its Board and its stockholders are able to assess the proxy access nomination adequately.

Proposed Section 2.16(g)

Proposed Section 2.16(g) establishes additional information the Stockholder Nominee must provide. Particularly:

• The Stockholder Nominee(s) must submit all completed and signed

questionnaires required of directors and officers of the Corporation;

 the Corporation may require any proposed Stockholder Nominee to furnish any information:

- O That may reasonably be requested by the Corporation to determine whether the Stockholder Nominee would be independent under Section 3.3 and otherwise qualifies as independent under the rules of the principal national securities exchange on which the outstanding capital stock of the Corporation is traded;
- that could be material to a reasonable stockholder's understanding of the independence, or lack thereof, of such Stockholder Nominee;
- that would be required to satisfy the requirements for qualification of directors under applicable foreign regulations; or
- o (that may reasonably be requested by the Corporation to determine the eligibility of such Stockholder Nominee to be included in the Corporation's proxy materials pursuant to this Section 2.16 or to serve as a director of the Corporation; and
- the Corporation may require the Eligible Stockholder to furnish any other information that may reasonably be requested by the Corporation to verify the Eligible Stockholder's continuous Ownership of the Required Shares for the Minimum Holding Period and through the date of the annual meeting.

Like the informational requirements for an Eligible Stockholder, which are set forth above, the informational requirements for the Stockholder Nominee ensure that both Cboe and its stockholders will have sufficient information about the Stockholder Nominee. Among other things, this information will ensure that Cboe is able to comply with its disclosure and other requirements under applicable law and that Cboe, its Board and its stockholders are able to assess the proxy access nomination adequately.

Proposed Section 2.16(h)

Proposed Section 2.16(h) provides that an Eligible Stockholder may provide, at its option, to the Secretary, at the time the Notice of Proxy Access Nomination is provided, a written statement, not to exceed 500 words, in support of its Stockholder Nominee(s)' candidacy (a "Supporting Statement"). Only one Supporting Statement may be submitted by an Eligible Stockholder (including any group of stockholders together constituting an Eligible Stockholder) in support of its Stockholder Nominee(s). Notwithstanding anything to the

contrary contained in Section 2.16, the Corporation may omit from its proxy materials any information or Supporting Statement (or portion thereof) that it, in good faith, believes is untrue in any material respect (or omits to state a material fact necessary in order to make the statements made, in light of the circumstances under which they are made, not misleading) or would violate any applicable law, rule or regulation. The Exchange notes proposed Section 2.16(h) allows Choe to comply with Rule 14a-9 under the Act 13 and to protect its stockholders from information that is materially untrue or that violates any law, rule or regulation.

Proposed Section 2.16(i)

Pursuant to proposed Section 2.16(i), each Eligible Stockholder or Stockholder Nominee must promptly notify Choe's Corporate Secretary of any information or communications provided by the Eligible Stockholder or Stockholder Nominee, as the case may be, to Cboe or its stockholders that when provided was not, or thereafter ceases to be, true and correct in all material respects or omits a material fact necessary to make the statements made, in light of the circumstances under which they were made, not misleading and of the information that is required to correct any such defect. An Eligible Stockholder shall also provide immediate notice to the Corporation if the Eligible Stockholder ceases to own any of the Required Shares prior to the date of the annual meeting. In addition, any person providing any information to the Corporation pursuant to Section 2.16(i) shall be required to update or supplement such information, if necessary, so that all such information shall be true and correct as of the (i) as of the record date for determining the stockholders entitled to receive notice of the meeting and (ii) as of the date that is ten (10) business days prior to the meeting (or any postponement, adjournment or recess thereof), and such update shall be received by the Secretary at the principal executive offices of the Corporation (A) not later than five (5) business days after the record date for determining the stockholders entitled to receive notice of such meeting (in the case of an update required to be made under clause (i)) and (B) not later than seven (7) business

¹² A "Voting Commitment" is defined as any agreement, arrangement or understanding with any person or entity as to how the Stockholder Nominee would vote or act on any issue or question as a

¹³ See 17 CFR 240.14a–9, which generally prohibits proxy solicitations that contain any statement which, at the time and in the light of the circumstances under which it is made, is false or misleading with respect to any material fact, or which omits to state any material fact necessary in order to make the statements therein not false or misleading.

days prior to the date for the meeting, if practicable, or, if not practicable, on the first practicable date prior to the meeting or any adjournment, recess or postponement thereof (in the case of an update required to be made pursuant to clause (ii)).

This provision further makes clear that providing any such notification, update or supplement, shall not be deemed to cure any defect in any previously provided information or communications or limit the remedies available to the Corporation relating to such defect (including the right to omit a Stockholder Nominee from its proxy materials). This provision is intended to protect Cboe's stockholders by requiring an Eligible Stockholder or Stockholder Nominee to give Choe notice of information previously provided that is materially untrue. Choe may then decide what action to take with respect to such defect, which may include, as noted above, omitting the relevant Stockholder Nominee from its proxy materials.

Proposed Section 2.16(j)

Proposed Section 2.16(j) provides that Cboe shall not be required to include a Stockholder Nominee in its proxy materials for any meeting of stockholders under certain circumstances. In these situations, the proxy access nomination shall be disregarded and no vote on such Stockholder Nominee will occur, even if Cboe has received proxies in respect of the vote. These circumstances occur when the Stockholder Nominee:

- Would not be an independent director under Section 3.3, under the rules of the principal national securities exchange on which the outstanding capital stock of the Corporation is traded, any applicable rules of the Securities and Exchange Commission and any publicly disclosed standards used by the Board in determining and disclosing independence of the Corporation's directors, in each case as determined by the Board in its sole discretion;
- would not meet the audit committee independence requirements under the rules of the principal national securities exchange on which the outstanding capital stock of the Corporation is traded;
- if elected, intended to resign as a director of the Corporation prior to the end of the full term for which he or she is standing for election;
- is or has been subject to any statutory disqualification under Section 3(a)(39) of the Act;
- is or has been subject to disqualification under 17 CFR 1.63;

- if elected, would cause the Corporation to be in violation of these Bylaws, the Certificate of Incorporation, the rules of the principal national securities exchange on which the outstanding capital stock of the Corporation is traded, or any applicable law, rule or regulation;
- is or has been, within the past three years, an officer or director of a competitor, as defined for purposes of Section 8 of the Clayton Antitrust Act of 1914:
- is a named subject of a pending criminal proceeding (excluding traffic violations and other minor offenses) or has been convicted in such a criminal proceeding within the past 10 years;
- is subject to any order of the type specified in Rule 506(d) of Regulation D promulgated under the Securities Act of 1933, as amended;
- has provided any information to the Corporation or its stockholders that was untrue in any material respect or that omitted to state a material fact necessary to make the statements made, in light of the circumstances in which they were made, not misleading; or
- breaches or fails, or the Eligible Stockholder breaches or fails, to comply with its obligations pursuant to the CGM Bylaws, including, but not limited to, Section 2.16 and any agreement, representation or undertaking required by Section 2.16.

Cboe believes these provisions will protect the Corporation and its stockholders by allowing it to exclude certain categories of objectionable Stockholder Nominees from the proxy statement.

Proposed Section 2.16(k)

Proposed Section 2.16(k) provides that notwithstanding anything to the contrary contained in the CGM Bylaws, if (i) a Stockholder Nominee and/or the applicable Eligible Stockholder breaches any of its agreements or representations or fails to comply with any of its obligations under this Section 2.16 or (ii) a Stockholder Nominee otherwise becomes ineligible for inclusion in the Corporation's proxy materials pursuant to this Section 2.16, or dies, becomes disabled or otherwise becomes ineligible or unavailable for election at the annual meeting, in each case as determined by the Board or the chairman of the meeting, (1) the Corporation may omit or, to the extent feasible, remove the information concerning such Stockholder Nominee and the related Supporting Statement from its proxy materials and/or otherwise communicate to its stockholders that such Stockholder Nominee will not be eligible for election

at the annual meeting, (2) the Corporation shall not be required to include in its proxy materials any successor or replacement nominee proposed by the applicable Eligible Stockholder or any other Eligible Stockholder and (3) the chairman of the meeting shall declare such nomination to be invalid and such nomination shall be disregarded, notwithstanding that proxies in respect of such vote may have been received by the Corporation. Choe believes this provision protects the Corporation and its stockholders by providing the Board or the chairman of the stockholder meeting limited authority to disqualify a proxy access nominee when that nominee or the sponsoring stockholder(s) have breached an obligation under the proxy access provision.

Proposed Section 2.16(l)

Proposed Section 2.16(l) states that the following Stockholder Nominees who are included in the Corporation's proxy materials for a particular annual meeting of stockholders will be ineligible to be a Stockholder Nominee for the next two annual meetings: (i) Stockholder Nominee who withdraws from or becomes ineligible or unavailable for election at the annual meeting; or (ii) Stockholder Nominee who does not receive at least 25% of the votes cast in favor of such Stockholder Nominee's election. For the avoidance of doubt, Section 2.16(l) also clarifies that this provision shall not prevent any stockholder from nominating any person to the Board pursuant to Section 2.11 of the CGM Bylaws. Section 2.16(l) will save the Corporation and its stockholders the time and expense of analyzing and addressing subsequent proxy access nominations regarding individuals who were included in the proxy materials for a particular annual meeting but ultimately did not stand for election or receive a substantial amount of votes. After the next two annual meetings, these Stockholder Nominees would again be eligible for nomination through the proxy access provisions of the Bylaws.

Proposed Section 2.16(m)

Proposed Section 2.16(m) provides that notwithstanding the provisions of proposed Section 2.16, if the Eligible Stockholder providing notice (or a qualified representative of the Eligible Stockholder) does not appear in person (including virtually, in the case of a meeting held solely by means of remote communication) at the stockholder meeting to present the nomination of such Stockholder Nominee, such proposed nomination shall not be

presented by the Corporation and shall not be transacted, notwithstanding that proxies in respect of such vote may have been received by the Corporation. For purposes of this Section 2.16, to be considered a qualified representative of the Eligible Stockholder providing notice, a person must be a duly authorized officer, manager or partner of such stockholder or must be authorized by a writing executed by such stockholder or an electronic transmission delivered by such stockholder to act for such stockholder as proxy at the meeting and such writing or electronic transmission, or a reliable reproduction of the writing or electronic transmission, must be provided to the Corporation at least twenty-four (24) hours prior to the meeting.

Proposed Section 2.16(n)

In case there are matters involving a proxy access nomination that are open to interpretation, proposed Section 2.16(n) states that the Board (or any other person or body authorized by the Board) shall have exclusive power and authority to interpret the proxy access provisions of the Bylaws and make all determinations deemed necessary or advisable in connection with proposed Section 2.16 as to any person, facts or circumstances. In addition, all actions, interpretations and determinations of the Board (or any person or body authorized by the Board) with respect to the proxy access provisions shall be final, conclusive and binding on the Corporation, the stockholders and all other parties. While Choe has attempted to implement a clear, detailed and thorough proxy access provision, there may be matters about future proxy access nominations that are open to interpretation. In these cases, Cboe believes it is reasonable and necessary to designate an arbiter to make final decisions on these points and that the Board is best-suited to act as that arbiter.

Proposed Section 2.16(o)

For the avoidance of doubt, proposed Section 2.16(o) states that the proxy access provisions outlined in proposed Section 2.16 shall be the exclusive means for stockholders to include nominees in the Corporation's proxy materials. Stockholders may, of course, continue to propose nominees through other means, but the Board will have final authority to determine whether to include those nominees in the Corporation's proxy materials.

Revisions to Other Sections of the Bylaws

Choe also proposes to make conforming changes to Sections 2.10 and 2.11 to provide clarifications and prevent confusion. First, the Exchange proposes to add a reference to Section 2.11 and proposed Section 2.16 to clarify the exact bylaw provisions relating to stockholder nominees. Next, the Exchange proposes to amend Section 2.11. Section 2.11 currently describes the business that may be properly brought before an annual meeting of stockholders and the methods by which nominations of persons for election to the Board may be made at an annual meeting of stockholders. Choe proposes to add proxy access nominations (i.e., reference to Section 2.16) to the list of methods. Current Section 2.11(a)(i) also states, among other things, that compliance with Section 2.11 shall be the exclusive means for a stockholder to propose business or director nominations before an annual meeting stockholders. The Exchange proposes to clarify that Sections 2.11 and 2.16 are the exclusive means for a stockholder to make a director nomination.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act. 14 Specifically. the Exchange believes the proposed rule change is consistent with the Section $6(b)(5)^{15}$ requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

In light of a shareholder proposal received from a stockholder, Cboe is proposing changes to its Bylaws to implement proxy access. The Exchange believes that this filing furthers the objectives of Section 6(b)(5) of the Act because the proposed rule change would be consistent with and facilitate a governance and regulatory structure that 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 regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. Particularly, the Exchange believes that, by permitting an Eligible Stockholder of Cboe that meets the stated requirements to nominate directors and have its nominees included in Cboe's annual meeting proxy statement, the proposed rule change strengthens the corporate governance of the Exchange's ultimate parent company, which is beneficial to both investors and the public interest.

Additionally, the procedural requirements are designed to help protect investors by stating clearly and explicitly the procedures stockholders must follow in order to submit a proper proxy access nomination. The informational requirements are designed to enhance investor protection by helping to ensure among other things, that the Corporation and its stockholders have full and accurate information about nominating stockholders and their nominees and that such stockholders and nominees comply with applicable laws, regulations and other requirements. Moreover, as noted above, proxy access has become commonplace among companies and the Exchange believes its core provisions are common among companies that have adopted proxy access, including the parent companies of other exchanges that have adopted similar proxy access provisions. 16

Finally, the remaining changes to existing provisions of the CGM Bylaws are clarifying in nature, and they enhance investor protection and the public interest by preventing confusion with respect to the operation of the Bylaw provisions.

B. Self-Regulatory Organization's Statement on Burden on Competition

Because the proposed rule change relates to the governance of the Corporation and not to the operations of the Exchange, the Exchange does not believe that the proposed rule change

^{14 15} U.S.C. 78f(b).

¹⁵ 15 U.S.C. 78f(b)(5).

¹⁶ See Securities Exchange Release No. 79357
(November 18, 2016) 81 FR 85283 (November 25, 2016) (SR-NASDAQ-2016-127; SR-BX-2016-051; SR-ISE-2016-22; SR-ISEGemini-2016-10; SR-ISEMercury-2016-16; SR-PHLX-2016-93; SR-BSECC-2016-001; SR-SCCP-2016-01). See also Securities Exchange Release No. 77782 (May 6, 2016) 81 FR 29600 (May 12, 2016) (SR-NYSE-2016-14; SR-NYSEArca-2016-25; SR-NYSEMKT-2016-20).

will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not designed to address any competitive issue or have any impact on competition; rather, adoption of a proxy access bylaw by the Corporation is intended to enhance corporate governance and accountability to stockholders.

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

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission shall: (a) By order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (http://www.sec.gov/rules/sro.shtml); or
- Send an email to *rule-comments@* sec.gov. Please include File Number SR-CboeBZX-2021-028 on the subject line.

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR-CboeBZX-2021-028. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (http://www.sec.gov/rules/sro.shtml). Copies of the

submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-CboeBZX-2021-028 and should be submitted on or before May 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. 17

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–09446 Filed 5–4–21; 8:45 am] BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-91709; File No. SR-NYSENAT-2021-12]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Effective Date in Commentary .10 Under NYSE National Rule 2.1210

April 29, 2021.

Pursuant to Section 19(b)(1) ¹ of the Securities Exchange Act of 1934 (the "Exchange Act") ² and Rule 19b–4 thereunder,³ notice is hereby given that on April 19, 2021, NYSE National, Inc. ("NYSE National" or the "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the self-

3 17 CFR 240.19b-4.

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 a rule change to extend the effective date in Commentary .10 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) under NYSE National Rule 2.1210 (Registration Requirements) applicable to ETP Holders, from April 30, 2021 to June 30, 2021. The Exchange does not anticipate providing any further extensions to the temporary relief identified in this proposed rule change beyond June 30, 2021.4 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 these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to extend the effective date in Commentary .10 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) under NYSE National Rule 2.1210 (Registration Requirements) applicable to ETP Holders,⁵ from April 30, 2021 to June 30, 2021. The proposed rule change would extend the 120-day period that

^{17 17} CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

⁴ If due to unforeseen circumstances a further extension is necessary, the Exchange will submit a separate rule filing to further extend the temporary relief

⁵The term "ETP Holder" means the Exchangeapproved holder of an ETP. See NYSE National Rule 1.1(i). The term "ETP" refers to an Equity Trading Permit issued by the Exchange for effecting approved securities transactions on the Exchange. See NYSE National Rule 1.1(h).

certain individuals can function as a principal without having successfully passed an appropriate qualification examination through June 30, 2021, and would apply only to those individuals who were designated to function as a principal prior to March 3, 2021. This proposed rule change is based on a filing recently submitted by the Financial Industry Regulatory Authority, Inc. ("FINRA") 6 and is intended to harmonize the Exchange's registration rules with those of FINRA so as to promote uniform standards across the securities industry.

In response to COVID–19 global pandemic, last year FINRA began providing temporary relief by way of frequently asked questions ("FAQs") ⁷ to address disruptions to the administration of FINRA qualification examinations caused by the pandemic that have significantly limited the ability of individuals to sit for examinations due to Prometric test center capacity issues.⁸

FINRA published the first FAQ on March 20, 2020, providing that individuals who were designated to function as principals under FINRA Rule 1210.04 9 prior to February 2, 2020, would be given until May 31, 2020, to pass the appropriate principal qualification examination. 10 FINRA revised the FAQ to extend the expiration of the temporary relief to pass the appropriate principal examination until June 30, 2020, and then until August 31, 2020.

On September 25, 2020, NYSE National filed with the Commission a

proposed rule change for immediate effectiveness to extend the temporary relief provided via the FAO by adopting temporary Commentary .10 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) under NYSE National Rule 2.1210 (Registration Requirements). 11 Pursuant to this rule filing, individuals who were designated prior to September 3, 2020, to function as a principal under NYSE National Rule 2.1210.10 had until December 31, 2020, to pass the appropriate qualification examination. The Exchange thereafter filed a proposed rule change to extend the expiration date of the temporary relief from December 31, 2020, to April 30,

As mentioned in the prior filings, FINRA began providing, and then extended, temporary relief to address the interruptions in the administration of FINRA qualification examinations at Prometric test centers and the limited ability of individuals to sit for the examinations caused by the COVID-19 pandemic.¹³ The prior filings also noted that the pandemic could result in firms potentially experiencing significant disruptions to their normal business operations that may be exacerbated by being unable to keep principal positions filled. Specifically, the limitation of inperson activities and staff absenteeism as a result of the health and welfare concerns stemming from COVID-19 could result in firms having difficulty finding other qualified individuals to transition into that role or requiring them to reallocate employee time and resources away from other critical responsibilities at the firm.

While there are signs of improvement, the COVID–19 conditions necessitating the temporary relief persist and FINRA has determined that there is a continued need for this temporary relief beyond April 30, 2021. Although Prometric has resumed testing in many of its U.S. test centers, Prometric's safety practices mean that currently not all test centers are open, some of the open test centers are at limited capacity, and some open test centers are delivering only certain examinations that have been deemed

essential by the local government.¹⁴ In addition, while certain states have started to ease COVID–19 restrictions on businesses and social activities, public health officials continue to emphasize the importance for individuals to keep taking numerous steps to protect themselves and help slow the spread of the disease.¹⁵

Although the COVID-19 conditions necessitating the temporary relief persist, in the FINRA Filing, FINRA stated that an extension of the relief is necessary only until June 30, 2021, because FINRA recently expanded the availability of online examinations. Prior to this expansion, the ongoing effects of the pandemic made it impracticable for FINRA members to ensure that the individuals who they had designated to function in a principal capacity, as set forth in FINRA Rule 1210.04, could successfully sit for and pass an appropriate qualification examination within the 120-calendar day period required under the rule.16 Specifically, if the individual wanted to take a qualifying examination, they were required to accept the health risks associated with taking an in-person examination because those examinations were not available online. On February 24, 2021, however, FINRA adopted an interim accommodation request process to allow candidates to take additional FINRA examinations online, including the General Securities Principal ("Series 24") examination.¹⁷ Because the qualifying examination has been made available online only recently, FINRA is concerned that individuals who have been designated to function in a principal capacity may not have sufficient time to schedule, study for, and take the applicable examination before April 30, 2021, the date the temporary relief is set to expire.

These ongoing circumstances make it impracticable for ETP Holders to ensure that the individuals whom they have designated to function in a principal capacity, as set forth in NYSE National Rule 2.1210.03, are able to successfully sit for and pass an appropriate qualification examination within the 120-calendar day period required under the rule, or to find other qualified staff to fill this position. Therefore, NYSE

⁶ See Exchange Act Release No. 91506 (April 8, 2021) 86 FR 19671 (April 14, 2021) (SR–FINRA–2021–005) (the "FINRA Filing"). The Exchange notes that the FINRA Filing also provides temporary relief to individuals registered with FINRA as Operations Professionals under FINRA Rule 1220. The Exchange does not have a registration category for Operations Professionals and therefore, the Exchange is not proposing to adopt that aspect of the FINRA Filing.

 $^{^{7}\,}See\ https://www.finra.org/rules-guidance/keytopics/covid-19/faq#qe.$

⁸ At the outset of the COVID–19 pandemic, all FINRA qualification examinations were administered at test centers operated by Prometric. Based on the health and welfare concerns resulting from COVID–19, in March 2020 Prometric closed all of its test centers in the United States and Canada and began to slowly reopen some of them at limited capacity in May. Currently, Prometric has resumed testing in many of its United States and Canada test centers, at either full or limited occupancy, based on local and government mandates.

 $^{^{9}\,\}mathrm{NYSE}$ National Rule 2.1210.03 is the corresponding rule to FINRA Rule 1210.04.

¹⁰ FINRA Rule 1210.04 (Requirements for Registered Persons Functioning as Principals for a Limited Period) allows a member firm to designate certain individuals to function in a principal capacity for 120 calendar days before having to pass an appropriate principal qualification examination NYSE National Rule 2.1210.03 provides the same allowance to ETP Holders.

¹¹ See Exchange Act Release No. 90117 (October 7, 2020), 85 FR 65116 (October 14, 2020) (Notice of Filing and Immediate Effectiveness of SR–NYSENAT–2020–30).

¹² See Exchange Act Release No. 90771 (December 22, 2020), 85 FR 86629 (December 30, 2020) (Notice of Filing and Immediate Effectiveness of SR–NYSENAT–2020–38).

¹³ Information about the continued impact of COVID–19 on FINRA-administered examinations is available at https://www.finra.org/rules-guidance/key-topics/covid-19/exams.

¹⁴Information from Prometric about its safety practices and the impact of COVID–19 on its operations is available at https://www.prometric.com/covid-19-update/corona-virus-update. See also supra note 13.

¹⁵ See, e.g., Centers for Disease Control and Prevention, How to Protect Yourself & Others, https://www.cdc.gov/coronavirus/2019-ncov/ prevent-getting-sick/prevention.html.

¹⁶ See supra note 13.

¹⁷ Id.

National is proposing to extend the effective date of the temporary relief provided through SR–NYSENAT–2020–38 until June 30, 2021. The proposed rule change would apply only to those individuals who were designated to function as a principal prior to March 3, 2021. Any individuals designated to function as a principal on or after March 3, 2021, would need to successfully pass an appropriate qualification examination within 120 days.

NYSE National believes that this proposed continued extension of time is tailored to address the needs and constraints on an ETP Holder's operations during the COVID-19 pandemic, without significantly compromising critical investor protection. The proposed extension of time will help to minimize the impact of COVID-19 on ETP Holders by providing continued flexibility so that ETP Holders can ensure that principal positions remain filled. The potential risks from the proposed extension of the 120-day period are mitigated by the ETP Holder's continued requirement to supervise the activities of these designated individuals and ensure compliance with federal securities laws and regulations, as well as NYSE National rules. NYSE National has filed the proposed rule change for immediate effectiveness and has requested that the Commission waive the requirement that the proposed rule change not become operative for 30 days after the date of the filing, so NYSE National can implement the proposed rule change immediately.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Exchange Act, 18 in general, and furthers the objectives of Section 6(b)(5),19 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 proposed rule change is intended to minimize the impact of COVID–19 on ETP Holder operations by extending the 120-day period certain individuals may function as a principal without having successfully passed an appropriate qualification examination under NYSE

National Rule 2.1210.03 until June 30, 2021. The proposed rule change does not relieve ETP Holders from maintaining, under the circumstances, a reasonably designed system to supervise the activities of their associated persons to achieve compliance with applicable securities laws and regulations, and with applicable NYSE National rules that directly serve investor protection. In a time when faced with unique challenges resulting from the COVID-19 pandemic, NYSE National believes that the proposed rule change is a sensible accommodation that will continue to afford ETP Holders the ability to ensure that critical positions are filled and client services maintained, while continuing to serve and promote the protection of investors and the public interest in this unique environment.

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 Exchange Act. As set forth in the prior filings, the proposed rule change is intended solely to extend temporary relief necessitated by the continued impacts of the COVID-19 pandemic and the related health and safety risks of conducting in-person activities. In its filing, FINRA noted that the proposed rule change is necessary to temporarily rebalance the attendant benefits and costs of the obligations under FINRA Rule 1210 in response to the impacts of the COVID-19 pandemic that would otherwise result if the temporary relief was to expire on April 30, 2021. The Exchange accordingly incorporates FINRA's abbreviated economic impact assessment by reference.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section

19(b)(3)(A) of the Act ²⁰ and Rule 19b–4(f)(6) thereunder.²¹

A proposed rule change filed under Rule 19b-4(f)(6) normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b-4(f)(6)(iii), the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative immediately upon filing. As noted above, the Exchange stated that the conditions necessitating the temporary relief continue to exist and the proposed extension of time will help minimize the impact of the COVID-19 outbreak on NYSE National ETP Holders' operations by allowing them to keep principal positions filled and minimizing disruptions to client services and other critical responsibilities. Despite signs of improvement, the Exchange further stated that the ongoing extenuating circumstances of the COVID-19 pandemic make it impractical to ensure that individuals designated to act in these capacities are able to take and pass the appropriate qualification examination during the 120-calendar day period required under the rules.

The Exchange observed that, following a nationwide closure of all test centers earlier in the year, some test centers have re-opened, but are operating at limited capacity or are only delivering certain examinations that have been deemed essential by the local government.²² However, on February 24, 2021, FINRA began providing the General Securities Principal (Series 24) Examination online through an interim accommodation request process.²³ Prior to this change, if individuals wanted to take these qualifying examinations, they were required to accept the health risks associated with taking an in-person examination. Even with the expansion of online qualifications examinations, the Exchange stated that extending the

¹⁸ 15 U.S.C. 78f(b).

¹⁹ 15 U.S.C. 78f(b)(5).

²⁰ 15 U.S.C. 78s(b)(3)(A).

²¹ 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.

²² See supra notes 13 and 14. The Exchange states that Prometric has also had to close some reopened test centers due to incidents of COVID-19 cases.

²³ See supra note 13 (including the February 24, 2021 announcement of the interim accommodation process for candidates to take certain examinations, including the General Securities Principal (Series 24) Examination, online.)

expiration date of the relief set forth in SR-NYSENAT-2020-38 until June 30, 2021 is still needed. The Exchange stated that this temporary relief will provide flexibility to allow individuals who have been designated to function in a principal sufficient time to schedule, study for and take the applicable examination before the temporary relief expires. Notably, the Exchange stated that it does not anticipate providing any further extensions to the temporary amendments and that any individuals designated to function as a principal on or after March 3, 2021 will need to successfully pass an appropriate qualification examination within 120 davs.

For these reasons, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest.²⁴ Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.²⁵

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (http://www.sec.gov/rules/sro.shtml); or
- Send an email to rule-comments@ sec.gov. Please include File Number SR– NYSENAT-2021-12 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-2021-12. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (http://www.sec.gov/ rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSENAT-2021-12 and should be submitted on or before May

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. 26

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–09438 Filed 5–4–21; 8:45 am]

BILLING CODE 8011-01-P

²⁶ 17 CFR 200.30-3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-91707; File No. SR-NYSEArca-2021-30]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Effective Date in Commentary .10 under NYSE Arca Rule 2.1210

April 29, 2021.

Pursuant to Section 19(b)(1) ¹ of the Securities Exchange Act of 1934 (the "Exchange Act") ² and Rule 19b–4 thereunder,³ notice is hereby given that on April 19, 2021, NYSE Arca, Inc. ("NYSE Arca" or the "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the 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 a rule change to extend the effective date in Commentary .10 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) under NYSE Arca Rule 2.1210 (Registration Requirements) applicable to Equity Trading Permit ("ETP") Holders, Options Trading Permit ("OTP") Holders and OTP Firms, from April 30, 2021 to June 30, 2021. The Exchange does not anticipate providing any further extensions to the temporary relief identified in this proposed rule change beyond June 30, 2021.4 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

²⁴ As noted above by the Exchange, this proposal is an extension of temporary relief provided in SR–NYSENAT–2020–30 and SR–NYSENAT–2020–38 where the Exchange also requested and the Commission granted a waiver of the 30-day operative delay. *See* SR–NYSENAT–2020–30, 85 FR at 65118 and SR–NYSENAT–2020–38, 85 FR at 86631–32.

²⁵ For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78e(f)

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

^{3 17} CFR 240.19b-4.

⁴ If due to unforeseen circumstances a further extension is necessary, the Exchange will submit a separate rule filing to further extend the temporary relief.

on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to extend the effective date in Commentary .10 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) under NYSE Arca Rule 2.1210 (Registration Requirements) applicable to ETP Holders, OTP Holders and OTP Firms (collectively, "Members"),5 from April 30, 2021 to June 30, 2021. The proposed rule change would extend the 120-day period that certain individuals can function as a principal without having successfully passed an appropriate qualification examination through June 30, 2021, and would apply only to those individuals who were designated to function as a principal prior to March 3, 2021. This proposed rule change is based on a filing recently submitted by the Financial Industry Regulatory Authority, Inc. ("FINRA") 6 and is

intended to harmonize the Exchange's registration rules with those of FINRA so as to promote uniform standards across the securities industry.

In response to COVID–19 global pandemic, last year FINRA began providing temporary relief by way of frequently asked questions ("FAQs") ⁷ to address disruptions to the administration of FINRA qualification examinations caused by the pandemic that have significantly limited the ability of individuals to sit for examinations due to Prometric test center capacity issues.⁸

FINRA published the first FAQ on March 20, 2020, providing that individuals who were designated to function as principals under FINRA Rule 1210.04 ° prior to February 2, 2020, would be given until May 31, 2020, to pass the appropriate principal qualification examination. ¹0 FINRA revised the FAQ to extend the expiration of the temporary relief to pass the appropriate principal examination until June 30, 2020, and then until August 31, 2020.

On September 25, 2020, NYSE Arca filed with the Commission a proposed rule change for immediate effectiveness to extend the temporary relief provided via the FAQ by adopting temporary Commentary .10 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) under NYSE Arca Rule 2.1210 (Registration Requirements). 11 Pursuant to this rule filing, individuals who were designated prior to September 3, 2020, to function as a principal under NYSE Arca Rule 2.1210.10 had until December 31, 2020, to pass the appropriate qualification examination. The Exchange thereafter filed a proposed rule change to extend the expiration date of the temporary

relief from December 31, 2020, to April 30, 2021. 12

As mentioned in the prior filings, FINRA began providing, and then extended, temporary relief to address the interruptions in the administration of FINRA qualification examinations at Prometric test centers and the limited ability of individuals to sit for the examinations caused by the COVID-19 pandemic.¹³ The prior filings also noted that the pandemic could result in firms potentially experiencing significant disruptions to their normal business operations that may be exacerbated by being unable to keep principal positions filled. Specifically, the limitation of inperson activities and staff absenteeism as a result of the health and welfare concerns stemming from COVID-19 could result in firms having difficulty finding other qualified individuals to transition into that role or requiring them to reallocate employee time and resources away from other critical responsibilities at the firm.

While there are signs of improvement, the COVID-19 conditions necessitating the temporary relief persist and FINRA has determined that there is a continued need for this temporary relief beyond April 30, 2021. Although Prometric has resumed testing in many of its U.S. test centers, Prometric's safety practices mean that currently not all test centers are open, some of the open test centers are at limited capacity, and some open test centers are delivering only certain examinations that have been deemed essential by the local government.¹⁴ In addition, while certain states have started to ease COVID-19 restrictions on businesses and social activities, public health officials continue to emphasize the importance for individuals to keep taking numerous steps to protect themselves and help slow the spread of the disease.15

Although the COVID-19 conditions necessitating the temporary relief persist, in the FINRA Filing, FINRA stated that an extension of the relief is necessary only until June 30, 2021, because FINRA recently expanded the

 $^{^{5}}$ The term "ETP Holder" refers to a sole proprietorship, partnership, corporation, limited liability company or other organization in good standing that has been issued an ETP. An ETP Holder must be a registered broker or dealer pursuant to Section 15 of the Exchange Act. See NYSE Arca Rule 1.1(o). The term "ETP" refers to an Equity Trading Permit issued by the Exchange for effecting approved securities transactions on the Exchange's Trading Facilities. See NYSE Arca Rule 1.1(n). The term "OTP Holder" refers to a natural person, in good standing, who has been issued an OTP. An OTP Holder must be a registered broker or dealer pursuant to Section 15 of the Exchange Act. Under the Exchange's rules, an OTP Holder has the status as a "member" of the Exchange as that term is defined in Section 3 of the Exchange Act. See NYSE Arca Rule 1.1(nn). The term "OTP" refers to an Options Trading Permit issued by the Exchange for effecting approved securities transactions on the Exchange's Trading Facilities. See NYSE Arca Rule 1.1(mm). The term "OTP Firm" refers to a sole proprietorship, partnership, corporation, limited liability company or other organization in good standing who holds an OTP or upon whom an individual OTP Holder has conferred trading privileges on the Exchange's Trading Facilities pursuant to and in compliance with Exchange rules. An OTP Firm must be a registered broker or dealer pursuant to Section 15 of the Exchange Act. See NYSE Arca Rule 1.1(00).

⁶ See Exchange Act Release No. 91506 (April 8, 2021) 86 FR 19671 (April 14, 2021) (SR–FINRA–2021–005) (the "FINRA Filing"). The Exchange notes that the FINRA Filing also provides temporary relief to individuals registered with FINRA as Operations Professionals under FINRA Rule 1220. The Exchange does not have a registration category for Operations Professionals and therefore, the Exchange is not proposing to adopt that aspect of the FINRA Filing.

⁷ See https://www.finra.org/rules-guidance/key-topics/covid-19/faq#qe.

⁸ At the outset of the COVID–19 pandemic, all FINRA qualification examinations were administered at test centers operated by Prometric. Based on the health and welfare concerns resulting from COVID–19, in March 2020 Prometric closed all of its test centers in the United States and Canada and began to slowly reopen some of them at limited capacity in May. Currently, Prometric has resumed testing in many of its United States and Canada test centers, at either full or limited occupancy, based on local and government mandates.

⁹NYSE Arca Rule 2.1210.03 is the corresponding rule to FINRA Rule 1210.04.

¹⁰ FINRA Rule 1210.04 (Requirements for Registered Persons Functioning as Principals for a Limited Period) allows a member firm to designate certain individuals to function in a principal capacity for 120 calendar days before having to pass an appropriate principal qualification examination. NYSE Arca Rule 2.1210.03 provides the same allowance to Members.

¹¹ See Exchange Act Release No. 90113 (October 7, 2020), 85 FR 65110 (October 14, 2020) (Notice of Filing and Immediate Effectiveness of SR-NYSEArca-2020-87).

¹² See Exchange Act Release No. 90760 (December 21, 2020), 85 FR 85828 (December 29, 2020) (Notice of Filing and Immediate Effectiveness of SR-NYSEArca-2020-112).

¹³ Information about the continued impact of COVID–19 on FINRA-administered examinations is available at https://www.finra.org/rules-guidance/key-topics/covid-19/exams.

¹⁴ Information from Prometric about its safety practices and the impact of COVID–19 on its operations is available at https://www.prometric.com/covid-19-update/corona-virus-update.See also supra note 13.

¹⁵ See, e.g., Centers for Disease Control and Prevention, How to Protect Yourself & Others, https://www.cdc.gov/coronavirus/2019-ncov/ prevent-getting-sick/prevention.html.

availability of online examinations. Prior to this expansion, the ongoing effects of the pandemic made it impracticable for FINRA members to ensure that the individuals who they had designated to function in a principal capacity, as set forth in FINRA Rule 1210.04, could successfully sit for and pass an appropriate qualification examination within the 120-calendar day period required under the rule.16 Specifically, if the individual wanted to take a qualifying examination, they were required to accept the health risks associated with taking an in-person examination because those examinations were not available online. On February 24, 2021, however, FINRA adopted an interim accommodation request process to allow candidates to take additional FINRA examinations online, including the General Securities Principal ("Series 24") examination. 17 Because the qualifying examination has been made available online only recently, FINRA is concerned that individuals who have been designated to function in a principal capacity may not have sufficient time to schedule, study for, and take the applicable examination before April 30, 2021, the date the temporary relief is set to expire.

These ongoing circumstances make it impracticable for Members to ensure that the individuals whom they have designated to function in a principal capacity, as set forth in NYSE Arca Rule 2.1210.03, are able to successfully sit for and pass an appropriate qualification examination within the 120-calendar day period required under the rule, or to find other qualified staff to fill this position. Therefore, NYSE Arca is proposing to extend the effective date of the temporary relief provided through SR-NYSEArca-2020-112 until June 30, 2021. The proposed rule change would apply only to those individuals who were designated to function as a principal prior to March 3, 2021. Any individuals designated to function as a principal on or after March 3, 2021, would need to successfully pass an appropriate qualification examination within 120 days.

NYSE Arca believes that this proposed continued extension of time is tailored to address the needs and constraints on a Member's operations during the COVID–19 pandemic, without significantly compromising critical investor protection. The proposed extension of time will help to minimize the impact of COVID–19 on Members by providing continued flexibility so that Members can ensure

that principal positions remain filled. The potential risks from the proposed extension of the 120-day period are mitigated by the Member's continued requirement to supervise the activities of these designated individuals and ensure compliance with federal securities laws and regulations, as well as NYSE Arca rules. NYSE Arca has filed the proposed rule change for immediate effectiveness and has requested that the Commission waive the requirement that the proposed rule change not become operative for 30 days after the date of the filing, so NYSE Arca can implement the proposed rule change immediately.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Exchange Act, 18 in general, and furthers the objectives of Section 6(b)(5),19 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 proposed rule change is intended to minimize the impact of COVID-19 on Member operations by extending the 120-day period certain individuals may function as a principal without having successfully passed an appropriate qualification examination under NYSE Arca Rule 2.1210.03 until June 30, 2021. The proposed rule change does not relieve Members from maintaining under the circumstances, a reasonably designed system to supervise the activities of their associated persons to achieve compliance with applicable securities laws and regulations, and with applicable NYSE Arca rules that directly serve investor protection. In a time when faced with unique challenges resulting from the COVID-19 pandemic, NYSE Arca believes that the proposed rule change is a sensible accommodation that will continue to afford Members the ability to ensure that critical positions are filled and client services maintained, while continuing to serve and promote the protection of investors and the public interest in this unique environment.

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 Exchange Act. As set forth in the prior filings, the proposed rule change is intended solely to extend temporary relief necessitated by the continued impacts of the COVID-19 pandemic and the related health and safety risks of conducting in-person activities. In its filing, FINRA noted that the proposed rule change is necessary to temporarily rebalance the attendant benefits and costs of the obligations under FINRA Rule 1210 in response to the impacts of the COVID-19 pandemic that would otherwise result if the temporary relief was to expire on April 30, 2021. The Exchange accordingly incorporates FINRA's abbreviated economic impact assessment by reference.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act ²⁰ and Rule 19b–4(f)(6) thereunder.²¹

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b–4(f)(6)(iii), the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become

¹⁸ 15 U.S.C. 78f(b).

^{19 15} U.S.C. 78f(b)(5).

²⁰ 15 U.S.C. 78s(b)(3)(A).

²¹ 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.

¹⁶ See supra note 13. ¹⁷ Id.

operative immediately upon filing. As noted above, the Exchange stated that the conditions necessitating the temporary relief continue to exist and the proposed extension of time will help minimize the impact of the COVID-19 outbreak on NYSE Arca Members operations by allowing them to keep principal positions filled and minimizing disruptions to client services and other critical responsibilities. Despite signs of improvement, the Exchange further stated that the ongoing extenuating circumstances of the COVID-19 pandemic make it impractical to ensure that individuals designated to act in these capacities are able to take and pass the appropriate qualification examination during the 120-calendar day period required under the rules.

The Exchange observed that, following a nationwide closure of all test centers earlier in the year, some test centers have re-opened, but are operating at limited capacity or are only delivering certain examinations that have been deemed essential by the local government.²² However, on February 24, 2021, FINRA began providing the General Securities Principal (Series 24) Examination online through an interim accommodation request process.23 Prior to this change, if individuals wanted to take these qualifying examinations, they were required to accept the health risks associated with taking an in-person examination. Even with the expansion of online qualifications examinations, the Exchange stated that extending the expiration date of the relief set forth in SR-NYSEArca-2020-112 until June 30, 2021 is still needed. The Exchange stated that this temporary relief will provide flexibility to allow individuals who have been designated to function in a principal sufficient time to schedule, study for and take the applicable examination before the temporary relief expires. Notably, the Exchange stated that it does not anticipate providing any further extensions to the temporary amendments and that any individuals designated to function as a principal on or after March 3, 2021 will need to successfully pass an appropriate qualification examination within 120 days.

For these reasons, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest.²⁴ Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.²⁵

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (http://www.sec.gov/rules/sro.shtml); or
- Send an email to *rule-comments@* sec.gov. Please include File Number SR–NYSEArca–2021–30 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-2021-30. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (http://www.sec.gov/ rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the

proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSEArca-2021-30 and should be submitted on or before May 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. 26

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021-09436 Filed 5-4-21; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-91731; File No. SR-NYSECHX-2021-08]

Self-Regulatory Organizations; NYSE Chicago, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending the Fee Schedule of NYSE Chicago, Inc.

April 29, 2021.

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 April 16, 2021, 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.

²² See supra notes 13 and 14. The Exchange states that Prometric has also had to close some reopened test centers due to incidents of COVID-19 cases.

²³ See supra note 13 (including the February 24, 2021 announcement of the interim accommodation process for candidates to take certain examinations, including the General Securities Principal (Series 24) Examination, online.)

²⁴ As noted above by the Exchange, this proposal is an extension of temporary relief provided in SR–NYSEArca–2020–87 and SR–NYSEArca–2020–112 where the Exchange also requested and the Commission granted a waiver of the 30-day operative delay. *See* SR–NYSEArca–2020–87, 85 FR at 65112 and SR–NYSEArca–2020–112, 85 FR at 85830.

²⁵ For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

²⁶ 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.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Fee Schedule of NYSE Chicago, Inc. ("Fee Schedule") regarding colocation services and fees to add further specificity as to how monthly fees for dedicated cabinets are calculated. 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 its Fee Schedule regarding colocation services and fees ⁴ to add further specificity as to how monthly fees for dedicated cabinets are calculated. The proposed change is not substantive and would not change the amount or structure of the fees.

The Exchange offers Users ⁵ dedicated and partial cabinets to house their

servers and other equipment.⁶ Each dedicated cabinet has a standard power allocation of either 4 kilowatts ("kW") or 8 kW, but additional power can be added if the User requests.⁷ Users may request that such additional power be allocated to a dedicated cabinet when it is first set up or later.

A User pays a monthly fee based on the power allocated to its dedicated cabinets. As previously indicated,⁸ the tiered fee is based on the total kWs allocated to all of a User's dedicated cabinets, not the kWs allocated to an individual dedicated cabinet. For example, a User that has two dedicated cabinets with a total power allocation of 12 kW has a monthly charge of \$1,200 per kW for the first eight kW and \$1,050 per kW for the next four kW (between 9 kW and 12 kW), for a total of \$13,800, irrespective of how the User divides the 12 kW between its two cabinets.

To further clarify how the fees are calculated, in a non-substantive change, the Exchange proposes to make the following edits to the Fee Schedule:

- Revise the title "Monthly Fee per Cabinet" to read "Monthly Fee for Cabinets"; and
- under the heading "Dedicated Cabinet," add the following text: "Monthly fee is based on total kWs allocated to all of a User's dedicated cabinets".

The Exchange does not propose to change the fees.

Application and Impact of the Proposed Changes

The proposed change is not expected to have any impact on Users. Users are currently subject to the described services and fees, none of which is new or novel. Current Users would not incur any new or changed fees and the Exchange does not expect to attract any new Users as a result of the proposed change. The change would simply add clarity to the Fee Schedule concerning the monthly fee for dedicated cabinets.

The proposed change is not targeted at, or expected to be limited in applicability to, a specific segment of market participant, as colocation is available to any market participant that wishes to be a User.

The proposed change is not otherwise intended to address any other issues, and the Exchange is not aware of any problems that member organizations would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,9 in general, and furthers the objectives of Section 6(b)(5) of the Act,10 in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange further believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,¹¹ because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed rule change is reasonable because it would add clarity to the Fee Schedule regarding how the monthly fee for dedicated cabinets is calculated, clarifying that the monthly fee for dedicated cabinets is based on the aggregate number of kW allocated to all the User's dedicated cabinets, and not charged on a per-cabinet basis. It would add detail previously stated in rule filings with the Commission 12 to the Fee Schedule. Doing so would remove impediments to, and perfecting the mechanisms of, a free and open market and a national market system and, in general, protecting investors and the public interest because the change would add clarity and transparency to the Exchange rules, alleviating potential investor or market participant confusion.

The proposed change is equitable, as it would add clarity for all market participants with respect to how the monthly fee for dedicated cabinets is calculated. At the same time, it is a non-substantive change that would not impact the services available to Users or

⁴ The Exchange initially filed rule changes relating to its co-location services with the Securities and Exchange Commission ("Commission") in 2019. See Securities Exchange Act Release No. 87408 (October 28, 2019), 84 FR 58778 (November 1, 2019) (SR–NYSECHX–2019–27). The Exchange is an indirect subsidiary of Intercontinental Exchange, Inc. ("ICE"). Through its ICE Data Services business, ICE operates a data center in Mahwah, New Jersey, from which the Exchange provides co-location services to Users.

⁵ For purposes of the Exchange's co-location services, a "User" means any market participant that requests to receive co-location services directly from the Exchange. See id., at note 6. As specified in the Fee Schedule, a User that incurs co-location fees for a particular co-location service pursuant thereto would not be subject to co-location fees for the same co-location service charged by the Exchange's affiliates New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., and NYSE National, Inc. (together, the "Affiliate SROs"). Each Affiliate SRO has submitted substantially the same proposed rule change to propose the changes described herein. See SR—

 $[\]label{eq:NYSE-2021-26} NYSE-2021-26, SR-NYSEAMER-2021-22, SR-NYSEArca-2021-26, and SR-NYSENAT-2021-10.$

 $^{^6\,}See$ Securities Exchange Act Release No. 84 FR 58778, supra note 4.

⁷Presently, the maximum amount of power that can be allocated to one dedicated cabinet is 15 kW.

⁸ See Securities Exchange Act Release No. 65237 (August 31, 2011), 76 FR 55432 (September 7, 2011) (SR-NYSE-2011-46).

^{9 15} U.S.C. 78f(b).

^{10 15} U.S.C. 78f(b)(5).

^{11 15} U.S.C. 78f(b)(4).

¹² See 76 FR 55432, supra note 8.

the fees charged for such services. The Exchange does not expect to attract any new Users as a result of the proposed change. The proposed change is not expected to have any impact on Users. Users are currently subject to the described services and fees, none of which is new or novel.

For the reasons above, the proposed changes do not unfairly discriminate between or among market participants that are otherwise capable of satisfying any applicable colocation fees, requirements, terms, and conditions established from time to time by the Exchange.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,13 the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act because it is ministerial in nature and is not designed to have any competitive impact. Rather, the change would simply add clarity to the Fee Schedule regarding how the monthly fee for dedicated cabinets is calculated, clarifying that the monthly fee for dedicated cabinets is based on the aggregate number of kW allocated to all the User's dedicated cabinets, and not charged on a per-cabinet basis. The change would add clarity and transparency to the Exchange rules, alleviating potential investor or market participant confusion.

For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

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 Act ¹⁴ and Rule 19b–4(f)(6) thereunder. ¹⁵ 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.¹⁶

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) ¹⁷ 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 (http://www.sec.gov/rules/sro.shtml); or
- Send an email to *rule-comments@* sec.gov. Please include File Number SR-NYSECHX-2021-08 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–2021–08. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (http://www.sec.gov/rules/sro.shtml). Copies of the submission, all subsequent

amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSECHX-2021-08 and should be submitted on or before May

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority, 18

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021-09450 Filed 5-4-21; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-91713; File No. SR-NYSEArca-2021-26]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending the NYSE Arca Options Fees and Charges and the NYSE Arca Equities Fees and Charges Schedules

April 29, 2021.

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 April 16, 2021, 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

^{13 15} U.S.C. 78f(b)(8).

¹⁴ 15 U.S.C. 78s(b)(3)(A)(iii).

^{15 17} CFR 240.19b-4(f)(6).

^{16 17} CFR 240.19b—4(f)(6). In addition, Rule 19b—4(f)(6) requires the Exchange 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.

^{17 15} U.S.C. 78s(b)(2)(B).

¹⁸ 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.

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 the NYSE Arca Options Fees and Charges and the NYSE Arca Equities Fees and Charges (together, the "Fee Schedules") regarding colocation services and fees to add further specificity as to how monthly fees for dedicated cabinets are calculated. 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 its Fee Schedules regarding colocation services and fees ⁴ to add further specificity as to how monthly fees for dedicated cabinets are calculated. The proposed change is not substantive and would not change the amount or structure of the fees.

The Exchange offers Users ⁵ dedicated and partial cabinets to house their

servers and other equipment.⁶ Each dedicated cabinet has a standard power allocation of either 4 kilowatts ("kW") or 8 kW, but additional power can be added if the User requests.⁷ Users may request that such additional power be allocated to a dedicated cabinet when it is first set up or later.

A User pays a monthly fee based on the power allocated to its dedicated cabinets. As previously indicated,8 the tiered fee is based on the total kWs allocated to all of a User's dedicated cabinets, not the kWs allocated to an individual dedicated cabinet. For example, a User that has two dedicated cabinets with a total power allocation of 12 kW has a monthly charge of \$1,200 per kW for the first eight kW and \$1,050 per kW for the next four kW (between 9 kW and 12 kW), for a total of \$13,800, irrespective of how the User divides the 12 kW between its two cabinets.

To further clarify how the fees are calculated, in a non-substantive change, the Exchange proposes to make the following edits to the Fee Schedules:

- Revise the title "Monthly Fee per Cabinet" to read "Monthly Fee for Cabinets"; and
- under the heading "Dedicated Cabinet," add the following text: "Monthly fee is based on total kWs allocated to all of a User's dedicated cabinets".

The Exchange does not propose to change the fees.

Application and Impact of the Proposed Changes

The proposed change is not expected to have any impact on Users. Users are currently subject to the described services and fees, none of which is new or novel. Current Users would not incur any new or changed fees and the Exchange does not expect to attract any new Users as a result of the proposed change. The change would simply add clarity to the Fee Schedules concerning the monthly fee for dedicated cabinets.

The proposed change is not targeted at, or expected to be limited in

applicability to, a specific segment of market participant, as colocation is available to any market participant that wishes to be a User.

The proposed change is not otherwise intended to address any other issues, and the Exchange is not aware of any problems that member organizations would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,9 in general, and furthers the objectives of Section 6(b)(5) of the Act,10 in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange further believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,¹¹ because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed rule change is reasonable because it would add clarity to the Fee Schedules regarding how the monthly fee for dedicated cabinets is calculated, clarifying that the monthly fee for dedicated cabinets is based on the aggregate number of kW allocated to all the User's dedicated cabinets, and not charged on a per-cabinet basis. It would add detail previously stated in rule filings with the Commission 12 to the Fee Schedules. Doing so would remove impediments to, and perfecting the mechanisms of, a free and open market and a national market system and, in general, protecting investors and the public interest because the change would add clarity and transparency to the Exchange rules, alleviating potential

⁴ The Exchange initially filed rule changes relating to its co-location services with the Securities and Exchange Commission ("Commission") in 2010. See Securities Exchange Act Release No. 63275 (November 8, 2010), 75 FR 70048 (November 16, 2010) (SR–NYSEArca–2010–100). The Exchange is an indirect subsidiary of Intercontinental Exchange, Inc. ("ICE"). Through its ICE Data Services business, ICE operates a data center in Mahwah, New Jersey, from which the Exchange provides co-location services to Users.

⁵For purposes of the Exchange's co-location services, a "User" means any market participant that requests to receive co-location services directly from the Exchange. See Securities Exchange Act Release No. 76010 (September 29, 2015), 80 FR 60197 (October 5, 2015) (SR–NYSEArca–2015–82). As specified in the Fee Schedules, a User that incurs co-location fees for a particular co-location

service pursuant thereto would not be subject to colocation fees for the same co-location service charged by the Exchange's affiliates New York Stock Exchange LLC, NYSE American LLC, NYSE Chicago, Inc., and NYSE National, Inc. (together, the "Affiliate SROs"). Each Affiliate SRO has submitted substantially the same proposed rule change to propose the changes described herein. See SR–NYSE–2021–26, SR–NYSEAMER–2021–22, SR–NYSECHX–2021–08, and SR–NYSENAT–2021–10.

⁶ See Securities Exchange Act Release No. 71130 (December 18, 2013), 78 FR 77765 (December 24, 2013) (SR-NYSEArca-2013-143).

 $^{^{7}}$ Presently, the maximum amount of power that can be allocated to one dedicated cabinet is 15 kW.

⁸ See Securities Exchange Act Release No. 65236 (August 31, 2011), 76 FR 55437 (September 7, 2011) (SR-NYSEArca-2011-65).

^{9 15} U.S.C. 78f(b).

^{10 15} U.S.C. 78f(b)(5).

^{11 15} U.S.C. 78f(b)(4).

¹² See 76 FR 55437, supra note 8.

investor or market participant confusion.

The proposed change is equitable, as it would add clarity for all market participants with respect to how the monthly fee for dedicated cabinets is calculated. At the same time, it is a non-substantive change that would not impact the services available to Users or the fees charged for such services. The Exchange does not expect to attract any new Users as a result of the proposed change. The proposed change is not expected to have any impact on Users. Users are currently subject to the described services and fees, none of which is new or novel.

For the reasons above, the proposed changes do not unfairly discriminate between or among market participants that are otherwise capable of satisfying any applicable colocation fees, requirements, terms, and conditions established from time to time by the Exchange.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act, 13 the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act because it is ministerial in nature and is not designed to have any competitive impact. Rather, the change would simply add clarity to the Fee Schedules regarding how the monthly fee for dedicated cabinets is calculated, clarifying that the monthly fee for dedicated cabinets is based on the aggregate number of kW allocated to all the User's dedicated cabinets, and not charged on a per-cabinet basis. The change would add clarity and transparency to the Exchange rules, alleviating potential investor or market participant confusion.

For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

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 Act 14 and Rule 19b-4(f)(6) thereunder. 15 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.16

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) ¹⁷ 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 (http://www.sec.gov/rules/sro.shtml); or
- Send an email to *rule-comments@* sec.gov. Please include File Number SR-NYSEArca-2021-26 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-2021-26. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (http://www.sec.gov/ rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSEArca-2021-26 and should be submitted on or before May 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁸

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–09442 Filed 5–4–21; 8:45 am]

BILLING CODE 8011-01-P

^{13 15} U.S.C. 78f(b)(8).

¹⁴ 15 U.S.C. 78s(b)(3)(A)(iii).

^{15 17} CFR 240.19b-4(f)(6).

¹⁶ 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires the Exchange 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.

¹⁷ 15 U.S.C. 78s(b)(2)(B).

^{18 17} CFR 200.30-3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-91711; File No. SR-NYSE-2021-26]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending the New York Stock Exchange Price List

April 29, 2021.

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 April 16, 2021, New York Stock Exchange LLC ("NYSE" or the "Exchange") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the New York Stock Exchange Price List ("Price List") regarding colocation services and fees to add further specificity as to how monthly fees for dedicated cabinets are calculated. 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 its Price List regarding colocation services and fees ⁴ to add further specificity as to how monthly fees for dedicated cabinets are calculated. The proposed change is not substantive and would not change the amount or structure of the fees.

The Exchange offers Users ⁵ dedicated and partial cabinets to house their servers and other equipment. ⁶ Each dedicated cabinet has a standard power allocation of either 4 kilowatts ("kW") or 8 kW, but additional power can be added if the User requests. ⁷ Users may request that such additional power be allocated to a dedicated cabinet when it is first set up or later.

A User pays a monthly fee based on the power allocated to its dedicated cabinets. As previously indicated, 8 the tiered fee is based on the total kWs allocated to all of a User's dedicated cabinets, not the kWs allocated to an individual dedicated cabinet. For example, a User that has two dedicated cabinets with a total power allocation of 12 kW has a monthly charge of \$1,200 per kW for the first eight kW and \$1,050 per kW for the next four kW (between 9 kW and 12 kW), for a total of \$13,800,

irrespective of how the User divides the 12 kW between its two cabinets.

To further clarify how the fees are calculated, in a non-substantive change, the Exchange proposes to make the following edits to the Price List:

- Revise the title "Monthly Fee per Cabinet" to read "Monthly Fee for Cabinets"; and
- under the heading "Dedicated Cabinet," add the following text: "Monthly fee is based on total kWs allocated to all of a User's dedicated cabinets".

The Exchange does not propose to change the fees.

Application and Impact of the Proposed Changes

The proposed change is not expected to have any impact on Users. Users are currently subject to the described services and fees, none of which is new or novel. Current Users would not incur any new or changed fees and the Exchange does not expect to attract any new Users as a result of the proposed change. The change would simply add clarity to the Price List concerning the monthly fee for dedicated cabinets.

The proposed change is not targeted at, or expected to be limited in applicability to, a specific segment of market participant, as colocation is available to any market participant that wishes to be a User.

The proposed change is not otherwise intended to address any other issues, and the Exchange is not aware of any problems that member organizations would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,9 in general, and furthers the objectives of Section 6(b)(5) of the Act,10 in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange further believes that the

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

^{3 17} CFR 240.19b-4.

⁴The Exchange initially filed rule changes relating to its co-location services with the Securities and Exchange Commission ("Commission") in 2010. See Securities Exchange Act Release No. 62960 (September 21, 2010), 75 FR 59310 (September 27, 2010) (SR–NYSE–2010–56). The Exchange is an indirect subsidiary of Intercontinental Exchange, Inc. ("ICE"). Through its ICE Data Services business, ICE operates a data center in Mahwah, New Jersey, from which the Exchange provides co-location services to Users.

⁵ For purposes of the Exchange's co-location services, a "User" means any market participant that requests to receive co-location services directly from the Exchange. See Securities Exchange Act Release No. 76008 (September 29, 2015), 80 FR 60190 (October 5, 2015) (SR-NYSE-2015-40). As specified in the Price List, a User that incurs colocation fees for a particular co-location service pursuant thereto would not be subject to co-location fees for the same co-location service charged by the Exchange's affiliates NYSE American LLC, NYSE Arca, Inc., NYSE Chicago, Inc., and NYSE National, Inc. (together, the "Affiliate SROs"). Each Affiliate SRO has submitted substantially the same proposed rule change to propose the changes described herein. See SR-NYSEAMER-2021-22, SR-NYSEArca-2021-26, SR-NYSECHX-2021-08, and SR-NYSENAT-2021-10.

⁶ See Securities Exchange Act Release No. 71122 (December 18, 2013), 78 FR 77739 (December 24, 2013) (SR-NYSE-2013-81).

 $^{^{7}}$ Presently, the maximum amount of power that can be allocated to one dedicated cabinet is 15 kW.

⁸ See Securities Exchange Act Release No. 65237 (August 31, 2011), 76 FR 55432 (September 7, 2011) (SR-NYSE-2011-46).

^{9 15} U.S.C. 78f(b).

¹⁰ 15 U.S.C. 78f(b)(5).

proposed rule change is consistent with Section 6(b)(4) of the Act,¹¹ because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed rule change is reasonable because it would add clarity to the Price List regarding how the monthly fee for dedicated cabinets is calculated, clarifying that the monthly fee for dedicated cabinets is based on the aggregate number of kW allocated to all the User's dedicated cabinets, and not charged on a per-cabinet basis. It would add detail previously stated in rule filings with the Commission 12 to the Price List. Doing so would remove impediments to, and perfecting the mechanisms of, a free and open market and a national market system and, in general, protecting investors and the public interest because the change would add clarity and transparency to the Exchange rules, alleviating potential investor or market participant confusion.

The proposed change is equitable, as it would add clarity for all market participants with respect to how the monthly fee for dedicated cabinets is calculated. At the same time, it is a non-substantive change that would not impact the services available to Users or the fees charged for such services. The Exchange does not expect to attract any new Users as a result of the proposed change. The proposed change is not expected to have any impact on Users. Users are currently subject to the described services and fees, none of which is new or novel.

For the reasons above, the proposed changes do not unfairly discriminate between or among market participants that are otherwise capable of satisfying any applicable colocation fees, requirements, terms, and conditions established from time to time by the Exchange.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,¹³ the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act because it is ministerial in nature and is not designed to have any competitive impact. Rather, the change would simply add clarity to the Price List regarding how the monthly fee for dedicated cabinets is calculated, clarifying that the monthly fee for dedicated cabinets is based on the aggregate number of kW allocated to all the User's dedicated cabinets, and not charged on a per-cabinet basis. The change would add clarity and transparency to the Exchange rules, alleviating potential investor or market participant confusion.

For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

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 Act ¹⁴ and Rule 19b-4(f)(6) thereunder.15 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.16

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) ¹⁷ 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 (http://www.sec.gov/rules/sro.shtml); or
- Send an email to *rule-comments@ sec.gov*. Please include File Number SR–NYSE–2021–26 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-2021-26. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (http://www.sec.gov/ rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSE-2021-26 and should be submitted on or before May 26, 2021.

^{11 15} U.S.C. 78f(b)(4).

¹² See 76 FR 55432, supra note 8.

^{13 15} U.S.C. 78f(b)(8).

¹⁴ 15 U.S.C. 78s(b)(3)(A)(iii).

^{15 17} CFR 240.19b-4(f)(6).

^{16 17} CFR 240.19b—4(f)(6). In addition, Rule 19b—4(f)(6) requires the Exchange 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.

^{17 15} U.S.C. 78s(b)(2)(B).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. 18

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–09440 Filed 5–4–21; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-91708; File No. SR-NYSECHX-2021-09]

Self-Regulatory Organizations; NYSE Chicago, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Effective Date in Interpretation and Policy .10 Under NYSE Chicago Article 6, Rule 13

April 29, 2021.

Pursuant to Section 19(b)(1) ¹ of the Securities Exchange Act of 1934 ("Act" or "Exchange Act") ² and Rule 19b–4 thereunder, ³ notice is hereby given that on April 19, 2021, NYSE Chicago, Inc. ("NYSE Chicago" or the "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the 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 a rule change to extend the effective date in Interpretation and Policy .10 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) under NYSE Chicago Article 6, Rule 13 (Registration Requirements) applicable to Participants, from April 30, 2021 to June 30, 2021. The Exchange does not anticipate providing any further extensions to the temporary relief identified in this proposed rule change beyond June 30, 2021.4 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 these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to extend the effective date in Interpretation and Policy .10 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) under NYSE Chicago Article 6, Rule 13 (Registration Requirements) applicable to Participants,⁵ from April 30, 2021 to June 30, 2021. The proposed rule change would extend the 120-day period that certain individuals can function as a principal without having successfully passed an appropriate qualification examination through June 30, 2021, and would apply only to those individuals who were designated to function as a principal prior to March 3, 2021. This proposed rule change is based on a filing recently submitted by the Financial Industry Regulatory Authority, Inc. ("FINRA") 6 and is intended to harmonize the Exchange's registration rules with those of FINRA so as to promote uniform standards across the securities industry

In response to COVID–19 global pandemic, last year FINRA began providing temporary relief by way of frequently asked questions ("FAQs")⁷ to address disruptions to the administration of FINRA qualification examinations caused by the pandemic that have significantly limited the ability of individuals to sit for examinations due to Prometric test center capacity issues.⁸

FINRA published the first FAQ on March 20, 2020, providing that individuals who were designated to function as principals under FINRA Rule 1210.04 9 prior to February 2, 2020, would be given until May 31, 2020, to pass the appropriate principal qualification examination. 10 FINRA revised the FAQ to extend the expiration of the temporary relief to pass the appropriate principal examination until June 30, 2020, and then until August 31, 2020.

On September 25, 2020, NYSE Chicago filed with the Commission a proposed rule change for immediate effectiveness to extend the temporary relief provided via the FAQ by adopting temporary Interpretation and Policy .10 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) under NYSE Chicago Article 6, Rule 13 (Registration Requirements). 11 Pursuant to this rule filing, individuals who were designated prior to September 3, 2020, to function as a principal under Interpretation and Policy .10 of NYSE Chicago Article 6, Rule 13 had until December 31, 2020, to pass the appropriate qualification examination. The Exchange thereafter filed a proposed rule change to extend the expiration date of the temporary relief from December 31, 2020, to April $30, 2021.^{12}$

¹⁸ 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.

⁴ If due to unforeseen circumstances a further extension is necessary, the Exchange will submit a separate rule filing to further extend the temporary relief.

⁵ The term "Participant" means any Participant Firm that holds a valid Trading Permit and any person associated with a Participant Firm who is registered with the Exchange. A Participant shall be considered a "member" of the Exchange for purposes of the Exchange Act. See NYSE Chicago Article 1, Rule 1(s).

⁶ See Exchange Act Release No. 91506 (April 8, 2021) 86 FR 19671 (April 14, 2021) (SR–FINRA–2021–005) (the "FINRA Filing"). The Exchange notes that the FINRA Filing also provides temporary relief to individuals registered with FINRA as Operations Professionals under FINRA Rule 1220. The Exchange does not have a registration category for Operations Professionals and therefore, the Exchange is not proposing to adopt that aspect of the FINRA Filing.

⁷ See https://www.finra.org/rules-guidance/key-topics/covid-19/faq#qe.

⁸ At the outset of the COVID–19 pandemic, all FINRA qualification examinations were administered at test centers operated by Prometric. Based on the health and welfare concerns resulting from COVID–19, in March 2020 Prometric closed all of its test centers in the United States and Canada and began to slowly reopen some of them at limited capacity in May. Currently, Prometric has resumed testing in many of its United States and Canada test centers, at either full or limited occupancy, based on local and government mandates.

⁹Interpretation and Policy .03 under NYSE Chicago Article 6, Rule 13 is the corresponding rule to FINRA Rule 1210.04.

¹⁰ FINRA Rule 1210.04 (Requirements for Registered Persons Functioning as Principals for a Limited Period) allows a member firm to designate certain individuals to function in a principal capacity for 120 calendar days before having to pass an appropriate principal qualification examination Interpretation and Policy .03 under NYSE Chicago Article 6, Rule 13 provides the same allowance to Participants.

¹¹ See Exchange Act Release No. 90114 (October 7, 2020), 85 FR 64556 (October 13, 2020) (Notice of Filing and Immediate Effectiveness of SR–NYSECHX–2020–28).

¹² See Exchange Act Release No. 90762 (December 21, 2020), 85 FR 85756 (December 29, 2020) (Notice of Filing and Immediate Effectiveness of SR-NYSECHX-2020-33).

As mentioned in the prior filings, FINRA began providing, and then extended, temporary relief to address the interruptions in the administration of FINRA qualification examinations at Prometric test centers and the limited ability of individuals to sit for the examinations caused by the COVID-19 pandemic.¹³ The prior filings also noted that the pandemic could result in firms potentially experiencing significant disruptions to their normal business operations that may be exacerbated by being unable to keep principal positions filled. Specifically, the limitation of inperson activities and staff absenteeism as a result of the health and welfare concerns stemming from COVID-19 could result in firms having difficulty finding other qualified individuals to transition into that role or requiring them to reallocate employee time and resources away from other critical responsibilities at the firm.

While there are signs of improvement, the COVID-19 conditions necessitating the temporary relief persist and FINRA has determined that there is a continued need for this temporary relief beyond April 30, 2021. Although Prometric has resumed testing in many of its U.S. test centers, Prometric's safety practices mean that currently not all test centers are open, some of the open test centers are at limited capacity, and some open test centers are delivering only certain examinations that have been deemed essential by the local government.14 In addition, while certain states have started to ease COVID-19 restrictions on businesses and social activities, public health officials continue to emphasize the importance for individuals to keep taking numerous steps to protect themselves and help slow the spread of the disease.15

Although the COVID—19 conditions necessitating the temporary relief persist, in the FINRA Filing, FINRA stated that an extension of the relief is necessary only until June 30, 2021, because FINRA recently expanded the availability of online examinations. Prior to this expansion, the ongoing effects of the pandemic made it impracticable for FINRA members to ensure that the individuals who they

had designated to function in a principal capacity, as set forth in FINRA Rule 1210.04, could successfully sit for and pass an appropriate qualification examination within the 120-calendar day period required under the rule. 16 Specifically, if the individual wanted to take a qualifying examination, they were required to accept the health risks associated with taking an in-person examination because those examinations were not available online. On February 24, 2021, however, FINRA adopted an interim accommodation request process to allow candidates to take additional FINRA examinations online, including the General Securities Principal ("Series 24") examination. 17 Because the qualifying examination has been made available online only recently, FINRA is concerned that individuals who have been designated to function in a principal capacity may not have sufficient time to schedule, study for, and take the applicable examination before April 30, 2021, the date the temporary relief is set to expire.

These ongoing circumstances make it impracticable for Participants to ensure that the individuals whom they have designated to function in a principal capacity, as set forth in Interpretation and Policy .03 under Article 6, Rule 13, are able to successfully sit for and pass an appropriate qualification examination within the 120-calendar day period required under the rule, or to find other qualified staff to fill this position. Therefore, NYSE Chicago is proposing to extend the effective date of the temporary relief provided through SR-NYSECHX-2020-33 until June 30, 2021. The proposed rule change would apply only to those individuals who were designated to function as a principal prior to March 3, 2021. Any individuals designated to function as a principal on or after March 3, 2021, would need to successfully pass an appropriate qualification examination within 120 days.

NYSE Chicago believes that this proposed continued extension of time is tailored to address the needs and constraints on a Participant's operations during the COVID–19 pandemic, without significantly compromising critical investor protection. The proposed extension of time will help to minimize the impact of COVID–19 on Participants by providing continued flexibility so that Participants can ensure that principal positions remain filled. The potential risks from the proposed extension of the 120-day period are mitigated by the Participant's

continued requirement to supervise the activities of these designated individuals and ensure compliance with federal securities laws and regulations, as well as NYSE Chicago rules. NYSE Chicago has filed the proposed rule change for immediate effectiveness and has requested that the Commission waive the requirement that the proposed rule change not become operative for 30 days after the date of the filing, so NYSE Chicago can implement the proposed rule change immediately.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Exchange Act,18 in general, and furthers the objectives of Section 6(b)(5),19 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 proposed rule change is intended to minimize the impact of COVID-19 on Participants' operations by extending the 120-day period certain individuals may function as a principal without having successfully passed an appropriate qualification examination under Interpretation and Policy .03 under Article 6, Rule 13 until June 30, 2021. The proposed rule change does not relieve Participants from maintaining, under the circumstances, a reasonably designed system to supervise the activities of their associated persons to achieve compliance with applicable securities laws and regulations, and with applicable NYSE Chicago rules that directly serve investor protection. In a time when faced with unique challenges resulting from the COVID-19 pandemic, NYSE Chicago believes that the proposed rule change is a sensible accommodation that will continue to afford Participants the ability to ensure that critical positions are filled and client services maintained, while continuing to serve and promote the protection of investors and the public interest in this unique environment.

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

¹³ Information about the continued impact of COVID–19 on FINRA-administered examinations is available at https://www.finra.org/rules-guidance/key-topics/covid-19/exams.

¹⁴ Information from Prometric about its safety practices and the impact of COVID-19 on its operations is available at https://www.prometric.com/covid-19-update/corona-virus-update. See also supra note 13.

¹⁵ See, e.g., Centers for Disease Control and Prevention, How to Protect Yourself & Others, https://www.cdc.gov/coronavirus/2019-ncov/ prevent-getting-sick/prevention.html.

¹⁶ See supra note 13.

¹⁷ Id.

^{18 15} U.S.C. 78f(b).

^{19 15} U.S.C. 78f(b)(5).

necessary or appropriate in furtherance of the purposes of the Exchange Act. As set forth in the prior filings, the proposed rule change is intended solely to extend temporary relief necessitated by the continued impacts of the COVID-19 pandemic and the related health and safety risks of conducting in-person activities. In its filing, FINRA noted that the proposed rule change is necessary to temporarily rebalance the attendant benefits and costs of the obligations under FINRA Rule 1210 in response to the impacts of the COVID-19 pandemic that would otherwise result if the temporary relief was to expire on April 30, 2021. The Exchange accordingly incorporates FINRA's abbreviated economic impact assessment by reference.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act ²⁰ and Rule 19b–4(f)(6) thereunder.²¹

A proposed rule change filed under Rule 19b-4(f)(6) normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b-4(f)(6)(iii), the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative immediately upon filing. As noted above, the Exchange stated that the conditions necessitating the temporary relief continue to exist and the proposed extension of time will help minimize the impact of the COVID-19

outbreak on NYSE Chicago Participants' operations by allowing them to keep principal positions filled and minimizing disruptions to client services and other critical responsibilities. Despite signs of improvement, the Exchange further stated that the ongoing extenuating circumstances of the COVID–19 pandemic make it impractical to ensure that individuals designated to act in these capacities are able to take and pass the appropriate qualification examination during the 120-calendar day period required under the rules.

The Exchange observed that, following a nationwide closure of all test centers earlier in the year, some test centers have re-opened, but are operating at limited capacity or are only delivering certain examinations that have been deemed essential by the local government.²² However, on February 24, 2021, FINRA began providing the General Securities Principal (Series 24) Examination online through an interim accommodation request process.²³ Prior to this change, if individuals wanted to take these qualifying examinations, they were required to accept the health risks associated with taking an in-person examination. Even with the expansion of online qualifications examinations, the Exchange stated that extending the expiration date of the relief set forth in SR-NYSECHX-2020-33 until June 30, 2021 is still needed. The Exchange stated that this temporary relief will provide flexibility to allow individuals who have been designated to function in a principal sufficient time to schedule, study for and take the applicable examination before the temporary relief expires. Notably, the Exchange stated that it does not anticipate providing any further extensions to the temporary amendments and that any individuals designated to function as a principal on or after March 3, 2021 will need to successfully pass an appropriate qualification examination within 120 days.

For these reasons, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest.²⁴ Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.²⁵

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (http://www.sec.gov/rules/sro.shtml); or
- Send an email to *rule-comments@* sec.gov. Please include File Number SR–NYSECHX–2021–09 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-2021-09. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (http://www.sec.gov/ rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and

²⁰ 15 U.S.C. 78s(b)(3)(A).

²¹17 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.

 $^{^{22}\,}See~supra$ notes 13 and 14. The Exchange notes that Prometric has also had to close some reopened test centers due to incidents of COVID–19 cases.

²³ See supra note 13 (including the February 24, 2021 announcement of the interim accommodation process for candidates to take certain examinations, including the General Securities Principal (Series 24) Examination, online.)

²⁴ As noted above by the Exchange, this proposal is an extension of temporary relief provided in SR-NYSECHX-2020-28 and SR-NYSECHX-2020-33 where the Exchange also requested and the Commission granted a waiver of the 30-day

operative delay. See SR-NYSECHX-2020-28, 85 FR at 64558 and SR-NYSECHX-2020-33, 85 FR at 85758.

²⁵ For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSECHX-2021-09 and should be submitted on or before May 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. $^{26}\,$

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–09437 Filed 5–4–21; 8:45 am] BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91703; File No. SR–MIAX–2021–13]

Self-Regulatory Organizations; Miami International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Interpretation and Policy .13 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) To Exchange Rule 1900, Registration Requirements, To Extend the Expiration Date of the Temporary Amendment Set Forth in SR-MIAX-2020-42 from April 30, 2021 to June 30, 2021

April 29, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act" or "Exchange Act") ¹ and Rule 19b–4 thereunder, ² notice is hereby given that on April 21, 2021, Miami International Securities Exchange, LLC ("MIAX" or the "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been substantially 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 is filing a proposal to amend Interpretation and Policy .13 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) to Exchange Rule 1900, Registration Requirements, to extend the expiration date of the temporary amendment set forth in SR–MIAX–2020–42 from April 30, 2021 to June 30, 2021. The Exchange does not anticipate providing any further extensions to the temporary amendment identified in this proposed rule change beyond June 30, 2021.

The text of the proposed rule change is available on the Exchange's website at http://www.miaxoptions.com/rule-filings/, at MIAX's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Interpretation and Policy .13 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) to Exchange Rule 1900, Registration Requirements, to extend the expiration date of the temporary amendment set forth in SR-MIAX-2020-42 from April 30, 2021 to June 30, 2021. The proposed rule change would extend the 120-day period that certain individuals can function as principals without having successfully passed an appropriate qualification examination through June 30, 2021,3 and would apply only to

those individuals who were designated to function as principals prior to March 3, 2021. This proposed rule change is based on a filing recently submitted by the Financial Industry Regulatory Authority, Inc. ("FINRA") ⁴ and is intended to harmonize the Exchange's registration rules with those of FINRA so as to promote uniform standards across the securities industry.

In response to the COVID–19 global pandemic, last year FINRA began providing temporary relief by way of frequently asked questions ("FAQs") ⁵ to address disruptions to the administration of FINRA qualification examinations caused by the pandemic that have significantly limited the ability of individuals to sit for examinations due to Prometric test center capacity issues.⁶

FINRA published the first FAQ on March 20, 2020, providing that individuals who were designated to function as principals under FINRA Rule 1210.04 7 prior to February 2, 2020, would be given until May 31, 2020, to pass the appropriate principal qualification examination.8 On May 19, 2020, FINRA extended the relief to pass the appropriate examination until June 30, 2020. On June 29, 2020, FINRA again extended the temporary relief providing that individuals who were designated to function as principals under FINRA Rule 1210.04 prior to May 4, 2020, would be given until August 31,

notes that the FINRA Filing also provides temporarily relief to individuals registered with FINRA as Operations Professionals under FINRA Rule 1220. The Exchange does not have a registration category for Operations Professionals and therefore, the Exchange is not proposing to adopt that aspect of the FINRA Filing. If the Exchange seeks to provide additional temporary relief from the rule requirement identified in this proposal beyond June 30, 2021, it will submit a separate rule filing to further extend the temporary extension of time.

²⁶ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Exchange Act Release No. 91506 (April 8, 2021) 86 FR 19671 (April 14, 2021) (SR–FINRA–2021–005) (the "FINRA Filing"). The Exchange

⁴ See id.

⁵ See https://www.finra.org/rules-guidance/key-topics/covid-19/faq#qe.

⁶At the outset of the COVID–19 pandemic, all FINRA qualification examinations were administered at test centers operated by Prometric. Based on the health and welfare concerns resulting from COVID–19, in March 2020 Prometric closed all of its test centers in the United States and Canada and began to slowly reopen some of them at limited capacity in May. Currently, Prometric has resumed testing in many of its United States and Canada test centers, at either full or limited occupancy, based on local and government mandates.

⁷ Exchange Rule 1900, Interpretation and Policy .04, is the corresponding rule to FINRA Rule 1210.04.

⁸ FINRA Rule 1210.04 (Requirements for Registered Persons Functioning as Principals for a Limited Period) allows a FINRA-member firm to designate certain individuals to function in a principal capacity for 120 calendar days before having to pass an appropriate principal qualification examination. Exchange Rule 1900, Interpretation and Policy .04, provides the same allowance to Exchange Members.

2020, to pass the appropriate principal qualification examination. On August 28, 2020, FINRA filed with the Commission a proposed rule change for immediate effectiveness to extend the temporary relief provided via the two FAQs by adopting: (1) Temporary Supplementary Material .12 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) under FINRA Rule 1210 (Registration Requirements), and (2) temporary Supplementary Material .07 (Temporary Extension of the Limited Period for Persons to Function as Operations Professionals) under FINRA Rule 1220 (Registration Categories).9 Pursuant to this rule filing, individuals who were designated prior to September 3, 2020, to function as a principal under FINRA Rule 1210.04 would have until December 31, 2020, to pass the appropriate qualification examination.

Thereafter, on December 9, 2020, FINRA filed with the Commission a proposed rule change for immediate effectiveness to extend the limited period for registered persons to function as a principal through April 30, 2021.10 Pursuant to this rule filing, individuals who were designated prior to January 1, 2021 to function as a principal would have until April 30, 2021 to pass the appropriate qualifying examination. On December 28, 2020, the Exchange filed with the Commission a proposed rule change for immediate effectiveness to extend the limited period for registered persons to function as a principal through April 30, 2021.¹¹

The Exchange continues to closely monitor the impact of the COVID-19 pandemic on Members,12 investors, and other stakeholders. The Exchange initially provided temporary relief to address the interruptions in the administration of FINRA qualification examinations at Prometric test centers and the limited ability of individuals to sit for the examinations caused by the COVID-19 pandemic. 13 As mentioned in the FINRA Filing (SR–FINRA–2021–

005), FINRA noted that the pandemic could result in firms potentially experiencing significant disruptions to their normal business operations that may be exacerbated by being unable to keep principal positions filled. Specifically, FINRA noted that the limitation of in-person activities and staff absenteeism as a result of the health and welfare concerns stemming from COVID-19 could result in firms having difficulty finding other qualified individuals to transition into those roles or requiring them to reallocate employee time and resources away from other critical responsibilities at the firm's organization.

While there are signs of improvement, the COVID-19 conditions necessitating the temporary relief persist and the Exchange has determined that there is a continued need for this temporary relief beyond April 30, 2021. Although Prometric has resumed testing in many of its U.S. test centers, Prometric's safety practices mean that currently not all test centers are open, some of the open test centers are at limited capacity, and some open test centers are delivering only certain examinations that have been deemed essential by the local government.¹⁴ In addition, while certain states have started to ease COVID-19 restrictions on businesses and social activities, public health officials continue to emphasize the importance for individuals to keep taking numerous steps to protect themselves and help slow the spread of the disease. 15

Although the COVID–19 conditions necessitating the temporary relief persist, the Exchange believes that an extension of the relief is necessary only until June 30, 2021, because FINRA recently expanded the availability of online examinations. Prior to this expansion, the ongoing effects of the pandemic made it impracticable for Members to ensure that the individuals who they had designated to function in a principal capacity, as set forth in Exchange Rule 1900, Interpretation and Policy .04, could successfully sit for and pass an appropriate qualification examination within the 120-calendar day period required under the rules.16 Specifically, if the individual wanted to take a qualifying examination, they were required to accept the health risks associated with taking an in-person

examination because those examinations were not available online. On February 24, 2021, however, FINRA adopted an interim accommodation request process to allow candidates to take additional FINRA examinations online, including the General Securities Principal ("Series 24") and Operations Professional ("Series 99") examinations.¹⁷ Because the Series 24 qualifying examination has been made available online only recently, the Exchange is concerned that individuals who have been designated to function in a principal capacity may not have sufficient time to schedule, study for, and take the applicable examination before April 30, 2021, the date the temporary amendment is set to expire. Therefore, the Exchange proposes to extend the expiration date of the temporary amendment set forth in Exchange Rule 1900, Interpretation and Policy .13, from April 30, 2021 until June 30, 2021. The proposed rule change would apply only to those individuals who have been designated to function as a principal prior to March 3, 2021. As noted above, the Exchange does not anticipate providing any further extensions to the temporary amendment and any individuals designated to function as a principal on or after March 3, 2021, will need to successfully pass an appropriate qualification examination within 120 days.

The Exchange believes that this proposed continued extension of time is tailored to address the needs and constraints on a Member's operations during the COVID-19 pandemic, without significantly compromising critical investor protection. The proposed extension of time will help to minimize the impact of COVID-19 on Members by providing continued flexibility so that Members can ensure that principal positions remain filled. The potential risks from the proposed extension of the 120-day period are mitigated by a Member's continued requirement to supervise the activities of these designated individuals and ensure compliance with federal securities laws and regulations, as well as Exchange and FINRA rules.

The Exchange has filed the proposed rule change for immediate effectiveness and has requested that the Commission waive the requirement that the proposed rule change not become operative for 30 days after the date of the filing, so the Exchange can implement the proposed rule change immediately.

⁹ See Exchange Act Release No. 89732 (September 1, 2020), 85 FR 55535 (September 8, 2020) (Notice of Filing and Immediate Effectiveness of File No. SR-FINRA-2020-026).

¹⁰ See Exchange Act Release No. 90617 (December 9, 2020), 85 FR 81258 (December 15, 2020) (SR-FINRA-2020-043).

¹¹ See Exchange Act Release No. 90830 (December 28, 2020), 86 FR 624 (December 30, 2020) (SR-MIAX-2020-42).

¹²The term "Member" means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed "members" under the Exchange Act. See Exchange Rule 100.

¹³ Information about the continued impact of COVID-19 on FINRA-administered examinations is available at https://www.finra.org/rules-guidance/ key-topics/covid-19/exams.

¹⁴ Information from Prometric about its safety practices and the impact of COVID-19 on its operations is available at https://www.prometric. com/corona-virusupdate. See also supra note 13.

¹⁵ See, e.g., Centers for Disease Control and Prevention, How to Protect Yourself & Others. https://www.cdc.gov/coronavirus/2019-ncov/ prevent-gettingsick/prevention.html.

¹⁶ See supra note 13.

¹⁷ Id.

2. Statutory Basis

The Exchange believes that its proposed rule change is consistent with Section 6(b) of the Act 18 in general, and furthers the objectives of Section 6(b)(5) of the Act 19 in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

The proposed rule change is intended to minimize the impact of COVID-19 on Member operations by further extending the 120-day period certain individuals may function as a principal without having successfully passed an appropriate qualification examination under Exchange Rule 1900, Interpretation and Policy .04, until June 30, 2021. The proposed rule change does not relieve Members from maintaining, under the circumstances, a reasonably designed system to supervise the activities of their associated persons to achieve compliance with applicable securities laws and regulations, and with applicable Exchange and FINRA rules that directly serve investor protection. In a time when faced with unique challenges resulting from the COVID–19 pandemic, the Exchange believes that the proposed rule change is a sensible accommodation that will continue to afford Members the ability to ensure that critical positions are filled and client services maintained, while continuing to serve and promote the protection of investors and the public interest in this unique environment.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is intended to provide temporary relief given the impacts of the COVID-19 pandemic crisis and to also maintain consistency with the rules of other self-regulatory organizations ("SROs") with respect to the registration requirements applicable to Members and their registered personnel. In that regard, the Exchange believes that any burden on competition would be clearly outweighed by providing Members with temporary

relief in this unique environment while also ensuring clear and consistent requirements applicable across SROs and mitigating any risk of SROs implementing different standards in these important areas. In its filings, FINRA provides an abbreviated economic impact assessment maintaining that the changes are necessary to temporarily rebalance the attendant benefits and costs of the obligations under FINRA Rule 1210 in response to the impacts of the COVID-19 pandemic that is equally applicable to the changes the Exchange proposes.²⁰ The Exchange accordingly incorporates FINRA's abbreviated economic impact assessment by reference.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act ²¹ and Rule 19b–4(f)(6) thereunder.²²

A proposed rule change filed under Rule 19b-4(f)(6) normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b-4(f)(6)(iii), the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative immediately upon filing. As noted above, the Exchange stated that the conditions necessitating the temporary relief continue to exist and the proposed extension of time will help minimize the impact of the COVID-19

outbreak on Members' operations by allowing them to keep principal positions filled and minimizing disruptions to client services and other critical responsibilities. Despite signs of improvement, the Exchange further stated that the ongoing extenuating circumstances of the COVID–19 pandemic make it impractical to ensure that individuals designated to act in a principal capacity are able to take and pass the appropriate qualification examination during the 120-calendar day period required under the rules.

The Exchange observed that, following a nationwide closure of all test centers earlier in the year, some test centers have re-opened, but are operating at limited capacity or are only delivering certain examinations that have been deemed essential by the local government.²³ However, on February 24, 2021, FINRA began providing the General Securities Principal (Series 24) Examination online through an interim accommodation request process.²⁴ Prior to this change, if individuals wanted to take these qualifying examinations, they were required to accept the health risks associated with taking an in-person examination. Even with the expansion of online qualifications examinations, the Exchange stated that extending the expiration date of the relief set forth in SR-MIAX-2020-42 until June 30, 2021 is still needed. The Exchange stated that this temporary relief will provide flexibility to allow individuals who have been designated to function as a principal sufficient time to schedule, study for and take the applicable examination before the temporary relief expires. Notably, the Exchange stated that it does not anticipate providing any further extensions to the temporary amendment and that any individuals designated to function as a principal on or after March 3, 2021 will need to successfully pass an appropriate qualification examination within 120

For these reasons, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest.²⁵ Accordingly, the Commission

¹⁸ 15 U.S.C. 78f(b).

¹⁹ 15 U.S.C. 78f(b)(5).

 $^{^{20}\,}See~supra$ notes 3 and 10; see also Exchange Act Release No. 89732 (September 1, 2020), 85 FR 55535 (September 8, 2020) (SR–FINRA–2020–26).

²¹ 15 U.S.C. 78s(b)(3)(A).

²² 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.

 $^{^{23}\,}See\ supra$ notes 13 and 14. The Exchange notes that Prometric has also had to close some reopened test centers due to incidents of COVID–19 cases.

²⁴ See supra note 13 (including the February 24, 2021 announcement of the interim accommodation process for candidates to take certain examinations, including the General Securities Principal (Series 24) Examination, online.)

²⁵ As noted above by the Exchange, this proposal is an extension of temporary relief provided in SR–MIAX–2020–42 where the Exchange also requested and the Commission granted a waiver of the 30-day operative delay. See SR–MIAX–2020–42, 86 FR at 626

hereby waives the 30-day operative delay and designates the proposal operative upon filing.²⁶

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (http://www.sec.gov/rules/sro.shtml); or
- Send an email to *rule-comments@* sec.gov. Please include File Number SR–MIAX–2021–13 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-MIAX-2021-13. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (http://www.sec.gov/ rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official

business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MIAX–2021–13 and should be submitted on or before May 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. 27

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–09433 Filed 5–4–21; 8:45 am] BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-91696; File No. SR-Phlx-2021-24]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change to the Exchange's Pricing Schedule at Options 7 To Adopt Pricing for Index Options on the Nasdaq 100 Micro Index

April 28, 2021.

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 April 15, 2021, Nasdaq PHLX LLC ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's Pricing Schedule at Options 7 to adopt pricing for index options on the Nasdaq 100 Micro Index, as described further below.

The text of the proposed rule change is available on the Exchange's website at https://listingcenter.nasdaq.com/rulebook/phlx/rules, at the principal

office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange recently received approval to list index options on the Nasdaq 100 Micro Index ("XND") on a pilot basis.³ XND will be same in all respects as the current Nasdaq 100 Index options contract ("NDX") listed on the Exchange, except it will be based on 1/100th of the value of Nasdaq 100 Index, and will be P.M. settled with an exercise settlement value based on the closing index value of Nasdaq 100 Index on the day of expiration.⁴ The Exchange will begin to list XND on April 15, 2021.

The Exchange now proposes to amend its Pricing Schedule to adopt pricing for XND. By way of background, certain proprietary products such as NDX and NDXP are commonly excluded from a variety of fee programs. The Exchange notes that the reason for such exclusion is because the Exchange has expended considerable resources developing and maintaining its proprietary products. Similar to NDX and NDXP, XND is a proprietary product. As such, the Exchange proposes to establish transaction fees for XND that are similarly structured to the transaction fees for NDX and NDXP with some differences as noted below. The Exchange also proposes to exclude XND from several pricing programs in the same manner as which NDX and NDXP are excluded today.

²⁶ For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. ⁷⁸⁶(f)

^{27 17} CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

 $^{^3\,}See$ Securities Exchange Act Release No. 91524 (April 9, 2021) (SR–Phlx–2021–07).

⁴ *Id.* The Exchange notes that similar features are available with other index options contracts listed on the Exchange, including P.M. settled options on the full value of the Nasdaq-100 Index ("NDXP").

Options 7, Section 1.B

Today, the Customer ⁵ Rebates in Section 1.B of the Pricing Schedule are not paid on NDX or NDXP in any rebate category. However, NDX or NDXP contracts count toward the volume requirement to qualify for a Customer Rebate Tier. The Exchange proposes to apply the Customer Rebate program in the same manner for XND.

Options 7, Section 4

Options Transaction Charges and Surcharges

Today, as set forth in Options 7, Section 4, electronic (both simple and complex orders) and floor Options Transaction Charges for NDX and NDXP are \$0.75 per contract for all Non-Customers.⁶ No Options Transaction Charges for NDX and NDXP apply to Customers. Furthermore, a \$0.25 per contract surcharge is assessed to Non-Customers in NDX and NDXP.

The Exchange now proposes to establish a similar pricing structure for XND where all Non-Customers will be assessed a uniform Options Transaction Charge for electronic (simple and complex orders) and floor transactions, and Customers will not be assessed any Options Transaction Charges. Specifically, the Exchange proposes to assess Non-Customers a uniform electronic and floor Options Transaction Charge of \$0.10 per contract in XND. As noted above, Customers will receive free executions in XND. The Exchange also proposes to assess Non-Customers a surcharge of \$0.10 per contract in XND. The Exchange is proposing to assess a lower Options Transaction Charge and surcharge for XND as compared to NDX and NDXP because XND is based on 1/ 100 of the value of the Nasdaq 100 Index whereas both NDX and NDXP are based on the full value of the Nasdaq 100 Index. The Exchange therefore seeks to assess corresponding reduced fees for XND.

Fee Programs

Today, NDX and NDXP are excluded from a variety of fee programs in Options 7, Section 4. The Exchange proposes to update Options 7, Section 4 to similarly exclude XND from these fee programs. NDX and NDXP are currently excluded from the \$0.12 per contract surcharge assessed to electronic Complex Orders that remove liquidity from the Complex Order Book and auctions, excluding PIXL, in Non-Penny Symbols.⁷ The Exchange proposes to extend this exclusion to XND.

Today, Lead Market Makers ⁸ and Market Makers ⁹ are subject to a "Monthly Market Maker Cap" of \$500,000 for: (i) Electronic Option Transaction Charges, excluding surcharges and excluding options overlying NDX and NDXP; and (ii) QCC Transaction Fees (as defined in Exchange Options 3, Section 12 and Floor QCC Orders, as defined in Options 8, Section 30(e)). The Exchange proposes to similarly exclude XND from the Monthly Market Maker Cap.

Today, Firms ¹⁰ are subject to a maximum fee of \$75,000 ("Monthly Firm Fee Cap") where Firm Floor Option Transaction Charges and QCC Transaction Fees, in the aggregate, for one billing month will not exceed the Monthly Firm Fee Cap per member organization when such members are trading in their own proprietary account. NDX and NDXP transactions are currently excluded from the Monthly Firm Fee Cap. The Exchange proposes to likewise exclude XND transactions from the Monthly Firm Fee Cap.

Cap.

Today, the Exchange waives the Firm Floor Options Transaction Charges in Options 7, Section 4 for members executing facilitation orders pursuant to Options 8, Section 30 when such members are trading in their own proprietary account (including Cabinet Options Transaction Charges). The Firm Floor Options Transaction Charges will be waived for the buy side of a transaction if the same member or its affiliates under Common Ownership 11 represents both sides of a Firm transaction when such members are trading in their own proprietary account. In addition, the Broker-Dealer 12 Floor Options Transaction

Charge (including Cabinet Options Transaction Charges) will be waived for members executing facilitation orders pursuant to Options 8, Section 30 when such members would otherwise incur this charge for trading in their own proprietary account contra to a Customer ("BD-Customer Facilitation"), if the member's BD-Customer Facilitation average daily volume (including both FLEX and non-FLEX transactions) exceeds 10,000 contracts per day in a given month.¹³ NDX and NDXP transactions are currently excluded from each of the waivers set forth in the above paragraph. The Exchange proposes to likewise exclude XND transactions from the foregoing waivers.

Today, transactions in NDX and NDXP are excluded from the "Strategy Caps" in Options 7, Section 4. Strategy Caps limit the fees that otherwise apply to certain categories of market participants when they engage in floor options transactions while employing strategies set forth in the Pricing Schedule, namely dividend, merger, short stock interest, reversal and conversion, jelly roll, or box spread strategies. The Exchange proposes to likewise exclude transactions in XND from Strategy Caps.

Today, no Marketing Fees are assessed on transactions in NDX or NDXP. The Exchange proposes to likewise exclude XND transactions from the Marketing Fees.

Options 7, Section 6
PIXL Pricing

Today, options overlying NDX and NDXP are not subject to Options 7, Section 6.A. PIXL Pricing. 14 The Exchange proposes to likewise exclude XND from PIXL Pricing in Options 7, Section 6.A. Like NDX and NDXP transactions, XND transactions in PIXL will be subject to Options 7, Section 5.A pricing. 15

FLEX Transaction Fees

Today, FLEX options are assessed the transaction fees set forth in Options 7,

⁵ The term "Customer" applies to any transaction that is identified by a member or member organization for clearing in the Customer range at The Options Clearing Corporation ("OCC") which is not for the account of a broker or dealer or for the account of a "Professional" (as that term is defined in Options 1, Section 1(b)(45)).

⁶ The term "Non-Customer" applies to transactions for the accounts of Lead Market Makers, Market Makers, Firms, Professionals, Broker-Dealers and JBOs.

⁷ See Options 7, Section 4, note 7. The Exchange notes that XND, like NDX and NDXP, is a Non-Penny Symbol.

⁸ The term "Lead Market Maker" applies to transactions for the account of a Lead Market Maker (as defined in Options 2, Section 12(a)).

⁹ The term "Market Maker" is defined in Options 1, Section 1(b)(28) as a member of the Exchange who is registered as an options Market Maker pursuant to Options 2, Section 12(a).

¹⁰The term "Firm" applies to any transaction that is identified by a member or member organization for clearing in the Firm range at OCC.

¹¹ The term "Common Ownership" shall mean members or member organizations under 75% common ownership or control.

¹² The term "Broker-Dealer" applies to any transaction which is not subject to any of the other

transaction fees applicable within a particular category.

¹³ The Exchange will correct the typo in the rule text from "BDCustomer Facilitation" to "BD-Customer Facilitation."

 $^{^{14}\,\}mathrm{The}$ Exchange will remove the stray comma from the rule text.

¹⁵ As discussed later in this filing, the Exchange is also proposing to relocate NDX and NDXP pricing from Options 7, Section 4 into a separate schedule with XND pricing within Options 7, Section 5.A. Accordingly, the current reference to Options 7, Section 4 NDX and NDXP pricing within the PIXL pricing schedule will be updated to Options 7, Section 5.A.

Section 6.B. ¹⁶ Pursuant to this Section 6.B, the NDX and NDXP options surcharge of \$0.25 per contract applies to FLEX NDX and NDXP options for all Non-Customers. ¹⁷ Furthermore, the NDX and NDXP Options Transaction Charges of \$0.75 per contract (Non-Customer) and \$0.00 per contract (Customer) currently within Options 7, Section 4 apply to FLEX NDX and NDXP options. ¹⁸

The Exchange proposes to charge FLEX XND options in a similar manner. Specifically, the Exchange will apply the proposed XND options surcharge of \$0.10 per contract to Non-Customers in FLEX XND options. Further, the Exchange will apply the proposed XND Options Transaction Charges of \$0.10 per contract (Non-Customer) and \$0.00

per contract (Customer) to FLEX XND options.

Market Access and Routing Subsidy ("MARS")

Today, as set forth in Options 7, Section 6.E, the Exchange provides MARS Payments to Phlx members that have System Eligibility ¹⁹ and have routed the requisite number of Eligible Contracts ²⁰ daily in a month, which were executed on Phlx. Currently, NDX and NDXP are not considered Eligible Contracts. Under this proposal, XND will likewise be excluded from Eligible Contracts.

Options 7, Section 5

In connection with the foregoing changes to adopt pricing for XND, the

Exchange proposes to relocate the pricing for NDX and NDXP and related notes presently set forth in Options 7, Section 4 regarding the Options Transaction Charges and the Non-Customer surcharge, and to group them with the proposed Options Transaction Charges and proposed Non-Customer surcharge for XND.21 The Exchange proposes to set forth the foregoing fees in new Section 5.A of Options 7, and title this section "Broad-Based Index Options." As proposed, the pricing schedule in Options 7, Section 5.A, which will apply to electronic (simple and complex orders) and floor transactions, will be as follows:

OPTIONS TRANSACTION CHARGES

Symbol	Customer	Professional	Lead market maker and market maker	Broker-dealer	Firm
NDX ¹	\$0.00	\$0.75	\$0.75	\$0.75	\$0.75
	0.00	0.75	0.75	0.75	0.75
	0.00	0.10	0.10	0.10	0.10

· These fees are per contract.

¹ A surcharge for NDX and NDXP of \$0.25 per contract will be assessed to Non-Customers.

² A surcharge for XND of \$0.10 per contract will be assessed to Non-Customers.

As shown above, the rates for NDX and NDXP are not changing; rather, the existing Options Transaction Charges and Non-Customer surcharges in Options 7, Section 4 are being relocated into Options 7, Section 5.A and grouped together with the proposed pricing for XND. The Exchange considers it appropriate to separate out NDX, NDXP, and XND pricing in the manner described above so that Phlx's pricing for these index options may be easily located within its Pricing Schedule. For the sake of clarity, the Exchange also proposes to amend the Options Transaction Charge header for Non-Penny Symbols in Options 7, Section 4, which already excludes NDX and

NDXP, to add XND to the list of excluded Non-Penny Symbols that will not be subject to this fee. The Exchange further proposes to amend its Pricing Schedule to update all current references to Options 7, Section 4 NDX and NDXP pricing to Options 7, Section 5.A.²²

The Exchange also proposes nonsubstantive, clean-up changes in Options 7, Section 5 to restructure the existing rule text. With the changes proposed above to add new Section 5.A of Options 7 to set forth NDX, NDXP, and XND pricing, the Exchange proposes to set forth Singly Listed Options pricing in new Section 5.B. The Exchange also proposes to set forth FX

Options pricing in new Section 5.C, and further proposes to relocate the language regarding U.S. dollar-settled foreign currency options into the new Section 5.C header. Accordingly, new Section 5.C will be titled, "FX Options: U.S. dollar-settled foreign currency options include XDB, XDE, XDN, XDS, XDA, XDZ and XDC." The Exchange is not amending any of the existing rates for Singly Listed Options or FX Options with this proposal. Lastly, the Exchange proposes to retitle Options 7, Section 5 as "Index and Singly Listed Options (Includes options overlying FX Options, equities, ETFs, ETNs, and indexes not listed on another exchange)."

[•] Floor transaction fees will apply to any "as of" or "reversal" adjustments for manually processed trades originally submitted electronically or through FBMS.

¹⁶ The characteristics of a FLEX option are described in Options 8, Section 34.

 $^{^{17}\,} The$ Exchange will correct the typo in the rule text from "Section 6, B" to "Section 6.B."

¹⁸ See supra note 15. All current references to Options 7, Section 4 NDX and NDXP pricing within the FLEX transaction fees schedule will be updated to Options 7, Section 5.A.

¹⁹To qualify for MARS, a Phlx member's routing system ("hereinafter System") would be required to: (1) Enable the electronic routing of orders to all of the U.S. options exchanges, including Phlx; (2) provide current consolidated market data from the U.S. options exchanges; and (3) be capable of interfacing with Phlx's API to access current Phlx match engine functionality. Further, the member's System would also need to cause Phlx to be the one

of the top five default destination exchanges for individually executed marketable orders if Phlx is at the national best bid or offer ("NBBO"). regardless of size or time, but allow any user to manually override Phlx as a default destination on an order-by-order basis. Notwithstanding the above, with respect to Complex Orders a Phlx member's routing system would not be required to enable the electronic routing of orders to all of the U.S. options exchanges or provide current consolidated market data from the U.S. options exchanges. Any Phlx member would be permitted to avail itself of this arrangement, provided that its order routing functionality incorporates the features described above and satisfies Phlx that it appears to be robust and reliable. The member remains solely responsible for implementing and operating its

²⁰ For the purpose of qualifying for the MARS Payment, Eligible Contracts include the following: Firm, Broker-Dealer, Joint Back Office or "JBO" or Professional equity option orders that are electronically delivered and executed. Eligible Contracts do not include floor-based orders, qualified contingent cross or "QCC" orders, price improvement or "PIXL" orders, or Singly Listed Orders.

²¹In particular, note 5 will be deleted in Options 7, Section 4 and relocated into new note 1 in Options 7, Section 5.A. Further, the note 8 language in Options 7, Section 4 will be copied into a new bullet point in Options 7, Section 5.A.

 $^{^{22}}$ In particular, the Exchange will update references within Options 7, Sections 6.A and 6.B.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,²³ in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,²⁴ in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

Options 7, Section 1.B

The Exchange's proposal to not pay the Customer Rebates in Options 7, Section 1.B on XND, but to count XND volume toward qualifying for a Customer Rebate Tier, similar to NDX and NDXP, is reasonable because the Exchange seeks to treat XND in the same manner as NDX and NDXP under this rebate program, NDX, NDXP, and XND represent similar options on the same underlying Nasdaq 100 Index. Further, it is reasonable to not pay Customer Rebates on XND in any rebate category because this index option will be exclusively listed on Phlx only. The original intent of the Customer Rebate Program was to pay rebates on electronically-delivered multiply-listed options. By definition, XND will not be a multiply-listed option, and the Exchange does not desire to pay rebates on XND because of the exclusivity of this option. While the Exchange will not pay any Customer Rebates on XND transactions, the Exchange also believes it is reasonable to count XND in the total volume to qualify a market participant for these rebates as market participants would be incentivized to transact in XND to qualify for the Customer Rebate Tiers.

The Exchange believes that its proposal to not pay Customer Rebates on XND, but to count XND volume toward the volume requirement to qualify for a rebate tier is equitable and not unfairly discriminatory because the Exchange would apply the rebate program as described uniformly for all market participants. Any market participant is eligible to earn a Customer Pobate

Options 7, Section 4

Options Transaction Charges and Surcharges

The Exchange believes it is reasonable to assess the proposed Options Transaction Charge and Non-Customer surcharge as discussed above for XND

because the proposed pricing reflects the exclusive and proprietary nature of this product. Similar to NDX and NDXP, the Exchange seeks to recoup the operational costs for listing proprietary products.²⁵ Also, pricing by symbol is a common practice on many U.S. options exchanges as a means to incentivize order flow to be sent to an exchange for execution in particular products. Other options exchanges price by symbol.26 Further, the Exchange notes that with its products, market participants are offered an opportunity to transact in NDX, NDXP, or XND, or separately execute options overlying PowerShares QQQ Trust ("QQQ").27 Offering such proprietary products provides market participants with a variety of choices in selecting the product they desire to utilize in order to transact in the Nasdaq 100 Index. When exchanges are able to recoup costs associated with offering proprietary products, it incentivizes growth and competition for the innovation of additional products.

Further, the Exchange believes that the proposed rates for XND are reasonable because they are well within the range of fees assessed for the Exchange's other proprietary products, namely NDX and NDXP.²⁸ The Exchange believes it is reasonable to charge lower rates for XND compared to NDX and NDXP because XND is based on 1/100 of the value of the Nasdaq 100 Index while both NDX and NDXP are based on the full value of the Nasdaq 100 Index. The Exchange therefore seeks to assess corresponding reduced fees for this product

The Exchange's proposal to assess the \$0.10 per contract Options Transaction Charge in XND is equitable and not unfairly discriminatory because the Exchange will assess this fee uniformly to all Non-Customers. The Exchange similarly believes that the proposed \$0.10 per contract XND surcharge is

equitable and not unfairly discriminatory because it will apply uniformly to all Non-Customers. The Exchange believes it is equitable and not unfairly discriminatory to assess no transaction fees to Customers for XND because Customer orders bring valuable liquidity to the market, which liquidity benefits other market participants. Customer liquidity benefits all market participants by providing more trading opportunities, which attracts Lead Market Makers and Market Makers. An increase in the activity of these market participants in turn facilitates tighter spreads, which may cause an additional corresponding increase in order flow from other market participants.

Fee Programs

The Exchange believes that the proposed updates in Options 7, Section 4 in connection with the application of certain fee programs to XND are reasonable, equitable, and not unfairly discriminatory. Particularly, the Exchange believes that it is reasonable to exclude XND from the Non-Penny complex surcharge in note 7 of Options 7, Section 4, Monthly Market Maker Cap, Monthly Firm Fee Cap, Floor Options Transaction Charge waivers, Strategy Caps, and Marketing Fees in the same manner in which NDX and NDXP are currently excluded from the same programs today. The Exchange believes it is appropriate to update these fee programs in a manner that similarly situates XND with NDX and NDXP as these are all proprietary products that are based on the Nasdaq 100 Index. In addition, similar to NDX and NDXP, the Exchange seeks to recoup the operational costs for listing proprietary products by excluding XND from programs that cap or waive transaction fees for market participants. As it relates to the Marketing Fee, the Exchange believes it is reasonable to exclude XND from this fee, similar to NDX and NDXP today, because the purpose of the Marketing Fee is to generate more Customer order flow to the Exchange. Because XND will be an exclusively listed product on Phlx, the Exchange does not believe that applying a marketing fee is necessary for this

The Exchange's proposal to exclude XND from the various fee programs in Options 7, Section 4 as discussed above is equitable and not unfairly discriminatory because the programs will equally exclude in the same manner all market participants' orders in XND. The Exchange notes that its proposal does not alter any of the existing fee programs, but instead merely proposes to exclude XND in

²³ 15 U.S.C. 78f(b).

²⁴ 15 U.S.C. 78f(b)(4) and (5).

²⁵ By way of example, in analyzing an obvious error, the Exchange would have additional data points available in establishing a theoretical price for a multiply listed option as compared to a proprietary product, which requires additional analysis and administrative time to comply with Exchange rules to resolve an obvious error.

²⁶ See pricing for the Mini-RUT Index options ("MRUT") on Cboe Exchange, Inc.'s Fees Schedule.
²⁷ QQQ is an exchange-traded fund based on the same Nasdaq 100 Index as NDX, NDXP, and XND.

²⁸ Specifically, the Exchange is proposing to assess Non-Customers an Options Transaction Charge of \$0.10 per contract in XND while Customers will receive free executions. Today, the Exchange assesses Non-Customers an Options Transaction Charge of \$0.75 per contract for both NDX and NDXP, and does not assess Customers an Options Transaction Charge. Additionally, the Exchange is proposing to assess Non-Customers a surcharge of \$0.10 per contract for XND whereas today, Non-Customers are assessed a surcharge of \$0.25 per contract for NDX and NDXP.

those programs in the same way that NDX and NDXP are currently excluded.

Options 7, Section 6

PIXL Pricing

The Exchange's proposal to exclude XND from PIXL pricing in Options 7, Section 6.A, and instead assess XND transactions in PIXL the proposed Options 7, Section 5.A pricing is reasonable because the Exchange intends to assess the same fees across the board for XND transactions (i.e., \$0.10 per contract for Non-Customers and free executions for Customers). This will align the pricing structure for XND with NDX and NDXP, which are currently assessed the same \$0.75 per contract Non-Customer fee across the board while Customers receive free executions.

The proposed changes are equitable and not unfairly discriminatory because the Exchange will uniformly exclude NDXP from PIXL pricing for all market participants, and instead uniformly charge them the Options 7, Section 5.A pricing.

FLEX Transaction Fees

The Exchange believes that its proposal to assess FLEX XND options the Options Transaction Charge and Non-Customer options surcharge in Options 7, Section 5.A is reasonable because the Exchange intends to assess the same fees across the board for XND transactions. Specifically, the Exchange will apply the proposed XND options surcharge of \$0.10 per contract to Non-Customers in FLEX XND options. Further, the Exchange will apply the proposed XND Options Transaction Charges of \$0.10 per contract (Non-Customer) and \$0.00 per contract (Customer) to FLEX XND options. FLEX NDX and NDXP options are likewise assessed the same Options Transaction Charge and Non-Customer options surcharge that NDX and NDXP options are assessed today. The Exchange's proposal is equitable and not unfairly discriminatory because the Exchange will uniformly apply these fees to FLEX NDX and NDXP options to all similarly situated market participants.

MARS

The Exchange believes it is reasonable to exclude XND from Eligible Contracts for purposes of qualifying for a MARS Payment in the same manner in which NDX and NDXP are currently excluded today. The Exchange believes it is appropriate to update its MARS program in a manner that similarly situates XND with its other proprietary products, NDX and NDXP, which are all based on the Nasdaq 100 Index.

The Exchange believes that its proposal is equitable and not unfairly discriminatory because the Exchange will uniformly exclude XND from MARS for all market participants.

Options 7, Section 5

The Exchange believes that the proposed changes to relocate and group the transaction fees for NDX, NDXP, and XND within Options 7, Section 5.A, and all of the non-substantive changes related to the relocation, each as discussed above, are reasonable, equitable, and not unfairly discriminatory. The proposed changes are all intended to bring greater clarity, and will ensure that the Exchange's pricing for NDX, NDXP, and XND may be easily located within its Pricing Schedule. The Exchange further believes that the proposed nonsubstantive changes in Options 7, Section 5 to restructure the existing rule text and retitle various section headers are reasonable, equitable, and not unfairly discriminatory as they will facilitate the use of the Pricing Schedule by 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 not necessary or appropriate in furtherance of the purposes of the Act. In terms of inter-market competition, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. The Exchange notes that with its products, market participants are offered an opportunity to transact in NDX, NDXP, or XND, or separately execute options overlying QQQ. Offering these products provides market participants with a variety of choices in selecting the product they desire to utilize to transact in the Nasdaq 100 Index.

Further, the Exchange does not believe that the proposed rule change will impose any burden on intra-market competition that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed XND pricing will apply uniformly to all similarly situated market participants. Specifically, all Non-Customers will be assessed a uniform Options Transaction Charge and options surcharge while Customers receive free executions. As discussed above, Customer liquidity benefits all market participants by providing more

trading opportunities, which attracts other market participants, thus facilitating tighter spreads and increased order flow.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.²⁹

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (http://www.sec.gov/rules/sro.shtml); or
- Send an email to *rule-comments@* sec.gov. Please include File Number SR–Phlx–2021–24 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–Phlx–2021–24. This file number should be included on the subject line if email is used. To help the

number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (http://www.sec.gov/rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule

²⁹ 15 U.S.C. 78s(b)(3)(A)(ii).

change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-Phlx-2021-24 and should be submitted on or before May 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. 30

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–09281 Filed 5–4–21; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-91710; File No. SR-PEARL-2021-18]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Interpretation and Policy .13 (Temporary Extension of the Limited Period for Registered Persons To Function as Principals) to Exchange Rule 3100, Registration Requirements, To Extend The Expiration Date of The Temporary Amendment Set Forth in SR-PEARL-2020-36 from April 30, 2021 to June 30, 2021

April 29, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act" or "Exchange Act") ¹ and Rule 19b–4 thereunder, ² notice is hereby given that on April 21, 2021, MIAX PEARL, LLC ("MIAX Pearl" or the "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described

in Items I and II below, which Items have been substantially 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 is filing a proposal to amend Interpretation and Policy .13 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) to Exchange Rule 3100, Registration Requirements, to extend the expiration date of the temporary amendment set forth in SR–PEARL–2020–36 from April 30, 2021 to June 30, 2021. The Exchange does not anticipate providing any further extensions to the temporary amendment identified in this proposed rule change beyond June 30, 2021.

The text of the proposed rule change is available on the Exchange's website at http://www.miaxoptions.com/rule-filings/pearl, at MIAX Pearl's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Interpretation and Policy .13 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) to Exchange Rule 3100, Registration Requirements, to extend the expiration date of the temporary amendment set forth in SR–PEARL–2020–36 from April 30, 2021 to June 30, 2021. The proposed rule change would extend the 120-day period that certain individuals can function as principals without having successfully passed an appropriate qualification examination through June

30, 2021,³ and would apply only to those individuals who were designated to function as principals prior to March 3, 2021. This proposed rule change is based on a filing recently submitted by the Financial Industry Regulatory Authority, Inc. ("FINRA") ⁴ and is intended to harmonize the Exchange's registration rules with those of FINRA so as to promote uniform standards across the securities industry.

In response to the COVID-19 global pandemic, last year FINRA began providing temporary relief by way of frequently asked questions ("FAQs") to address disruptions to the administration of FINRA qualification examinations caused by the pandemic that have significantly limited the ability of individuals to sit for examinations due to Prometric test center capacity issues.⁶

FINRA published the first FAQ on March 20, 2020, providing that individuals who were designated to function as principals under FINRA Rule 1210.04 ⁷ prior to February 2, 2020, would be given until May 31, 2020, to pass the appropriate principal qualification examination.⁸ On May 19, 2020, FINRA extended the relief to pass the appropriate examination until June 30, 2020. On June 29, 2020, FINRA again extended the temporary relief

⁸ FINRA Rule 1210.04 (Requirements for Registered Persons Functioning as Principals for a Limited Period) allows a FINRA-member firm to designate certain individuals to function in a principal capacity for 120 calendar days before having to pass an appropriate principal qualification examination. Exchange Rule 3100, Interpretation and Policy .04, provides the same allowance to Exchange Members.

³⁰ 17 CFR 200.30–3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Exchange Act Release No. 91506 (April 8, 2021) 86 FR 19671 (April 14, 2021) (SR-FINRA–2021–005) (the "FINRA Filing"). The Exchange notes that the FINRA Filing also provides temporarily relief to individuals registered with FINRA as Operations Professionals under FINRA Rule 1220. The Exchange does not have a registration category for Operations Professionals and therefore, the Exchange is not proposing to adopt that aspect of the FINRA Filing. If the Exchange seeks to provide additional temporary relief from the rule requirement identified in this proposal beyond June 30, 2021, it will submit a separate rule filing to further extend the temporary extension of time.

⁴ See id.

⁵ See https://www.finra.org/rules-guidance/key-topics/covid-19/faq#qe.

⁶At the outset of the COVID–19 pandemic, all FINRA qualification examinations were administered at test centers operated by Prometric. Based on the health and welfare concerns resulting from COVID–19, in March 2020 Prometric closed all of its test centers in the United States and Canada and began to slowly reopen some of them at limited capacity in May. Currently, Prometric has resumed testing in many of its United States and Canada test centers, at either full or limited occupancy, based on local and government mandates.

⁷Exchange Rule 3100, Interpretation and Policy .04, is the corresponding rule to FINRA Rule 1210.04.

providing that individuals who were designated to function as principals under FINRA Rule 1210.04 prior to May 4, 2020, would be given until August 31, 2020, to pass the appropriate principal qualification examination. On August 28, 2020, FINRA filed with the Commission a proposed rule change for immediate effectiveness to extend the temporary relief provided via the two FAQs by adopting: (1) Temporary Supplementary Material .12 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) under FINRA Rule 1210 (Registration Requirements), and (2) temporary Supplementary Material .07 (Temporary Extension of the Limited Period for Persons to Function as Operations Professionals) under FINRA Rule 1220 (Registration Categories).9 Pursuant to this rule filing, individuals who were designated prior to September 3, 2020, to function as a principal under FINRA Rule 1210.04 would have until December 31, 2020, to pass the appropriate qualification examination.

Thereafter, on December 9, 2020, FINRA filed with the Commission a proposed rule change for immediate effectiveness to extend the limited period for registered persons to function as a principal through April 30, 2021.10 Pursuant to this rule filing, individuals who were designated prior to January 1, 2021 to function as a principal would have until April 30, 2021 to pass the appropriate qualifying examination. On December 28, 2020, the Exchange filed with the Commission a proposed rule change for immediate effectiveness to extend the limited period for registered persons to function as a principal through April 30, 2021. 11

The Exchange continues to closely monitor the impact of the COVID–19 pandemic on Members, 12 investors, and other stakeholders. The Exchange initially provided temporary relief to address the interruptions in the administration of FINRA qualification examinations at Prometric test centers and the limited ability of individuals to

⁹ See Exchange Act Release No. 89732 (September 1, 2020), 85 FR 55535 (September 8, 2020) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2020–026).

sit for the examinations caused by the

COVID-19 pandemic. 13 As mentioned in the FINRA Filing (SR-FINRA-2021-005), FINRA noted that the pandemic could result in firms potentially experiencing significant disruptions to their normal business operations that may be exacerbated by being unable to keep principal positions filled. Specifically, FINRA noted that the limitation of in-person activities and staff absenteeism as a result of the health and welfare concerns stemming from COVID-19 could result in firms having difficulty finding other qualified individuals to transition into those roles or requiring them to reallocate employee time and resources away from other critical responsibilities at the firm's organization.

While there are signs of improvement, the COVID-19 conditions necessitating the temporary relief persist and the Exchange has determined that there is a continued need for this temporary relief beyond April 30, 2021. Although Prometric has resumed testing in many of its U.S. test centers, Prometric's safety practices mean that currently not all test centers are open, some of the open test centers are at limited capacity, and some open test centers are delivering only certain examinations that have been deemed essential by the local government.¹⁴ In addition, while certain states have started to ease COVID-19 restrictions on businesses and social activities, public health officials continue to emphasize the importance for individuals to keep taking numerous steps to protect themselves and help slow the spread of the disease. 15

Although the COVID-19 conditions necessitating the temporary relief persist, the Exchange believes that an extension of the relief is necessary only until June 30, 2021, because FINRA recently expanded the availability of online examinations. Prior to this expansion, the ongoing effects of the pandemic made it impracticable for Members to ensure that the individuals who they had designated to function in a principal capacity, as set forth in Exchange Rule 3100, Interpretation and Policy .04, could successfully sit for and pass an appropriate qualification examination within the 120-calendar

day period required under the rules.16 Specifically, if the individual wanted to take a qualifying examination, they were required to accept the health risks associated with taking an in-person examination because those examinations were not available online. On February 24, 2021, however, FINRA adopted an interim accommodation request process to allow candidates to take additional FINRA examinations online, including the General Securities Principal ("Series 24") and Operations Professional ("Series 99") examinations.¹⁷ Because the Series 24 qualifying examination has been made available online only recently, the Exchange is concerned that individuals who have been designated to function in a principal capacity may not have sufficient time to schedule, study for, and take the applicable examination before April 30, 2021, the date the temporary amendment is set to expire. Therefore, the Exchange proposes to extend the expiration date of the temporary amendment set forth in Exchange Rule 3100, Interpretation and Policy .13, from April 30, 2021 until June 30, 2021. The proposed rule change would apply only to those individuals who have been designated to function as a principal prior to March 3, 2021. As noted above, the Exchange does not anticipate providing any further extensions to the temporary amendment and any individuals designated to function as a principal on or after March 3, 2021, will need to successfully pass an appropriate qualification examination within 120 davs.

The Exchange believes that this proposed continued extension of time is tailored to address the needs and constraints on a Member's operations during the COVID-19 pandemic, without significantly compromising critical investor protection. The proposed extension of time will help to minimize the impact of COVID-19 on Members by providing continued flexibility so that Members can ensure that principal positions remain filled. The potential risks from the proposed extension of the 120-day period are mitigated by a Member's continued requirement to supervise the activities of these designated individuals and ensure compliance with federal securities laws and regulations, as well as Exchange and FINRA rules.

The Exchange has filed the proposed rule change for immediate effectiveness and has requested that the Commission waive the requirement that the proposed

¹⁰ See Exchange Act Release No. 90617 (December 9, 2020), 85 FR 81258 (December 15, 2020) (SR-FINRA-2020-043).

¹¹ See Exchange Act Release No. 90831 (December 30, 2020), 86 FR 633 (January 6, 2021) (SR-PEARL-2020-36).

¹² The term "Member" means an individual or organization that is registered with the Exchange pursuant to Chapter II of these Rules for purposes of trading on the Exchange as an "Electronic Exchange Member" or "Market Maker." Members are deemed "members" under the Exchange Act. See Exchange Rule 100.

¹³ Information about the continued impact of COVID–19 on FINRA-administered examinations is available at https://www.finra.org/rules-guidance/key-topics/covid-19/exams.

¹⁴ Information from Prometric about its safety practices and the impact of COVID–19 on its operations is available at https://www.prometric.com/corona-virusupdate. See also supra note 13.

¹⁵ See, e.g., Centers for Disease Control and Prevention, How to Protect Yourself & Others, https://www.cdc.gov/coronavirus/2019-ncov/ prevent-gettingsick/prevention.html.

¹⁶ See supra note 13.

¹⁷ Id.

rule change not become operative for 30 days after the date of the filing, so the Exchange can implement the proposed rule change immediately.

2. Statutory Basis

The Exchange believes that its proposed rule change is consistent with Section 6(b) of the Act 18 in general, and furthers the objectives of Section 6(b)(5) of the Act 19 in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

The proposed rule change is intended to minimize the impact of COVID-19 on Member operations by further extending the 120-day period certain individuals may function as a principal without having successfully passed an appropriate qualification examination under Exchange Rule 3100, Interpretation and Policy .04, until June 30, 2021. The proposed rule change does not relieve Members from maintaining, under the circumstances, a reasonably designed system to supervise the activities of their associated persons to achieve compliance with applicable securities laws and regulations, and with applicable Exchange and FINRA rules that directly serve investor protection. In a time when faced with unique challenges resulting from the COVID-19 pandemic, the Exchange believes that the proposed rule change is a sensible accommodation that will continue to afford Members the ability to ensure that critical positions are filled and client services maintained, while continuing to serve and promote the protection of investors and the public interest in this unique environment.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is intended to provide temporary relief given the impacts of the COVID–19 pandemic crisis and to also maintain consistency with the rules of other self-regulatory organizations ("SROs") with respect to the registration requirements applicable

to Members and their registered personnel. In that regard, the Exchange believes that any burden on competition would be clearly outweighed by providing Members with temporary relief in this unique environment while also ensuring clear and consistent requirements applicable across SROs and mitigating any risk of SROs implementing different standards in these important areas. In its filings, FINRA provides an abbreviated economic impact assessment maintaining that the changes are necessary to temporarily rebalance the attendant benefits and costs of the obligations under FINRA Rule 1210 in response to the impacts of the COVID-19 pandemic that is equally applicable to the changes the Exchange proposes.²⁰ The Exchange accordingly incorporates FINRA's abbreviated economic impact assessment by reference.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act ²¹ and Rule 19b–4(f)(6) thereunder.²²

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b–4(f)(6)(iii), the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative immediately upon filing. As

noted above, the Exchange stated that the conditions necessitating the temporary relief continue to exist and the proposed extension of time will help minimize the impact of the COVID-19 outbreak on Members' operations by allowing them to keep principal positions filled and minimizing disruptions to client services and other critical responsibilities. Despite signs of improvement, the Exchange further stated that the ongoing extenuating circumstances of the COVID-19 pandemic make it impractical to ensure that individuals designated to act in a principal capacity are able to take and pass the appropriate qualification examination during the 120-calendar day period required under the rules.

The Exchange observed that, following a nationwide closure of all test centers earlier in the year, some test centers have re-opened, but are operating at limited capacity or are only delivering certain examinations that have been deemed essential by the local government.23 However, on February 24, 2021, FINRA began providing the General Securities Principal (Series 24) Examination online through an interim accommodation request process.²⁴ Prior to this change, if individuals wanted to take these qualifying examinations, they were required to accept the health risks associated with taking an in-person examination. Even with the expansion of online qualifications examinations, the Exchange stated that extending the expiration date of the relief set forth in SR-PEARL-2020-36 until June 30, 2021 is still needed. The Exchange stated that this temporary relief will provide flexibility to allow individuals who have been designated to function as a principal sufficient time to schedule, study for and take the applicable examination before the temporary relief expires. Notably, the Exchange stated that it does not anticipate providing any further extensions to the temporary amendment and that any individuals designated to function as a principal on or after March 3, 2021 will need to successfully pass an appropriate qualification examination within 120 days.

For these reasons, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public

^{18 15} U.S.C. 78f(b).

¹⁹ 15 U.S.C. 78f(b)(5).

²⁰ See supra notes 3 and 10; see also Exchange Act Release No. 89732 (September 1, 2020), 85 FR 55535 (September 8, 2020) (SR–FINRA–2020–26).

²¹ 15 U.S.C. 78s(b)(3)(A).

 $^{^{22}}$ 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.

²³ See supra notes 13 and 14. The Exchange notes that Prometric has also had to close some reopened test centers due to incidents of COVID-19 cases.

²⁴ See supra note 13 (including the February 24, 2021 announcement of the interim accommodation process for candidates to take certain examinations, including the General Securities Principal (Series 24) Examination, online.)

interest.²⁵ Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.²⁶

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (http://www.sec.gov/rules/sro.shtml); or
- Send an email to *rule-comments@* sec.gov. Please include File Number SR–PEARL–2021–18 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-PEARL-2021-18. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (http://www.sec.gov/ rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the

public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-PEARL-2021-18 and should be submitted on or before May 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁷

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–09439 Filed 5–4–21; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-91701; File No. SR-EMERALD-2021-14]

Self-Regulatory Organizations; MIAX Emerald, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Exchange Rule 515, Execution of Orders and Quotes; Rule 516, Order Types Defined; Rule 517, Quote Types Defined; Rule 605, Market Maker Orders; and Rule 612, Aggregate Risk Manager To Eliminate Fill-or-Kill (FOK) Orders and FOK eQuotes

April 29, 2021.

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 April 19, 2021, MIAX Emerald, LLC ("MIAX Emerald" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Exchange Rule 515, Execution of Orders and Quotes; Rule 516, Order Types Defined; Rule 517 Quote Types Defined; Rule 605, Market Maker Orders; and Rule 612 Aggregate Risk Manager to eliminate Fill-or-Kill (FOK) Orders and FOK eQuotes from the rulebook and to delete references to same.

The text of the proposed rule change is available on the Exchange's website at http://www.miaxoptions.com/rule-filings/emerald at MIAX Emerald's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its rules to eliminate Fill-or-Kill Orders and Fill-or-Kill eQuotes. A Fill-or-Kill ("FOK") Order is described by the Exchange as a limit order that is to be executed in its entirety at a single price as soon as it is received and, if not so executed is cancelled.³ A Fill-or-Kill ("FOK") eQuote is described by the Exchange as an eQuote submitted by a Market Maker ⁴ that must be matched with another quote or order for an execution in its entirety at a single price upon receipt into the System ⁵ or will be immediately cancelled.⁶

Specifically, the Exchange now proposes to amend paragraph (c)(1) of Exchange Rule 515 to remove the

²⁵ As noted above by the Exchange, this proposal is an extension of temporary relief provided in SR–PEARL–2020–36 where the Exchange also requested and the Commission granted a waiver of the 30-day operative delay. *See* SR–PEARL–2020–36, 86 FR at 635–36.

²⁶ For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

^{27 17} CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Exchange Rule 516(b)(2).

⁴ The term "Market Makers" refers to "Lead Market Makers", "Primary Lead Market Makers" and "Registered Market Makers" collectively. *See* Exchange Rule 100.

⁵The term "System" means the automated trading system used by the Exchange for the trading of securities. *See* Exchange Rule 100.

⁶ See Exchange Rule 517(a)(2)(iv).

reference regarding Fill-or-Kill Orders. The Exchange proposes to remove the text in paragraph (f) in its entirety, but to leave paragraph (f) in place and mark it as reserved for future use. The Exchange proposes to remove subparagraph (2) of paragraph (b) of Exchange Rule 516 in its entirety, and to renumber current subparagraph (3) to new subparagraph (2). The Exchange proposes to remove subparagraph (iv) of paragraph (a)(2) from Rule 517 in its entirety, and to renumber current subparagraph (v) to new subparagraph (iv). Additionally, the Exchange proposes to remove subparagraph (4) of paragraph (d) from Rule 517 in its entirety, and to renumber current subparagraph (5) to new subparagraph (4). The Exchange proposes to amend paragraph (a) of Exchange Rule 605 to remove a reference to Fill-or-Kill Orders. The Exchange proposes to amend subparagraph (c) of Policy .02 of Exchange Rule 612 to remove a reference to FOK eQuotes and to make minor non substantive edits to the rule

MIAX Emerald is an affiliate exchange of the MIAX Options Exchange and offers similar functionality and similar order types as MIAX Options. MIAX Options Exchange Rule 516 states, It should be noted that some of the order types defined below are valid only during certain portions of the trading day (e.g., Opening Orders) or during certain events (e.g., Auction or Cancel Orders). If a Member submits an order type during a time period when the order type is not valid, the System will reject the order. It should also be noted that not all of the order types listed and described in this rule will be initially available for use on the Exchange. The Exchange will issue a Regulatory Circular listing which order types, among the order types set forth below, are available. Additional Regulatory Circulars will be issued as additional order types, among those order types set forth below, become available for use on the Exchange. Regulatory Circulars will also be issued when an order type that had been in usage on the Exchange will no longer be available for use.

MIAX Options recently issued Regulatory Circulars indicating that FOK Orders and FOK eQuotes will no longer be available for use on the MIAX Options Exchange.⁷ MIAX Emerald proposes to make both FOK Orders and FOK eQuotes unavailable on the MIAX Emerald Exchange so as to avoid confusion among Members ⁸ that may be Members of both MIAX Options and MIAX Emerald.⁹

2. Statutory Basis

The Exchange believes that its proposed rule change is consistent with Section 6(b) of the Act 10 in general, and furthers the objectives of Section 6(b)(5) of the Act 11 in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanisms 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 its proposal promotes just and equitable principles of trade and removes impediments to and perfects the mechanisms of a free and open market and a national market system and, in general, protects investors and the public interest by removing an order type from the Exchange that is not widely used by investors. Removing an infrequently used order type from the Exchange's rulebook benefits investors by simplifying the Exchange's rulebook.

Additionally, the Exchange believes that its proposal promotes just and equitable principles of trade and removes impediments to and perfects the mechanism of a free and open market and a national market system and, in general, protects investors and the public interest by aligning functionality available on the Exchange to that of its affiliate exchange. Specifically, the Exchange believes that although MIAX Emerald rules may, in certain instances, intentionally differ from MIAX Options rules, the proposed change will promote uniformity with the MIAX Options Exchange and allow MIAX Emerald to provide functionality similar to MIAX Options. MIAX

Emerald and MIAX Options may have a number of common Members, and where feasible the Exchange intends to provide consistency between MIAX Options and MIAX Emerald so as to avoid confusion among Members.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes the proposed rule change will not impose any burden on intra-market competition because the rules of the Exchange apply equally to all Members. Members may still receive an immediate execution on the Exchange by using an Immediate-or-Cancel Order. 12

The Exchange does not believe that the proposed rule change will impose any burden on inter-market competition as the Exchange's proposal is not designed to address any competitive issues. The Exchange's proposal removes an infrequently used order type from the Exchange and aligns its functionality to its affiliate Exchange, MIAX Options. Additionally, the Exchange believes the proposed rule change will not impose any burden on inter-market competition as option exchanges offer a variety of order types and not every option exchange offers every order type. 13

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

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

⁷ See MIAX Options Regulatory Circular 2021–20, Fill-or-Kill Orders will no longer be supported on the MIAX Options Exchange (April 8, 2021) available at https://www.miaxoptions.com/sites/default/files/circular-files/MIAX_Options_RC_2021_20.pdf; and MIAX Options Regulatory Circular 2021–21, Fill-or-Kill eQuotes will no longer be supported on the MIAX Options Exchange

⁽April 9, 2021) available at: https://www.miaxoptions.com/sites/default/files/circular-files/MIAX_Options_RC_2021_21.pdf.

⁸ The term "Member" means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed "members" under the Exchange Act. See Exchange Rule 100.

⁹ The Exchange notes that FOK Orders and FOK eQuotes are not available on the Exchange's other affiliate exchange, MIAX Pearl Options Exchange.

^{10 15} U.S.C. 78f(b).

^{11 15} U.S.C. 78f(b)(5).

¹² An Immediate-or-Cancel Order is an order that is to be executed in whole or in part upon receipt. Any portion not so executed is cancelled. An Immediate-or-Cancel Order is not valid during the Opening Process described in MIAX Emerald Rule 503. See Exchange Rule 516(c).

¹³ BOX Options Exchange supports a Fill and Kill (FAK) order type but not a Fill or Kill order type. See BOX Exchange Rule 7110. Nasdaq Phlx supports an All-or-None Order but not a Fill or Kill order type. See Nasdaq Phlx Options 3, Section 7(b)(5).

19(b)(3)(A) of the Act ¹⁴ and Rule 19b–4(f)(6) thereunder. ¹⁵

A proposed rule change filed pursuant to Rule 19b-4(f)(6) under the Act normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii) 16 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 the proposal may become operative immediately upon filing. The Exchange asserted that the waiver would allow the Exchange to harmonize its functionality to that of MIAX Options Exchange and thus reduce the potential for confusion among its Members. The Exchange also stated that it does not believe that removal of the FOK order type will impact users as this order type is infrequently used on the Exchange. For these reasons, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest, and will allow the Exchange to immediately align its functionality with MIAX Options Exchange and simplify its rulebook to remove an infrequently used order type. Accordingly, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.17

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and

arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act.

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (http://www.sec.gov/rules/sro.shtml); or
- Send an email to *rule-comments@ sec.gov*. Please include File Number SR–EMERALD-2021-14 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-EMERALD-2021-14. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (http://www.sec.gov/ rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-EMERALD-2021-14 and should be submitted on or before May 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. 18

J. Matthew DeLesDernier,

Assistant Secretary.
[FR Doc. 2021–09431 Filed 5–4–21; 8:45 am]
BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91714; File No. SR–BOX–2021–07]

Self-Regulatory Organizations; BOX Exchange LLC; Notice of Filing of Proposed Rule Change To Adopt BOX Rule 7670 To Establish a Virtual Trading Floor on BOX

April 29, 2021.

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 April 16, 2021, BOX Exchange LLC ("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 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 the Substance of the Proposed Rule Change

The Exchange proposes to establish BOX Rule 7670 to adopt a Virtual Trading Floor on BOX. The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public Reference Room and also on the Exchange's internet website at http://boxoptions.com.

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 these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

^{14 15} U.S.C. 78s(b)(3)(A).

¹⁵ 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 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.

¹⁶ 17 CFR 240.19b–4(f)(6)(iii).

¹⁷ For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

^{18 17} CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to establish BOX Rule 7670 to adopt a Virtual Trading Floor on BOX. This is a competitive filing that is based on a proposal submitted by Cboe Exchange, Inc. ("Cboe") and approved by the Commission.³

On March 20, 2020, as a precautionary measure to prevent the potential spread of coronavirus (COVID-19), BOX closed the Trading Floor located in Chicago, Illinois for an indefinite period of time. As a result of the closure of the Trading Floor, BOX operated in an electronic only trading mode. The Exchange continued to operate in an all-electronic capacity until May 4, 2020, when the Exchange reopened its Trading Floor with continued safety guidelines, policies and procedures in place. However, given the uncertainty related to the ongoing pandemic, which includes the possibility of the Exchange having to close its Trading Floor again, and given the possibility that the Exchange's Trading Floor may be inoperable or at capacity for other reasons in the future, the Exchange believes it is appropriate to continue to review and enhance its rules with regard to its business continuity plans. While BOX continued to operate in an all-electronic capacity while the physical Trading Floor was closed, an all-electronic trading environment cannot fully replicate open outcry trading. Therefore, the Exchange continues to evaluate potential enhancements that it believes would permit open outcry trading while the Trading Floor is inoperable to more closely replicate its trading environment that exists during normal operations.

There are certain features of open outcry trading that are difficult to replicate in an electronic trading environment, particularly the human interaction that permits persons to negotiate pricing and to facilitate executions of larger orders and high-risk complicated strategies. For example, from January 2, 2020 through March 21, 2020 (the last day on which the Trading Floor was open), Complex Orders for options with more than four legs represented approximately 11.3% of the total complex order average daily volume ('ÅDV'') during that timeframe. However, from March 22, 2020 (the first

day on which the Trading Floor was closed) through May 1, 2020 (the last day before the Trading Floor reopened), Participants executed zero complex orders for options with more than four legs. ⁴ This data, taken into consideration with feedback from Participants, demonstrates the difficulty market participants have with executing high-risk and complex strategies in an all-electronic trading capacity that does not allow for human interaction.

The Exchange believes the proposed rule change would further enhance the Exchange's trading environment when the physical Trading Floor is inoperable by permitting market participants that generally operate on the Trading Floor to continue to interact in a substantially similar manner as they do on the Trading Floor. Specifically, the Exchange proposes to adopt Rule 7670(a) which details the Loss of Trading Floor. If the Exchange Trading Floor becomes inoperable and the Exchange does not make a Virtual Trading Floor available, the Exchange will continue to operate in an electronic only environment while the Trading Floor is inoperable. Open outcry trading will not be available in the event the Trading Floor becomes inoperable except as otherwise set forth in Rule 7670 discussed herein. The Exchange reiterates that the proposed Virtual Trading Floor will only be activated if the physical Trading Floor becomes inoperable. Further, the Exchange has the discretion to not activate the Virtual Trading Floor if the physical Trading Floor becomes inoperable.

The Exchange proposes to adopt Rule 7670(a)(1) which will allow the Exchange to make available an audio and video communication program to serve as a "Virtual Trading Floor" during regular trading hours. In the program, the Exchange will create a 'Virtual Trading Pit.'' In the Virtual Trading Pit, each Participant authorized to access the Virtual Trading Floor (as described below) that enters the Virtual Trading Pit will be visible to all other Participants in that Virtual Trading Pit. Additionally, all Participants in that Virtual Trading Pit may speak to each other through the program. This will

allow the same communication capabilities Participants generally have on the physical Trading Floor so that they may conduct open outcry trading on the Virtual Trading Floor in the same manner as they do on the physical Trading Floor.

All rules related to open outcry trading will apply to open outcry trading on the Virtual Trading Floor in the same manner as they apply to open outcry trading on the physical Trading Floor, except as the context otherwise requires and as set forth in proposed subparagraph (a)(1)(A). Proposed subparagraph (a)(1)(A) lists certain terms in the rules related to open outcry trading on the physical Trading Floor that will be deemed to refer to corresponding terms related to open outcry trading on the Virtual Trading Floor. Specifically:

(i) References in the Rules to the "Floor," "Trading Floor," and "Exchange Floor" (and any other terms with the same meaning) will be deemed to refer to the "Virtual Trading Floor."

(ii) References in the Rules to "Pit" and "Crowd Area" (and any other terms with the same meaning) will be deemed to refer to the "Virtual Trading Pit."

(iii) The terms "in-crowd Floor Participant" mean a Floor Market Maker or a Floor Brooker representing an order in the Virtual Trading Pit on the Virtual Trading Floor.

Access to the Virtual Trading Floor will be substantially similar to access to the physical Trading Floor. Currently, admission to the physical Trading Floor is limited to Floor Participants, Exchange employees, Clerks employed by Floor Participants and registered with the Exchange, Exchange visitors that receive authorized admission to the Trading Floor pursuant to Exchange policy, and any other persons that the Exchange authorizes admission to the Trading Floor. Proposed Rule 7670(a)(1)(B) provides the same persons with access to the Virtual Trading Floor, except for visitors. While Clerks may access the Virtual Trading Floor, they may only perform the same functions for their associated organizations in connection with open outcry trading on the Virtual Trading Floor as they do for open outcry trading on the physical Trading Floor. The Exchange understands permitting Clerks to access the Virtual Trading Floor will provide them with access to the information that they normally have access to on the physical Trading Floor, which will make it more efficient for them to perform their tasks. Clerks will continue to be unable to enter into transactions on the Exchange. Additionally, as there is no physical equipment that would

³ See Securities Exchange Act Release No. 90658 (December 14, 2020) (Order Approving SR–CBOE–2020–055).

⁴The Exchange notes that from May 2, 2020 through July 31, 2020, Complex Orders for options with more than four legs represented approximately 6.9% of the total Complex Order ADV during that timeframe. The Exchange believes that this trading activity further demonstrates the need to execute certain high-risk and complex strategies with the assistance of human interaction and price negotiation that a Trading Floor best facilitates. The Exchange believes that the proposed Virtual Trading Floor will be an identical venue to that of the physical Trading Floor with respect to these types of trades.

need service on the Virtual Trading Floor, and no purpose for a visitor to observe the Virtual Trading Floor, the proposed rule change excludes visitors from accessing the Virtual Trading Floor.⁵

As is the case with the physical Trading Floor, the Exchange will provide access to the Virtual Trading Floor to Participants the Exchange has approved to perform a Trading Floor function (including Floor Brokers and Floor Market Makers). This includes Participants (and individuals that represent Participant organizations) that are currently authorized to perform Trading Floor functions, as well as any additional Participants that receive such authorization in the future. Each authorized individual will receive one log-in to the Virtual Trading Floor. The Exchange currently requires at least one Market Maker to be present on the physical Trading Floor (prior to a Floor Broker announcing an order for execution) 6 and believes it is necessary and appropriate to impose such requirement for the Virtual Trading Floor. Further, the Exchange notes that it will track which individuals participate in the Virtual Trading Floor, including when they log-in and log-out.

Under this proposal, Floor Participants are not required to display badges on the Virtual Trading Floor, as the size of the view on the communication program may not permit badges to be visible.8 Currently, on the physical Trading Floor, a Floor Market Maker has an appointment to trade open outcry in all classes trading on the Exchange (and must be physically present in the Crowd Area to trade in open outcry). Similarly, any Floor Market Maker authorized to act on the physical Trading Floor will receive access to the Virtual Trading Pit on the Virtual Trading Floor.

As set forth in Rule 7660, and subject to the requirements in that Rule, Floor Participants may use any communication device on the physical Trading Floor (which it must register

with the Exchange). Pursuant to proposed Rule 7670(a)(1)(C), Participants may use any equipment to access the Virtual Trading Floor. Prior to using a communications device for business purposes on the physical Trading Floor of the Exchange, Participants must register the communications device by identifying (in a form and manner prescribed by the Exchange) the hardware. Because individuals on the Virtual Trading Floor will not be on the Exchange premises (and thus will not be using Exchange provided bandwidth to be shared with all market participants and do not pose the same security risks), the proposed rule change will not require Participants to register devices they use while on the Virtual Trading Floor.⁹ Rule 7660 will otherwise apply in the same manner to the Virtual Trading Floor as it does to the physical Trading Floor (to the extent the context requires). This includes requirements related to audit trail and record retention, prohibition on using any device for the purpose of recording activities in the Virtual Trading Pit or maintaining an open line of continuous communication whereby a nonassociated person not located in the trading crowd may continuously monitor the activities in the trading

The Exchange will use a communication program that has audio and video capabilities, as well as "chat" functionality. Proposed Rule 7670(a)(1)(D) states that the Exchange may determine to require any Floor Market Maker or Floor Broker in the Virtual Trading Pit that wants to trade against an order represented for execution to express its bid or offer in a chat available in the Virtual Trading Pit. 10 The Exchange would require Participants to utilize the chat function

if BOX Trading Floor Officials determine that increased volume or activity in the Virtual Trading Crowd warrant mandatory use of the chat feature for Participants to maintain a fair and orderly market.¹¹ Chats will be visible to all Participants in the Virtual Trading Pit and will not be permitted directly between individual Participants (i.e., the Exchange will disable direct messaging functionality within the communication program). Participants on the physical Trading Floor only verbalize their interest to trade against a represented order, so not requiring bids and offers to be included in a chat conforms to current practice on the Trading Floor. However, given potential limitations of communication software (such as limitations on how many people may be heard at the same time in the Virtual Pit or potential buffering or echoing), the Exchange believes it may be appropriate to require market participants to use a chat tool in the communication program to indicate their interest in participating in a trade so that the representing Floor Broker is able to know the market from the trading crowd and fairly allocate the trade pursuant to the Rules. The Exchange believes the flexibility to impose this requirement in the Virtual Trading Pit is appropriate, as these limitations may ultimately not interfere with a Floor Broker's ability to hear all interest (particularly in a Virtual Trading Pit with few Participants) and thus the additional requirement may potentially slow down executions. Flexibility will permit the Exchange to balance system limitation. The Exchange notes that, regardless of whether it requires the chat function to be used, the Exchange will maintain records of all chats in the Virtual Trading Floor in accordance with its self-regulatory organization recordretention obligations.

The program also has a functionality that will permit Floor Brokers and Floor Market Makers on the Virtual Trading Floor to see an electronic blotter containing a running list of unexecuted orders that have been represented by Floor Brokers on the Virtual Trading Floor. Currently, Floor Brokers record the times at which they verbally represent orders on the Trading Floor by submitting their order to the Trading Host for execution. This information is generally only verbally available on the physical trading floor. However, similar

⁵ While the Exchange does not anticipate granting any other individuals with access to the Virtual Trading Floor outside of Participants and Exchange personnel, the Exchange believes the flexibility to permit Exchange personnel to access the Virtual Trading Floor is appropriate, such as to permit access to make updates to the communication program.

⁶ See BOX Rule 7580(a).

⁷ The Exchange notes that another options exchange with a Virtual Trading Floor has a similar requirement. See Securities Exchange Release Act No. 91299 (March 11, 2021), 86 FR 14661 (Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of SR-Phlx-2021-03).

⁸ The Virtual Trading Floor program will identify the Participant organization of each Participant in the Virtual Trading Pit.

⁹ The Exchange notes that Floor Participants will be required to inform the Exchange of the IF address that will be used to access the Virtual Trading Floor. Market participants will likely use home networks to connect to the Virtual Trading Floor platform (which is contained in the BOX trading environment). By requiring the submission of IP addresses to BOX, the Exchange is able to create a secure network available only to approved IP addresses. This, in turn, denies any outside (and not previously approved) connections from entering the Virtual Trading Floor and, thus secures the Virtual Trading environment to only those Participants approved by the Exchange. Further, the Exchange believes that requiring the submission of IP addresses connected to the Virtual Trading Floor is appropriate and will be of assistance to BOX employees if market participants experience any connection issues when trying to use the Virtual Trading Floor platform.

¹⁰ The Exchange will announce to all Participants any determination to require bids and offers to be expressed in a chat within the communication program by Regulatory Circular. The Exchange will provide such notice with sufficient advance notice.

¹¹The Exchange notes that another exchange with a Virtual Trading Floor has a similar requirement. See Securities Exchange Release Act No. 91299 (March 11, 2021), 86 FR 14661 (Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of SR–Phlx–2021–03).

to why the Exchange is making chat functionality available in the Virtual Trading Floor, the Exchange believes the additional information included in the blotter will benefit Virtual Trading Floor Participants given potential limitations of communication software (such as limitations on how many people may be heard at the same time in a virtual pit or potential buffering or echoing). For example, if a Floor Market Maker's personal device momentarily freezes, causing the Floor Market Maker to miss the terms of an order represented by a Floor Broker, the Floor Market Maker will still be able to see the terms of the order in the blotter and determine whether it wants to seek to trade with the order.

Further, pursuant to proposed Rule 7670(a)(1)(E), Floor Market Maker auotes will be considered firm in the event the Floor Market Maker is disconnected from the Virtual Trading Crowd and the parties have a Meeting of the Minds with respect to the terms of the transaction. A "Meeting of the Minds" means the contra-side(s) verbally confirmed participation in the trade. In the event that a Floor Market Maker is disconnected from the Virtual Trading Crowd, a Floor Market Maker quote would not be considered firm if the quote were provided and the parties did not have a Meeting of the Minds with respect to the terms of the transaction.

Today, a Floor Market Maker that experiences issues with internet connection, makes an error or otherwise is unaware of recent news in a particular option, would be held to a quote verbalized in open outcry. In the event that the negotiation continues and the terms change, the Floor Marker Maker would not be held to the new terms without additional acceptance of those terms. In the event that the transaction is not effectuated in the BOX Trading Host, the trade would not stand. To that end, the Exchange believes requiring quotes to remain firm once the parties have arrived at a Meeting of the Minds with respect to the terms of the transaction creates fair and equitable expectations for Participants trading in the Virtual Trading Crowd.

The Exchange notes that, regardless of whether it requires the chat function to be used, the Exchange will maintain records of all chats in the Virtual Trading Floor ¹² in accordance with its self-regulatory organization record retention obligations, as these are "correspondence" records subject to

those obligations, as set forth in proposed subparagraph (a)1)(F).13 Specifically, proposed 7670(a)(1)(F) states the Exchange will retain records of the chats, Participant logs, and any other records related to the virtual trading floor that are subject to the Exchange's record retention obligations under the Exchange Act. The Exchange does not currently plan to make video recordings of the virtual trading floor because the Exchange believes video is not subject to its record retention obligations. However, if the Exchange determined to make video recordings of the virtual trading floor, it would retain those video recordings in accordance with its record retention obligations. 14

Floor Officials will have access to the Virtual Trading Floor. Floor Officials will have the same authority to act in the Virtual Trading Floor as they do on the physical trading floor. Additionally, a BOX employee will be available to provide technical and operational support (in addition to regular Exchange support staff for floor operations) if Participants in the Virtual Trading Floor need assistance. If there was an issue with the communication program making the Virtual Trading Floor unavailable, the Exchange would operate in an all-electronic configuration (as it did earlier in 2020 when the physical Trading Floor was unavailable) until the communication program was available again.

While open outcry trading on the Virtual Trading Floor will occur with in-crowd market participants interacting with each other remotely through a computer communication program, all trading that occurs on the Virtual Trading Floor will occur in the same manner as it does on the physical Trading Floor. Specifically, open outcry trading on the Virtual Trading Floor will be subject to the same priority and allocation rules as open trading on the physical Trading Floor, as set forth in Rule 7600. Any risk controls and price protection mechanisms that apply to open outcry trading on the physical Trading Floor will apply in the same manner to open outcry trading on the Virtual Trading Floor. The Exchange will make the same order types and instructions available on the Virtual Trading Floor as it makes available on the physical Trading Floor. Floor Brokers will be subject to the responsibilities set forth in Rules 7570 and 7580 on the Virtual Trading Floor,

as they are on the physical Trading Floor.

In addition, marker participants participating on the Virtual Trading Floor will be subject to the same regulatory requirements on the Virtual Trading Floor as they are on the physical Trading Floor, including those set forth in Rule Series 3000 and 4000. Orders must be systematized 15 and represented,16 and transactions reported, in connection with the Virtual Trading Floor in the same manner as they are when trading on the physical Trading Floor. Therefore, the audit trail for open outcry trading on the Virtual Trading Floor will capture the same information that it does for open outcry trading on the physical Trading Floor. The Regulatory Division will be able to utilize preexisting Trading Floor surveillances to surveil for the activity occurring on the Virtual Trading Floor. Specifically, the Regulatory Division monitors open outcry trading using various automated surveillances, which incorporate systematized order and trade execution information and applicable time stamps, as well as other elements of the audit trail from the Floor Broker's order entry system(s) and the BOX matching engine. Because incrowd market participants will use the same tools to systematize and execute orders on the Virtual Trading Floor that they would use on the physical Trading Floor, and will be subject to the same trading rules and requirements, the Regulatory Staff's automated surveillances applicable to open outcry trading will incorporate the same audit trail information from open outcry trading on the Virtual Trading Floor that they do from open outcry trading on the physical Trading Floor. Additionally, Regulatory Staff will always be present on the Virtual Trading Floor and may access any records pertaining to the Virtual Trading Floor (i.e., chats) if they deem it necessary and appropriate to ensure compliance with BOX Rules.

Lastly, the Exchange notes that it has conducted meetings with Floor Participants in which the Exchange presented the functionality of the Virtual Trading Floor and has made the Virtual Trading Floor available for testing so that the Exchange will be ready to implement it if necessary. The Exchange has received positive feedback from Floor Participants regarding the Virtual Trading Floor and will continue to make updates as necessary and appropriate in response to comments it receives to make the Virtual Trading Floor replicate the open outcry trading

¹²The Exchange notes the information that will be displayed in the blotter is already retained as part of the BOX order audit trail.

¹³ See 15 U.S.C. 78q(a).

¹⁴ *Id.* The Exchange notes it will disable the ability of Participants to record the Virtual Trading Floor through the communication program.

¹⁵ See Rule 7580(e)(1).

¹⁶ See Rule 7580(e)(2).

experience on the physical Trading Floor as much as possible. The Exchange believes this will provide the opportunity for as seamless a rollout as possible if circumstances cause the Exchange to make the Virtual Trading Floor available.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act 17 in general, and furthers the objectives of Section 6(b)(5) of the Act 18 in particular, in that it is designed to 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 the proposed rule change is consistent with the Section $6(b)(\bar{5})^{19}$ requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes the proposed rule change will 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, as it will permit open outcry trading to continue in the event the Exchange's Trading Floor is inoperable. The Exchange again notes that the proposed Virtual Trading Floor will only be activated if the physical Trading Floor becomes inoperable. Further, the Exchange has the discretion to not activate the Virtual Trading Floor if the physical Trading Floor becomes inoperable. The Exchange believes that these factors, taken together, limit the scope of this proposal to extenuating circumstances that the Exchanges hopes to avoid. While the Exchange continues to believe that the physical Trading Floor is an essential function to BOX Market and hopes the physical Trading Floor does not become inoperable or require any closures in the future, the Exchange also believes it is appropriate to continue to review and enhance its rules with regard to its business continuity plans if the physical Trading Floor were to become inoperable. As such, the Exchange believes the adoption of a Virtual Trading Floor, which emulates the physical Trading

Floor, is reasonable and appropriate given the circumstances the world faces today.

As discussed above, there are certain features of open outcry trading that are difficult to replicate in an all-electronic trading environment. The Exchange has observed, and understands from various market participants, that they have had difficulty executing certain orders, such as larger orders and high-risk and complicated strategies, in an allelectronic trading environment without the element of human interaction to negotiate pricing for these orders. The proposed rule change would provide an environment in which this interaction would be available despite the inoperability of the physical Trading Floor. The Exchange believes the proposed rule change may facilitate continued trading of these orders if and when the Trading Floor is inoperable. As a result, the Exchange believes providing continuous access to open outcry trading when the physical Trading Floor is inoperable will remove impediments to a free and open market and will ultimately benefit investors, particularly those desiring to execute high-risk and complex trading strategies.

proposed rule change will promote just and equitable principles of trade, as open outcry trading on a Virtual Trading Floor will occur in accordance with the same trading rules and be subject to the

The Exchange also believes the

to open outcry trading on the physical Trading Floor, all of which have previously been filed with the Commission. The proposed rule change will merely permit this open outcry trading to occur in a virtual setting rather than a physical setting (which may be necessary and appropriate for health and safety purposes)—in other words, open outcry trading on a Virtual Trading Floor will occur while market participants operate remotely as they do

same regulatory requirements that apply

participants operate remotely as they do when they trade electronically. Specifically, open outcry trading on the Virtual Trading Floor will be subject to the same priority and allocation rules as open trading on the physical Trading Floor, as set forth in Rule 7600 series. As is the case for open outcry trading on the physical Trading Floor, open outcry trading on the Virtual Trading Floor is consistent with Section 11(a) of the Act, as IM–7600–5 (which will apply to open outcry trading on the Virtual Trading

Floor) requires Participants relying on Section 11(a)(1)(G) of the Act and Rule 11a1–1(T) thereunder (the so called "G exemption rule") as an exemption must yield priority to any bid (offer) at the same price of Public Customer orders the contraint the c

and broker-dealer orders resting in the Book, as well as any other bid (offer) that has priority over those Broker Dealer orders under this Rule. The Exchange may make the same order types and instructions available on the Virtual Trading Floor as it makes available on the physical Trading Floor. Floor Brokers will be subject to the responsibilities set forth in Rules 7570 and 7580 on the Virtual Trading Floor, as they are on the physical Trading Floor.

Additionally, Participants participating on the Virtual Trading Floor will be subject to the same regulatory requirements on the Virtual Trading Floor as they are on the physical Trading Floor, including those set forth in Rule Series 3000 and 4000. As previously noted, orders must be systematized and represented, and transactions reported, in connection with the Virtual Trading Floor in the same manner as they are when trading on the physical Trading Floor.²⁰ Therefore, the audit trail for open outcry trading on the Virtual Trading Floor will capture the same information that it does for open outcry trading on the physical Trading Floor. The Regulatory Division will be able to utilize preexisting floor surveillances to surveil for the activity occurring on the Virtual Trading Floor. Specifically, the Regulatory Division monitors open outcry trading using various automated surveillances, which incorporate systematized order and trade execution information and applicable time stamps, as well as other elements of the audit trail from the floor broker's order entry system(s) and the BOX matching engine. Because in-crowd market participants will use the same tools to systematize and execute orders on the Virtual Trading Floor that they would use on the physical Trading Floor, and will be subject to the same trading rules and requirements, the Regulatory Division's automated surveillances applicable to open outcry trading will incorporate the same audit trail information from open outcry trading on the Virtual Trading Floor that they do from open outcry trading on the physical Trading Floor. Additionally, Regulatory Division Staff

^{17 15} U.S.C. 78f(b).

^{18 15} U.S.C. 78f(b)(5).

¹⁹ Id.

²⁰ Pursuant to proposed Rule 7670(a)(1)(E), Floor Market Maker quotes will be considered firm in the event the Floor Market Maker is disconnected from the Virtual Trading Crowd and the parties have a Meeting of the Minds with respect to the terms of the transaction. A "Meeting of the Minds" means the contra-side(s) verbally confirmed participation in the trade. In the event that a Floor Market Maker is disconnected from the Virtual Trading Crowd, a Floor Market Maker quote would not be considered firm if the quote were provided and the parties did not have a Meeting of the Minds with respect to the terms of the transaction.

will always be present on the Virtual Trading Floor and may access any records pertaining to the Virtual Trading Floor (*i.e.*, chats) if they deem it necessary and appropriate to ensure compliance with BOX Rules. The Exchange believes it will promote just and equitable principles of trading for all open outcry trading to occur in substantially the same manner, whether it occurs while market participants are in the same physical setting or in remote settings being connected through a technological solution.

In addition, the Exchange believes the proposed rule change will not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers, as all individuals authorized to act on the physical Trading Floor (both Participant organizations authorized at the time the physical Trading Floor becomes inoperable and any Participant organization that becomes authorized after the physical Trading Floor becomes inoperable) will be provided with access to the Virtual Trading Floor.

Lastly, the Exchange notes that the proposed rule is a competitive response that is based on a proposal recently submitted by Cboe and approved by the Commission.²¹

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. In this regard and as indicated above, the Exchange notes that the rule change is being proposed as a competitive response to a filing submitted by Cboe that was recently approved by the Commission. Further, the Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, as all Participants authorized by the Exchange, or that become authorized by the Exchange, to transact on the Trading Floor will receive access to the Virtual Trading Floor. The Exchange does not believe that the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, as it relates solely to the location of open outcry trading on the Exchange. The proposed rule change will merely permit open outcry trading that generally occurs while market participants are located in the same

physical setting to occur while market participants are in a remote setting, connected by a technological solution (as electronic trading does).

The Exchange believes that the proposed rule change will relieve any burden on, or otherwise promote, competition. The Exchange believes the proposed rule change will provide market participants with continuous access to open outcry trading when the physical Trading Floor is inoperable. The Exchange believes this may facilitate continued, competitive price negotiations and trading of orders that the Exchange understands are more difficult to execute in an all-electronic trading environment without human interaction. Additionally, the proposed rule change will provide customer orders represented for open outcry execution with access to the same pool of liquidity when the Trading Floor is inoperable to which those orders would have access when the Trading Floor is operating in its normal state. Maintenance of this level of liquidity at all times, even when the physical Trading Floor is inoperable, may promote competition by providing these customer orders with increased liquidity than may otherwise be available, and thus increased execution opportunities and price discovery.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (http://www.sec.gov/rules/sro.shtml); or
- Send an email to *rule-comments@ sec.gov*. Please include File Number SR–BOX–2021–07 on the subject line.

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR-BOX-2021-07. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (http://www.sec.gov/ rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-BOX-2021-07, and should be submitted on or before May 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. 22

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–09443 Filed 5–4–21; 8:45 am]

BILLING CODE 8011-01-P

²¹ See supra note 3.

^{22 17} CFR 200.30-3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-91732; File No. SR-C2-2021-007]

Self-Regulatory Organizations; Cboe C2 Exchange, Inc.; Notice of Filing of a Proposed Rule Change To Amend the Sixth Amended and Restated Bylaws of Cboe C2 Exchange, Inc.'s Parent Corporation, Cboe Global Markets, Inc. To Implement Proxy Access

April 29, 2021.

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 April 26, 2021, Cboe C2 Exchange, Inc. ("Exchange" or "C2") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe C2 Exchange, Inc. (the "Exchange" or "C2") is filing with the Securities and Exchange Commission (the "Commission") a proposed rule change with respect to amendments to the Sixth Amended and Restated Bylaws (the "CGM Bylaws") of its parent corporation, Cboe Global Markets, Inc. ("Cboe" or "Corporation"). The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (http://markets.cboe.com/us/options/regulation/rule_filings/ctwo/), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of

the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Choe has received a stockholder proposal submitted pursuant to Rule 14a–8 under the Act ³ which requested that the CGM Board take steps to implement a "proxy access" bylaw provision. In general, proxy access bylaws allow a stockholder, or group of stockholders, who comply with certain requirements, to nominate candidates for service on a board and have those candidates included in a company's proxy materials. Such provisions have become common among S&P 500 companies.4 Choe has determined to take the stockholder's requested steps to implement proxy access. Accordingly, the Exchange now proposes to make these changes by adopting new Section 2.16 of the CGM Bylaws and making certain conforming changes to current Sections 2.10 and 2.11 of the CGM Bylaws, all of which are described further below.

In developing its proposal, Cboe generally tried to balance the relative weight of arguments for and against proxy access provisions. On the one hand, Cboe recognizes the significance of this issue to some investors, who see proxy access as an important accountability mechanism that allows them to participate in board elections through the nomination of stockholder candidates that are presented in a company's proxy statement. On the other hand, Cboe's proposed proxy access provision includes certain procedural requirements that are designed to help ensure, among other things, that Cboe and its stockholders will have full and accurate information about nominating stockholders and their nominees and that such stockholders and nominees will comply with applicable laws, regulations and other requirements. Additionally, the Exchange notes the proposed terms are common among companies that have adopted proxy access. The Exchange also notes that the parent companies of other exchanges have adopted substantively similar proxy access provisions and the Exchange does not

believe such provisions are materially different than the Exchange's proposal.⁵

The proposed rule change would add new Section 2.16 to the CGM Bylaws. Section 2.16 would permit a stockholder, or group of up to 20 stockholders, to nominate director nominees for the Cboe Board, so long as the stockholder(s) have owned at least three percent of Cboe's outstanding shares of capital stock continuously for at least three years. The director nominees would be included in Cboe's annual meeting proxy materials. The proposed provision would limit the number of proposed director nominees to the greater of (i) two or (ii) 20% of the number of Cboe directors in office (rounded down to the nearest whole number, but no less than two) provided that the stockholder(s) and nominee(s) satisfy the other conditions specified in the CGM Bylaws as described further below.

Proposed Section 2.16(a)

The Exchange first proposes to amend the CGM Bylaws to, as set forth in the first sentence of proposed Section 2.16(a), require the Corporation to include in its proxy statement, its form proxy and any ballot distributed at the stockholder meeting, the name of, and certain Required Information 6 about, any person nominated for election (the "Stockholder Nominee") to the Board by a stockholder or group of stockholders (the "Eligible Stockholder") 7 that satisfies the requirements set forth in the proxy access provision of CGM Bylaws.8 Proposed Section 2.16(a) will also make clear that Cboe is able to solicit against any Stockholder Nominee or include in

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See 17 CFR 240.14a–8, which requires companies that are subject to the federal proxy rules to include shareholder proposals in companies' proxy statements to shareholders, subject to certain procedural and substantive requirements.

 $^{^4}$ More than 75% of S&P 500 companies have adopted proxy access bylaw provisions.

⁵ See Securities Exchange Release No. 79357
(November 18, 2016) 81 FR 85283 (November 25, 2016) (SR-NASDAQ-2016-127; SR-BX-2016-051; SR-ISE-2016-22; SR-ISEGemini-2016-10; SR-ISEMercury-2016-16; SR-PHLX-2016-93; SR-BSECC-2016-001; SR-SCCP-2016-01). See also Securities Exchange Release No. 77782 (May 6, 2016) 81 FR 29600 (May 12, 2016) (SR-NYSE-2016-14; SR-NYSEArca-2016-25; SR-NYSEMKT-2016-20).

⁶The Required Information is the information provided to Cboe's Corporate Secretary about the Stockholder Nominee and the Eligible Stockholder that is required to be disclosed in the Corporation's proxy statement by the regulations promulgated under the Act, and if the Eligible Stockholder so elects, a written statement, not to exceed 500 words, in support of the Stockholder Nominee(s)' candidacy (the "Supporting Statement", as defined further below).

⁷ As used throughout the CGM Bylaws, the term "Eligible Stockholder" includes each member of a stockholder group that submits a proxy access nomination to the extent the context requires.

⁸ When the Corporation includes proxy access nominees in the proxy materials, such individuals will be included in addition to any persons nominated for election by at or the direction of the Board to the Board or any committee thereof.

its proxy materials the Corporation's own statements or other information relating to any Eligible Stockholder or Stockholder Nominee, including any information provided to the Corporation pursuant to Section 2.16. This provision clarifies that just because Cboe must include a Stockholder Nominee in its proxy materials if the proxy access provisions are satisfied, Cboe does not necessarily have to support that nominee.

Proposed Section 2.16(b)

Proposed Section 2.16(b) will provide that in order to utilize this provision, the Eligible Stockholder must expressly request at the time of providing a required notice to the Corporation of the proxy access nomination (the "Notice of Proxy Access Nomination") to have its nominee included in the Corporation's proxy materials. Proposed Section 2.16(b) also establishes the deadline for a timely Notice of Proxy Access Nomination. Specifically, such a notice must be delivered to the Cboe's Secretary at the principal executive offices of the Corporation not earlier than the open of business on the one hundred fiftieth (150th) day and not later than the close of business on the one hundred twentieth (120th) day prior to the first anniversary of the date that Choe first distributed its proxy statement to stockholders for the previous year's annual meeting of stockholders provided, however, that in the event the annual meeting is more than thirty (30) days before or after the anniversary date of the prior year's annual meeting, or if no annual meeting was held in the preceding year, to be timely, the Notice of Proxy Access Nomination must be received at the principal executive offices of the Corporation no earlier than one hundred fifty (150) days before such annual meeting and no later than the later of one hundred twenty (120) days before such annual meeting or the tenth (10th) day following the day on which public announcement (as defined in Section 2.11) of the date of such meeting is first made by the Corporation. Further Section 2.16 will provide that in no event shall any adjournment or postponement of an annual meeting or the announcement thereof commence a new time period (or extend any time period) for the giving of a Notice of Proxy Access Nomination as described above. Choe believes this notice period will provide stockholders an adequate window to submit nominees via proxy access, while also providing the Corporation adequate time to diligence a proxy access nominee before including them in the proxy statement

for the next annual meeting of stockholders.

Proposed Section 2.16(c)

Proposed Section 2.16(c) specifies that the maximum number ("the Permitted Number") of Stockholder Nominees nominated by all Eligible Stockholders that will be included in Choe's proxy materials with respect to an annual meeting of stockholders shall not exceed the greater of two or 20% of the total number of directors in office (rounded down to the nearest whole number) as of the last day on which a Notice of Proxy Access Nomination may be delivered pursuant to and in accordance with the proxy access provision of the Bylaws (the "Final Proxy Access Nomination Date"). In the event that one or more vacancies for any reason occurs after the Final Proxy Access Nomination Date but before the date of the annual meeting and the Board resolves to reduce the size of the Board in connection therewith, the Permitted Number of Stockholder Nominees included in Choe's proxy materials shall be calculated based on the number of directors in office as so reduced. In addition, the Permitted Number shall be reduced by (i) the number of individuals who will be included in the Corporation's proxy materials as director nominees recommended by the Board pursuant to an agreement, arrangement or other understanding with a stockholder or group of stockholders (other than any such agreement, arrangement or understanding entered into in connection with an acquisition of stock from the Corporation by such stockholder or group of stockholders) and/or (ii) the number of directors in office as of the Final Proxy Access Nomination Date who were included in the Corporation's proxy materials as Stockholder Nominees for any of the two preceding annual meetings of stockholders (including any persons counted as Stockholder Nominees pursuant to the immediately succeeding sentence) and whose reelection at the upcoming annual meeting is being recommended by the Board. Any individual nominated by an Eligible Stockholder for inclusion in the proxy materials pursuant to the proxy access provision of the CGM Bylaws whom the Board decides to nominate as a nominee of the Board, and any individual nominated by an Eligible Stockholder for inclusion in the proxy materials pursuant to the proxy access provision but whose nomination is subsequently withdrawn, shall be counted as one of the Stockholder Nominees for purposes of determining when the Permitted

Number of Stockholder Nominees has been reached. Any Eligible Stockholder submitting more than one Stockholder Nominee for inclusion in the proxy materials shall rank such Stockholder Nominees based on the order that the Eligible Stockholder desires such Stockholder Nominees to be selected for inclusion in the proxy statement in the event that the total number of Stockholder Nominees submitted by Eligible Stockholders pursuant to the proxy access provision exceeds the Permitted Number of nominees allowed. In the event that the number of Stockholder Nominees submitted by Eligible Stockholders pursuant to Section 2.16 exceeds the Permitted Number of nominees allowed, the highest ranking Stockholder Nominee who meets the requirements of the proxy access provision of the Bylaws from each Eligible Stockholder will be selected for inclusion in the proxy materials until the Permitted Number is reached, going in order of the amount (largest to smallest) of shares of Cboe's outstanding capital stock each Eligible Stockholder disclosed as owned in its respective Notice of Proxy Access Nomination submitted to Cooe. If the Permitted Number is not reached after the highest ranking Stockholder Nominee who meets the requirements of the proxy access provision of the Bylaws from each Eligible Stockholder has been selected, then the next highest ranking Stockholder Nominee who meets the requirements of Section 2.16 from each Eligible Stockholder will be selected for inclusion in the Corporation's proxy materials, and this process will continue as many times as necessary, following the same order each time, until the Permitted Number is reached. Additionally, notwithstanding anything to the contrary contained in proposed Section 2.16, Choe will not be required to include any Stockholder Nominees in its proxy materials pursuant to Section 2.16 for any meeting of stockholders for which the Secretary receives a notice (whether or not subsequently withdrawn) that the Eligible Stockholder or any other stockholder intends to nominate one or more persons for election to the Board pursuant to Section 2.11 of the CGM Bylaws. Choe believes it is reasonable to limit the Board seats available to proxy access nominees and to establish procedures for selecting candidates if the nominee limit is exceeded. The limitation on Board seats available to proxy access nominees ensures that proxy access cannot be used to take over the entire Board, which is not the stated

purpose of proxy access campaigns. The procedures for selecting candidates if the nominee limit is exceeded establish clear and rational guidelines for an orderly nomination process to avoid the Corporation having to make arbitrary judgments among candidates.

Proposed Section 2.16(d)

Proposed Section 2.16(d) defines who may qualify as an "Eligible Stockholder". Particularly, an Eligible Stockholder is a stockholder or group of no more than 20 stockholders 9 that (i) has owned continuously for at least three years (the "Minimum Holding Period'') a number of shares of capital stock of the Corporation that represents at least three percent of the outstanding shares of capital stock of the Corporation as of the date the Notice of Proxy Access Nomination is received (the "Required Shares"), (ii) continues to own the Required Shares through the date of the annual meeting and (iii) meets all other requirements of proposed Section 2.16. Choe believes it is reasonable to require each member of a nominating group to provide such information so that both the Corporation and its stockholders are fully informed about the entire group making the proxy access nomination. As such, Section 2.16(d) further makes clear that whenever the Eligible Stockholder consists of a group of stockholders (including a group of funds that are part of the same Qualifying Fund Group), (i) each provision in Section 2.16 that requires the Eligible Stockholder to provide any written statements, representations, undertakings, agreements or other instruments or to meet any other conditions shall be deemed to require each stockholder (including each individual fund) that is a member of such group to provide such statements, representations, undertakings, agreements or other instruments and to meet such other conditions (except that the members of such group may aggregate the shares that each member has owned continuously for the Minimum Holding Period in order to meet the three percent ownership requirement of the "Required Shares" definition) and (ii) a breach of any obligation, agreement or representation under Section 2.16 by any member of such group shall be

deemed a breach by the Eligible Stockholder. No stockholder may be a member of more than one group of stockholders constituting an Eligible Stockholder with respect to any annual meeting.

Proposed Section 2.16(e)

Proposed Section 2.16(e) clarifies, for the avoidance of doubt, how "ownership" will be defined for purposes of meeting the ownership requirements of the Required Shares. Specifically, an Eligible Stockholder shall be deemed to "own" only those outstanding shares of Choe's capital stock as to which the stockholder possesses both: (i) The full voting and investment rights pertaining to the shares; and (ii) the full economic interest in (including the opportunity for profit from and risk of loss on) such shares; provided that the number of shares calculated in accordance with clauses (i) and (ii) shall not include any shares: That are (1) sold by such stockholder or any of its affiliates in any transaction that has not been settled or closed; (2) borrowed by such stockholder or any of its affiliates for any purposes or purchased by such stockholder or any of its affiliates pursuant to an agreement to resell; or (3) subject to any option, warrant, forward contract, swap, contract of sale, other derivative or similar instrument or agreement entered into by such stockholder or any of its affiliates, whether any such instrument or agreement is to be settled with shares or with cash based on the notional amount or value of shares of Cboe's outstanding capital stock, in any such case which instrument or agreement has, or is intended to have, the purpose or effect of: (A) Reducing in any manner, to any extent or at any time in the future, such stockholder's or its affiliates' full right to vote or direct the voting of any such shares; and/or (B) hedging, offsetting or altering to any degree any gain or loss realized or realizable from maintaining the full economic ownership of such shares by such stockholder or its affiliates.

Further, a stockholder shall "own" shares held in the name of a nominee or other intermediary so long as the stockholder retains the right to instruct how the shares are voted with respect to the election of directors and possesses the full economic interest in the shares. A stockholder's ownership of shares shall be deemed to continue during any period in which (i) the stockholder has loaned such shares provided that the stockholder has the power to recall such loaned shares on five (5) business days' notice and includes in the Notice of

Proxy Access Nomination an agreement that it will (1) recall such loaned shares upon being notified that any of its Stockholder Nominees will be included in the Corporation's proxy materials and (2) will hold such shares through the date of the annual meeting or (ii) the stockholder has delegated any voting power by means of a proxy, power of attorney or other instrument or arrangement which is revocable at any time by the stockholder. Section 2.16(e) also clarifies that the terms "owned," "owning" and other variations of the word "own" shall have correlative meanings. Whether outstanding shares of Cboe's capital stock are "owned" for these purposes shall be determined by the Board. For purposes of Section 2.16, the term "affiliate" or "affiliates" shall have the meaning ascribed thereto under the rules and regulations of the Act.¹⁰ An Eligible Stockholder shall include in its Notice of Proxy Access Nomination the number of shares it is deemed to own for the purposes of proposed Section 2.16. In proposing the Required Shares and the Minimum Holding Period, Choe seeks to ensure that the Eligible Stockholder has had a sufficient stake in the Corporation for a sufficient amount of time and is not pursuing a short-term agenda.

Proposed Section 2.16(f)

Proposed Section 2.16(f) sets forth the information that an Eligible Stockholder must provide to Cboe's Corporate Secretary in writing within the deadline discussed above in order to make a proxy access nomination. This information includes:

- A statement by the Eligible Stockholder (1) setting forth and certifying as to the number of shares it owns and has owned continuously for the Minimum Holding Period and (2) agreeing to continue to own the Required Shares through the date of the annual meeting;
- one or more written statements from the record holder of the Required Shares (and from each intermediary through which the Required Shares are or have been held during the Minimum Holding Period) verifying that, as of a

⁹ For this purpose, any two or more funds that are part of the same Qualifying Fund Group may be counted as one stockholder. A "Qualifying Fund Group" means two or more funds that are (i) under common management and investment control, (ii) under common management and funded primarily by the same employer or (iii) a "group of investment companies" as such term is defined in Section 12(d)(1)(G)(ii) of the Investment Corporation Act of 1940, as amended.

¹⁰ Pursuant to Rule 12b–2 under the Act, "[a]n 'affiliate' of, or a person 'affiliated' with, a specified person, is a person that directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, the person specified." 17 CFR 240.12b–2. Further, "[t]he term 'control' (including the terms 'controlling,' 'controlled by' and 'under common control with') means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a person, whether through the ownership of voting securities, by contract, or otherwise." 17 CFR 240.12b–2.

date within seven calendar days prior to the date the Notice of Proxy Access Nomination is delivered to Cboe's Secretary at the principal executive offices of the Corporation, the Eligible Stockholder owns, and has owned continuously for the Minimum Holding Period, the Required Shares, and the Eligible Stockholder's agreement to provide, within five (5) business days after the record date for the annual meeting, written statements from the record holder and intermediaries verifying the Eligible Stockholder's continuous ownership of the Required Shares through the record date;

• a copy of the Schedule 14N that has been filed with the SEC as required by Rule 14a–18 under the Act; ¹¹

- the information, representations and agreements and other documents that are required to be set forth in or included with a stockholder's notice of nomination given pursuant to Section 2.11 of the CGM Bylaws;
- the written consent of each Stockholder Nominee to being named in the proxy statement as a nominee and to serving as a director if elected;
- a representation that the Eligible Stockholder:
- O Acquired the Required Shares in the ordinary course of business and not with the intent to change or influence control of Cboe, and does not presently have such intent;
- has not nominated and will not nominate for election any individual as a director at the annual meeting, other than its Stockholder Nominee(s);
- has not engaged and will not engage in, and has not and will not be a participant in another person's, "solicitation" within the meaning of Rule 14a–1(l) under the Act in support of the election of any individual as a director at the annual meeting, other than its Stockholder Nominee(s) or a nominee of the Board;
- has not distributed and will not distribute to any stockholder of the Corporation any form of proxy for the annual meeting other than the form distributed by the Corporation;
- has complied and will comply with all laws, rules and regulations applicable to solicitations and the use, if any, of soliciting material in connection with the annual meeting,
- has provided and will provide facts, statements and other information

in all communications with Cboe and its stockholders that are or will be true and correct in all material respects and do not and will not omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

• an undertaking that the Eligible Stockholder agrees to

 assume all liability stemming from any legal or regulatory violation arising out of the Eligible Stockholder's communications with the stockholders of the Corporation or out of the information that the Eligible Stockholder provided to the Corporation;

- o indemnify and hold harmless the Corporation and each of its Directors, officers and employees individually against any liability, loss or damages in connection with any threatened or pending action, suit or proceeding, whether legal, administrative or investigative, against the Corporation or any of its Directors, officers or employees arising out of any nomination submitted by the Eligible Stockholder pursuant to this Section 2.16 or any solicitation or other activity in connection therewith; and
- of file with the Securities and Exchange Commission any solicitation or other communication with the stockholders of the Corporation relating to the meeting at which its Stockholder Nominee(s) will be nominated, regardless of whether any such filing is required under Regulation 14A of the Act or whether any exemption from filing is available for such solicitation or other communication under Regulation 14A of the Act;
- in the case of a nomination by a group of stockholders that together is an Eligible Stockholder, the designation by all group members of one group member that is authorized to receive communications, notices and inquiries from the Corporation and to act on behalf of all members of the group with respect to all matters relating to the nomination under this Section 2.16 (including withdrawal of the nomination);
- in the case of a nomination by an Eligible Stockholder consisting of a group of stockholders in which two or more funds are intended to be treated as one stockholder for purposes of qualifying as an Eligible Stockholder, documentation reasonably satisfactory to the Corporation that demonstrates that the funds are part of the same Qualifying Fund Group; and
- a written representation and agreement by the Stockholder Nominee that such person:

- Will act as a representative of all of the stockholders of the Corporation while serving as a director;
- o will provide facts, statements and other information in all communications with the Corporation and its stockholders that are or will be true and correct in all material respects (and shall not omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading);
- is not and will not become a party to (i) any compensatory, payment or other financial agreement, arrangement or understanding with any person or entity other than the Corporation in connection with service or action as a director of the Corporation that has not been disclosed to the Corporation, (ii) any Voting Commitment that has not been disclosed to the Corporation or (iii) any Voting Commitment 12 that could reasonably be expected to limit or interfere with the Stockholder Nominee's ability to comply, if elected as a director of the Corporation, with its fiduciary duties under applicable law; and

o will abide by and comply with the CGM Bylaws, the Certificate of Incorporation and applicable policies of the Corporation including all applicable publicly disclosed corporate governance, conflict of interest, confidentiality and stock ownership and trading policies and guidelines of the Corporation, as well as the applicable provisions of the rules and regulations of the Securities and Exchange Commission and any stock exchange applicable to the Corporation.

In proposing the informational requirements for the Eligible Stockholder, Cboe's goal is to gather sufficient information about the Eligible Stockholder for both itself and its stockholders. Among other things, this information is designed to help ensure that Cboe is able to comply with its disclosure and other requirements under applicable law and that Cboe, its Board and its stockholders are able to assess the proxy access nomination adequately.

Proposed Section 2.16(g)

Proposed Section 2.16(g) establishes additional information the Stockholder Nominee must provide. Particularly:

 The Stockholder Nominee(s) must submit all completed and signed

¹¹ See 17 CFR 240.14n–101 and 17 CFR 240.14a–18, which generally require a Nominating Stockholder to provide notice to the Corporation of its intent to submit a proxy access nomination on a Schedule 14N and file that notice, including the required disclosure, with the Commission on the date first transmitted to the Corporation.

 $^{^{12}\,\}mathrm{A}$ ''Voting Commitment'' is defined as any agreement, arrangement or understanding with any person or entity as to how the Stockholder Nominee would vote or act on any issue or question as a director.

questionnaires required of directors and officers of the Corporation;

- the Corporation may require any proposed Stockholder Nominee to furnish any information:
- O That may reasonably be requested by the Corporation to determine whether the Stockholder Nominee would be independent under Section 3.3 and otherwise qualifies as independent under the rules of the principal national securities exchange on which the outstanding capital stock of the Corporation is traded;
- that could be material to a reasonable stockholder's understanding of the independence, or lack thereof, of such Stockholder Nominee;
- that would be required to satisfy the requirements for qualification of directors under applicable foreign regulations; or
- (that may reasonably be requested by the Corporation to determine the eligibility of such Stockholder Nominee to be included in the Corporation's proxy materials pursuant to this Section 2.16 or to serve as a director of the Corporation; and
- the Corporation may require the Eligible Stockholder to furnish any other information that may reasonably be requested by the Corporation to verify the Eligible Stockholder's continuous Ownership of the Required Shares for the Minimum Holding Period and through the date of the annual meeting.

Like the informational requirements for an Eligible Stockholder, which are set forth above, the informational requirements for the Stockholder Nominee ensure that both Cboe and its stockholders will have sufficient information about the Stockholder Nominee. Among other things, this information will ensure that Cboe is able to comply with its disclosure and other requirements under applicable law and that Cboe, its Board and its stockholders are able to assess the proxy access nomination adequately.

Proposed Section 2.16(h)

Proposed Section 2.16(h) provides that an Eligible Stockholder may provide, at its option, to the Secretary, at the time the Notice of Proxy Access Nomination is provided, a written statement, not to exceed 500 words, in support of its Stockholder Nominee(s)' candidacy (a "Supporting Statement"). Only one Supporting Statement may be submitted by an Eligible Stockholder (including any group of stockholders together constituting an Eligible Stockholder) in support of its Stockholder Nominee(s). Notwithstanding anything to the

contrary contained in Section 2.16, the Corporation may omit from its proxy materials any information or Supporting Statement (or portion thereof) that it, in good faith, believes is untrue in any material respect (or omits to state a material fact necessary in order to make the statements made, in light of the circumstances under which they are made, not misleading) or would violate any applicable law, rule or regulation. The Exchange notes proposed Section 2.16(h) allows Choe to comply with Rule 14a-9 under the Act 13 and to protect its stockholders from information that is materially untrue or that violates any law, rule or regulation.

Proposed Section 2.16(i)

Pursuant to proposed Section 2.16(i), each Eligible Stockholder or Stockholder Nominee must promptly notify Choe's Corporate Secretary of any information or communications provided by the Eligible Stockholder or Stockholder Nominee, as the case may be, to Cboe or its stockholders that when provided was not, or thereafter ceases to be, true and correct in all material respects or omits a material fact necessary to make the statements made, in light of the circumstances under which they were made, not misleading and of the information that is required to correct any such defect. An Eligible Stockholder shall also provide immediate notice to the Corporation if the Eligible Stockholder ceases to own any of the Required Shares prior to the date of the annual meeting. In addition, any person providing any information to the Corporation pursuant to Section 2.16(i) shall be required to update or supplement such information, if necessary, so that all such information shall be true and correct as of the (i) as of the record date for determining the stockholders entitled to receive notice of the meeting and (ii) as of the date that is ten (10) business days prior to the meeting (or any postponement, adjournment or recess thereof), and such update shall be received by the Secretary at the principal executive offices of the Corporation (A) not later than five (5) business days after the record date for determining the stockholders entitled to receive notice of such meeting (in the case of an update required to be made under clause (i)) and (B) not later than seven (7) business

days prior to the date for the meeting, if practicable, or, if not practicable, on the first practicable date prior to the meeting or any adjournment, recess or postponement thereof (in the case of an update required to be made pursuant to clause (ii)).

This provision further makes clear that providing any such notification, update or supplement, shall not be deemed to cure any defect in any previously provided information or communications or limit the remedies available to the Corporation relating to such defect (including the right to omit a Stockholder Nominee from its proxy materials). This provision is intended to protect Cboe's stockholders by requiring an Eligible Stockholder or Stockholder Nominee to give Choe notice of information previously provided that is materially untrue. Choe may then decide what action to take with respect to such defect, which may include, as noted above, omitting the relevant Stockholder Nominee from its proxy materials.

Proposed Section 2.16(j)

Proposed Section 2.16(j) provides that Cboe shall not be required to include a Stockholder Nominee in its proxy materials for any meeting of stockholders under certain circumstances. In these situations, the proxy access nomination shall be disregarded and no vote on such Stockholder Nominee will occur, even if Cboe has received proxies in respect of the vote. These circumstances occur when the Stockholder Nominee:

- Would not be an independent director under Section 3.3, under the rules of the principal national securities exchange on which the outstanding capital stock of the Corporation is traded, any applicable rules of the Securities and Exchange Commission and any publicly disclosed standards used by the Board in determining and disclosing independence of the Corporation's directors, in each case as determined by the Board in its sole discretion;
- would not meet the audit committee independence requirements under the rules of the principal national securities exchange on which the outstanding capital stock of the Corporation is traded;
- if elected, intended to resign as a director of the Corporation prior to the end of the full term for which he or she is standing for election;
- is or has been subject to any statutory disqualification under Section 3(a)(39) of the Act;
- is or has been subject to disqualification under 17 CFR 1.63;

¹³ See 17 CFR 240.14a-9, which generally prohibits proxy solicitations that contain any statement which, at the time and in the light of the circumstances under which it is made, is false or misleading with respect to any material fact, or which omits to state any material fact necessary in order to make the statements therein not false or misleading.

- if elected, would cause the Corporation to be in violation of these Bylaws, the Certificate of Incorporation, the rules of the principal national securities exchange on which the outstanding capital stock of the Corporation is traded, or any applicable law, rule or regulation;
- is or has been, within the past three years, an officer or director of a competitor, as defined for purposes of Section 8 of the Clayton Antitrust Act of
- is a named subject of a pending criminal proceeding (excluding traffic violations and other minor offenses) or has been convicted in such a criminal proceeding within the past 10 years;

• is subject to any order of the type specified in Rule 506(d) of Regulation D promulgated under the Securities Act of

1933, as amended;

 has provided any information to the Corporation or its stockholders that was untrue in any material respect or that omitted to state a material fact necessary to make the statements made, in light of the circumstances in which they were made, not misleading; or

• breaches or fails, or the Eligible Stockholder breaches or fails, to comply with its obligations pursuant to the CGM Bylaws, including, but not limited to, Section 2.16 and any agreement, representation or undertaking required by Section 2.16.

Choe believes these provisions will protect the Corporation and its stockholders by allowing it to exclude certain categories of objectionable Stockholder Nominees from the proxy statement.

Proposed Section 2.16(k)

Proposed Section 2.16(k) provides that notwithstanding anything to the contrary contained in the CGM Bylaws, if (i) a Stockholder Nominee and/or the applicable Eligible Stockholder breaches any of its agreements or representations or fails to comply with any of its obligations under this Section 2.16 or (ii) a Stockholder Nominee otherwise becomes ineligible for inclusion in the Corporation's proxy materials pursuant to this Section 2.16, or dies, becomes disabled or otherwise becomes ineligible or unavailable for election at the annual meeting, in each case as determined by the Board or the chairman of the meeting, (1) the Corporation may omit or, to the extent feasible, remove the information concerning such Stockholder Nominee and the related Supporting Statement from its proxy materials and/or otherwise communicate to its stockholders that such Stockholder Nominee will not be eligible for election

at the annual meeting, (2) the Corporation shall not be required to include in its proxy materials any successor or replacement nominee proposed by the applicable Eligible Stockholder or any other Eligible Stockholder and (3) the chairman of the meeting shall declare such nomination to be invalid and such nomination shall be disregarded, notwithstanding that proxies in respect of such vote may have been received by the Corporation. Choe believes this provision protects the Corporation and its stockholders by providing the Board or the chairman of the stockholder meeting limited authority to disqualify a proxy access nominee when that nominee or the sponsoring stockholder(s) have breached an obligation under the proxy access provision.

Proposed Section 2.16(l)

Proposed Section 2.16(l) states that the following Stockholder Nominees who are included in the Corporation's proxy materials for a particular annual meeting of stockholders will be ineligible to be a Stockholder Nominee for the next two annual meetings: (i) Stockholder Nominee who withdraws from or becomes ineligible or unavailable for election at the annual meeting; or (ii) Stockholder Nominee who does not receive at least 25% of the votes cast in favor of such Stockholder Nominee's election. For the avoidance of doubt, Section 2.16(l) also clarifies that this provision shall not prevent any stockholder from nominating any person to the Board pursuant to Section 2.11 of the CGM Bylaws. Section 2.16(l) will save the Corporation and its stockholders the time and expense of analyzing and addressing subsequent proxy access nominations regarding individuals who were included in the proxy materials for a particular annual meeting but ultimately did not stand for election or receive a substantial amount of votes. After the next two annual meetings, these Stockholder Nominees would again be eligible for nomination through the proxy access provisions of the Bylaws.

Proposed Section 2.16(m)

Proposed Section 2.16(m) provides that notwithstanding the provisions of proposed Section 2.16, if the Eligible Stockholder providing notice (or a qualified representative of the Eligible Stockholder) does not appear in person (including virtually, in the case of a meeting held solely by means of remote communication) at the stockholder meeting to present the nomination of such Stockholder Nominee, such proposed nomination shall not be

presented by the Corporation and shall not be transacted, notwithstanding that proxies in respect of such vote may have been received by the Corporation. For purposes of this Section 2.16, to be considered a qualified representative of the Eligible Stockholder providing notice, a person must be a duly authorized officer, manager or partner of such stockholder or must be authorized by a writing executed by such stockholder or an electronic transmission delivered by such stockholder to act for such stockholder as proxy at the meeting and such writing or electronic transmission, or a reliable reproduction of the writing or electronic transmission, must be provided to the Corporation at least twenty-four (24) hours prior to the meeting.

Proposed Section 2.16(n)

In case there are matters involving a proxy access nomination that are open to interpretation, proposed Section 2.16(n) states that the Board (or any other person or body authorized by the Board) shall have exclusive power and authority to interpret the proxy access provisions of the Bylaws and make all determinations deemed necessary or advisable in connection with proposed Section 2.16 as to any person, facts or circumstances. In addition, all actions, interpretations and determinations of the Board (or any person or body authorized by the Board) with respect to the proxy access provisions shall be final, conclusive and binding on the Corporation, the stockholders and all other parties. While Cboe has attempted to implement a clear, detailed and thorough proxy access provision, there may be matters about future proxy access nominations that are open to interpretation. In these cases, Cboe believes it is reasonable and necessary to designate an arbiter to make final decisions on these points and that the Board is best-suited to act as that arbiter.

Proposed Section 2.16(o)

For the avoidance of doubt, proposed Section 2.16(o) states that the proxy access provisions outlined in proposed Section 2.16 shall be the exclusive means for stockholders to include nominees in the Corporation's proxy materials. Stockholders may, of course, continue to propose nominees through other means, but the Board will have final authority to determine whether to include those nominees in the Corporation's proxy materials.

Revisions to Other Sections of the Bylaws

Choe also proposes to make conforming changes to Sections 2.10 and 2.11 to provide clarifications and prevent confusion. First, the Exchange proposes to add a reference to Section 2.11 and proposed Section 2.16 to clarify the exact bylaw provisions relating to stockholder nominees. Next, the Exchange proposes to amend Section 2.11. Section 2.11 currently describes the business that may be properly brought before an annual meeting of stockholders and the methods by which nominations of persons for election to the Board may be made at an annual meeting of stockholders. Choe proposes to add proxy access nominations (i.e., reference to Section 2.16) to the list of methods. Current Section 2.11(a)(i) also states, among other things, that compliance with Section 2.11 shall be the exclusive means for a stockholder to propose business or director nominations before an annual meeting stockholders. The Exchange proposes to clarify that Sections 2.11 and 2.16 are the exclusive means for a stockholder to make a director nomination.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act. 14 Specifically. the Exchange believes the proposed rule change is consistent with the Section $6(b)(\bar{5})^{15}$ requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

In light of a shareholder proposal received from a stockholder, Cboe is proposing changes to its Bylaws to implement proxy access. The Exchange believes that this filing furthers the objectives of Section 6(b)(5) of the Act because the proposed rule change would be consistent with and facilitate a governance and regulatory structure that 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 regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. Particularly, the Exchange believes that, by permitting an Eligible Stockholder of Cboe that meets the stated requirements to nominate directors and have its nominees included in Cboe's annual meeting proxy statement, the proposed rule change strengthens the corporate governance of the Exchange's ultimate parent company, which is beneficial to both investors and the public interest.

Additionally, the procedural requirements are designed to help protect investors by stating clearly and explicitly the procedures stockholders must follow in order to submit a proper proxy access nomination. The informational requirements are designed to enhance investor protection by helping to ensure among other things, that the Corporation and its stockholders have full and accurate information about nominating stockholders and their nominees and that such stockholders and nominees comply with applicable laws, regulations and other requirements. Moreover, as noted above, proxy access has become commonplace among companies and the Exchange believes its core provisions are common among companies that have adopted proxy access, including the parent companies of other exchanges that have adopted similar proxy access provisions. 16

Finally, the remaining changes to existing provisions of the CGM Bylaws are clarifying in nature, and they enhance investor protection and the public interest by preventing confusion with respect to the operation of the Bylaw provisions.

B. Self-Regulatory Organization's Statement on Burden on Competition

Because the proposed rule change relates to the governance of the Corporation and not to the operations of the Exchange, the Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not designed to address any competitive issue or have any impact on competition; rather, adoption of a proxy access bylaw by the Corporation is intended to enhance corporate governance and accountability to stockholders.

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

Within 45 days of the date of publication of this notice in the Federal Register or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission shall: (a) By order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (http://www.sec.gov/rules/sro.shtml); or
- Send an email to *rule-comments@ sec.gov*. Please include File Number SR–C2–2021–007 on the subject line.

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–C2–2021–007. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's

internet website (http://www.sec.gov/

rules/sro.shtml). Copies of the

¹⁴ 15 U.S.C. 78f(b).

¹⁵ U.S.C. 78f(b)(5).

¹⁶ See Securities Exchange Release No. 79357
(November 18, 2016) 81 FR 85283
(November 25, 2016) (SR-NASDAQ-2016-127; SR-BX-2016-051; SR-ISE-2016-22; SR-ISEGemini-2016-10; SR-ISEMercury-2016-16; SR-PHLX-2016-93; SR-BSECC-2016-001; SR-SCCP-2016-01). See also Securities Exchange Release No. 77782
(May 6, 2016) 81 FR 29600
(May 12, 2016) (SR-NYSE-2016-14; SR-NYSEArca-2016-25; SR-NYSEMKT-2016-20).

submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-C2-2021-007 and should be submitted on or before May 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. 17

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021-09430 Filed 5-4-21; 8:45 am]

BILLING CODE 8011-01-P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #16938 and #16939; HAWAII Disaster Number HI-00062]

Administrative Declaration of a Disaster for the State of Hawaii

AGENCY: U.S. Small Business

Administration. **ACTION:** Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of Hawaii dated 04/29/2021.

Incident: Severe Storms, Flooding, Landslides and Mudslides.

Incident Period: 03/08/2021 through 03/18/2021.

DATES: Issued on 04/29/2021.

Physical Loan Application Deadline Date: 06/28/2021.

Economic Injury (EIDL) Loan Application Deadline Date: 01/31/2022. ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: City and County of Honolulu

Contiguous Counties: None The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Avail-	
able Elsewhere	2.500
Homeowners without Credit	4.050
Available Elsewhere	1.250
Businesses with Credit Avail- able Elsewhere	6.000
Businesses without Credit	6.000
Available Elsewhere	3.000
Non-Profit Organizations with	0.000
Credit Available Elsewhere	2.000
Non-Profit Organizations with-	
out Credit Available Else-	
where	2.000
For Economic Injury:	
Businesses & Small Agricultural	
Cooperatives without Credit	0.000
Available Elsewhere	3.000
Non-Profit Organizations with- out Credit Available Else-	
where	2.000
WITOTO	2.000

The number assigned to this disaster for physical damage is 16938 6 and for economic injury is 16939 0.

The State which received an EIDL Declaration # is Hawaii.

(Catalog of Federal Domestic Assistance Number 59008)

Isabella Guzman,

Administrator.

[FR Doc. 2021–09401 Filed 5–4–21; 8:45 am]

BILLING CODE 8026-03-P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #16943 and #16944; New Jersey Disaster Number NJ-00061]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of New Jersey

AGENCY: U.S. Small Business

Administration. **ACTION:** Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of New Jersey (FEMA–4597–DR), dated 04/28/2021.

Incident: Severe Winter Storm and Snowstorm.

Incident Period: 01/31/2021 through 02/02/2021.

DATES: Issued on 04/28/2021.

Physical Loan Application Deadline Date: 06/28/2021.

Economic Injury (EIDL) Loan Application Deadline Date: 01/28/2022.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 04/28/2021, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Cape May, Morris, Ocean, Sussex, Warren.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with	
Credit Available Elsewhere	2.000
Non-Profit Organizations with-	
out Credit Available Else-	
where	2.000
For Economic Injury:	
Non-Profit Organizations with-	
out Credit Available Else-	
where	2.000

The number assigned to this disaster for physical damage is 16943 7 and for economic injury is 16944 0.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2021–09400 Filed 5–4–21; 8:45 am]

BILLING CODE 8026-03-P

^{17 17} CFR 200.30-3(a)(12).

DEPARTMENT OF STATE

[Public Notice: 11417]

60-Day Notice of Proposed Information Collection: Law Enforcement Officers Safety Act (LEOSA) Photographic Identification Card Application

ACTION: Notice of request for public comment.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this notice is to allow 60 days for public comment preceding submission of the collection to OMB.

DATES: The Department will accept comments from the public up to *July 6*, 2021.

ADDRESSES:

You may submit comments by any of the following methods:

- Web: Persons with access to the internet may comment on this notice by going to www.Regulations.gov. You can search for the document by entering "Docket Number: DOS-2021-0010" in the Search field. Then click the "Comment Now" button and complete the comment form.
 - Email: twerdahleh@state.gov.
- Regular Mail: Send written comments to: DS/DO, 1801 North Lynn Street, Arlington, VA 22209.

You must include the DS form number (if applicable), information collection title, and the OMB control number in any correspondence.

FOR FURTHER INFORMATION CONTACT:

Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Elizabeth Twerdahl, 1801 N Lynn Street, Arlington, VA 22209, who may be reached on 571–345–2187 or at twerdahleh@state.gov.

SUPPLEMENTARY INFORMATION:

- Title of Information Collection: LEOSA Photographic Identification Card Application.
 - OMB Control Number: None.
 - *Type of Request:* New Collection.
- Originating Office: Diplomatic Security, Domestic Operations Directorate (DS/DO).
 - Form Number: No form.
- Respondents: Current and former Diplomatic Security Service special agents.

- Estimated Number of Respondents: 70.
- Estimated Number of Responses: 70.
 - Average Time Per Response: 1 hour.
- Total Estimated Burden Time: 70 hours.
 - Frequency: Once per application.
 - Obligation to Respond: Voluntary.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including 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 comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

This information is being collected in response to the Department's requirements under the Law Enforcement Officers Safety Act of 2004 (LEOSA), as amended and codified at 18 U.S.C. 926C, which exempts a "qualified retired law enforcement officer" carrying a LEOSA photographic identification card from most state and local laws prohibiting the carriage of concealed firearms, subject to certain restrictions and exceptions.

Methodology

Applicants will fill out the application form either electronically or by hand and submit via email or mail.

Kevin E. Bryant,

Deputy Director, Office of Directives Management, Department of State. [FR Doc. 2021–09513 Filed 5–4–21; 8:45 am]

BILLING CODE 4710-43-P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36510]

Bogalusa Bayou Railroad, L.L.C. d/b/a Geaux Geaux Railroad—Acquisition and Operation Exemption—Geaux Geaux Railroad, LLC

Bogalusa Bayou Railroad, L.L.C. (BBR), a Class III railroad, filed a verified notice of exemption under 49 CFR 1150.41 to acquire title from Geaux Geaux Railroad, LLC, and to conduct common carrier operations over, two contiguous railroad line segments, totaling approximately 23.26 miles, extending between: (1) Milepost 0.0 at Slaughter, La., and a point lying westerly thereof at what would be milepost 11.0 ¹ at Zee, La. (the Zee Segment); and (2) milepost 345.84 (immediately north of Slaughter and the point of connection with the Zee Segment) and a point lying southerly thereof at milepost 358.1 at Maryland, La. (collectively, the Line).

The verified notice states that BBR has operated on the Line since 2015, and that it obtained Board authority to do so, less what is currently unregulated ancillary track from milepost 9.69 to milepost 11, in *Bogalusa Bayou Railroad—Operation Exemption—Geaux Geaux Railroad*, FD 35904 (STB served Feb. 13, 2015).

BBR certifies that the proposed acquisition of the Line does not involve an interchange commitment. BBR further certifies that its projected annual revenues as a result of this transaction will not result in its becoming a Class II or Class I rail carrier and will not exceed \$5 million.

The transaction may be consummated on or after May 19, 2021 (30 days after the verified notice of exemption was filed)

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions to stay must be filed no later than May 12, 2021 (at least seven days before the exemption becomes effective).

All pleadings, referring to Docket No. FD 36510, should be filed with the Surface Transportation Board via efiling on the Board's website. In addition, a copy of each pleading must be served on BBR's representative, Bradon J. Smith, Fletcher & Sippel LLC,

¹The verified notice indicates that currently there are no physical mileposts in place on the Zee Segment beyond milepost 9.69.

29 North Wacker Drive, Suite 800, Chicago, IL 60606.

According to BBR, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available at www.stb.gov.

Decided: April 29, 2021.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Aretha Laws-Byrum,

Clearance Clerk.

[FR Doc. 2021–09462 Filed 5–4–21; 8:45 am]

BILLING CODE 4915-01-P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36445]

Stillwater Central Railroad, L.L.C.— Lease Exemption With Interchange Commitment—BNSF Railway Company

Stillwater Central Railroad, L.L.C. (SCR), a Class III rail carrier, has filed a verified notice of exemption under 49 CFR 1150.41 to lease from the BNSF Railway Company (BNSF) and operate two rail line segments: (1) From milepost 549.01 on Line Segment 1003 at Wheatland easterly to milepost 540.65 on Line Segment 7405, immediately west of Shields Blvd.; and (2) from milepost 540.0 on Line Segment 1003 easterly to the end of BNSF ownership at milepost 536.4 on the same segment (including the North Yard) in Oklahoma County, Okla. (the Lines). The Lines total approximately 12.6 route miles.

According to the verified notice, SCR has leased and operated the Lines since 2005.¹ The verified notice states that SCR and BNSF have executed a revised lease agreement to govern SCR's leasehold of the Lines, which will extend the term of the lease until July 31, 2030. SCR states that it will continue to be the operator of the Lines.

According to SCR, the amended lease between SCR and BNSF contains an interchange commitment that affects interchange with carriers other than BNSF.² The affected interchange is with the Union Pacific Railroad Company at Oklahoma City, Okla., on Segment 2. As required under 49 CFR 1150.43(h), SCR provided additional information regarding the interchange commitment.

SCR has certified that its projected annual revenues as a result of this transaction will not result in SCR's becoming a Class II or Class I rail carrier, but that its projected annual revenues are anticipated to exceed \$5 million. Pursuant to 49 CFR 1150.42(e), if a carrier's projected annual revenues will exceed \$5 million, it must, at least 60 days before this exemption is to become effective, post a notice of its intent to undertake the proposed transaction at the workplace of the employees on the affected lines, serve a copy of the notice on the national offices of the labor unions with employees on the affected lines, and certify to the Board that it has done so. However, SCR, concurrently with its verified notice of exemption, filed a petition for waiver of the 60-day advance labor notice requirement. SCR's waiver request will be addressed in a separate decision. The Board will establish the effective date of the exemption in its separate decision on the waiver request.

If the notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than May 12, 2021.

All pleadings, referring to Docket No. FD 36445, should be filed with the Surface Transportation Board via efiling on the Board's website. In addition, one copy of each pleading must be served on SCR's representative: Bradon J. Smith, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 800, Chicago, IL 60606.

According to SCR, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic preservation reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available at www.stb.gov.

Decided: April 30, 2021.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2021–09505 Filed 5–4–21; 8:45 am]

BILLING CODE 4915-01-P

DEPARTMENT OF THE TREASURY

Mandatory Survey of Foreign Ownership of U.S. Securities

ACTION: Notice of reporting requirements.

AGENCY: Departmental Offices, Department of the Treasury. **SUMMARY:** By this Notice, the Department of the Treasury is informing the public that it is conducting a mandatory survey of foreign ownership of U.S. securities as of June 30, 2021. This mandatory survey is conducted under the authority of the International Investment and Trade in Services Survey Act. This Notice constitutes legal notification to all United States persons (defined below) who meet the reporting requirements set forth in this Notice that they must respond to, and comply with, this survey. Additional copies of the reporting forms SHLA (2021) and instructions may be printed from the internet at: https:// home.treasury.gov/data/treasuryinternational-capital-tic-system-homepage/tic-forms-instructions/forms-shl.

SUPPLEMENTARY INFORMATION:

Definition: A U.S. person is any individual, branch, partnership, associated group, association, estate, trust, corporation, or other organization (whether or not organized under the laws of any State), and any government (including a foreign government, the United States Government, a State or local government, and any agency, corporation, financial institution, or other entity or instrumentality thereof, including a government-sponsored agency), who resides in the United States or is subject to the jurisdiction of the United States.

Who Must Report: The panel for this survey is based primarily on the level of foreign resident holdings of U.S. securities reported on the June 2019 benchmark survey of foreign resident holdings of U.S. securities, and on the Aggregate Holdings of Long-Term Securities by U.S. and Foreign Residents (TIC SLT) report as of December 2020, and will consist mostly of the largest reporters. Entities required to report will be contacted individually by the Federal Reserve Bank of New York, Entities not contacted by the Federal Reserve Bank of New York have no reporting responsibilities.

What to Report: This report will collect information on foreign resident holdings of U.S. securities, including equities, short-term debt securities (including selected money market instruments), and long-term debt securities.

¹ See Stillwater Cent. R.R.—Lease & Operation Exemption—Burlington N. & Santa Fe Ry., FD 34610 (STB served Jan. 19, 2005).

² A copy of the lease with the interchange commitment was submitted under seal. *See* 49 CFR 1150.43(h)(1).

How to Report: Copies of the survey forms and instructions, which contain complete information on reporting procedures and definitions, may be obtained at the website address given above in the Summary, or by contacting the survey staff of the Federal Reserve Bank of New York at (212) 720-6300 or (646) 720-6300, email: SHLA.help@ ny.frb.org. The mailing address is: Federal Reserve Bank of New York, Data and Statistics Function, 6th Floor, 33 Liberty Street, New York, NY 10045-0001. Inquiries can also be made to the Federal Reserve Board of Governors, at (202) 452-3476, or to Dwight Wolkow, at (202) 923-0518, or by email: comments2TIC@treasury.gov.

When to Report: Data should be submitted to the Federal Reserve Bank of New York, acting as fiscal agent for the Department of the Treasury, by August 31, 2021.

Paperwork Reduction Act Notice: This data collection has been approved by the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act and assigned control number 1505-0123. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by OMB. The estimated average annual burden associated with this collection of information is 486 hours per report for the largest custodians of securities, and 110 hours per report for the largest issuers of securities that have data to report and are not custodians. Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be directed to the Department of the Treasury, Office of International Affairs, Attention Administrator, International Portfolio Investment Data Reporting Systems, Room 1050, Washington, DC 20220, and to OMB, Attention Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503.

Dwight D. Wolkow,

Administrator, International Portfolio Investment Data Reporting Systems. [FR Doc. 2021–09510 Filed 5–4–21; 8:45 am]

BILLING CODE 4810-AK-P

U.S.-CHINA ECONOMIC AND SECURITY REVIEW COMMISSION

Notice of Open Public Hearing

AGENCY: U.S.-China Economic and Security Review Commission. **ACTION:** Notice of open public hearing.

SUMMARY: Notice is hereby given of the following hearing of the U.S.-China Economic and Security Review Commission. The Commission is mandated by Congress to investigate, assess, and report to Congress annually on "the national security implications of the economic relationship between the United States and the People's Republic of China." Pursuant to this mandate, the Commission will hold a public hearing in Washington, DC on May 20, 2021 on "China in Latin America and the Caribbean."

DATES: The hearing is scheduled for Thursday, May 20, 2021, 9:30 a.m.

ADDRESSES: This hearing will be held with panelists and Commissioners participating in-person or online via videoconference. Members of the audience will be able to view a live webcast via the Commission's website at www.uscc.gov. Also, please check the Commission's website for possible changes to the hearing schedule. Reservations are not required to attend the hearing.

FOR FURTHER INFORMATION CONTACT: Any member of the public seeking further information concerning the hearing should contact Jameson Cunningham, 444 North Capitol Street NW, Suite 602, Washington DC 20001; telephone: 202–624–1496, or via email at *jcunningham@uscc.gov. Reservations are not required to attend the hearing.*

ADA Accessibility: For questions about the accessibility of the event or to request an accommodation, please contact Jameson Cunningham via email at <code>jcunningham@uscc.gov</code>. Requests for an accommodation should be made as soon as possible, and at least five business days prior to the event.

SUPPLEMENTARY INFORMATION:

Background: This is the fifth public hearing the Commission will hold during its 2021 report cycle. The hearing will examine China's political, economic, and security engagement with Latin America and the Caribbean. The opening panel will examine China's overall strategy for diplomatic and political engagement with Latin American and Caribbean countries, identify Beijing's main objectives and strategies, and consider their implications for countries in the region as well as the United States. The second panel will assess Chinese economic engagement and competition with the United States in Latin America and the Caribbean, explore Chinese infrastructure investment, development aid, and financing to the region, and discuss China's COVID-19 diplomacy. The third panel will analyze the elements and geopolitical consequences

of China's growing security presence and influence in Latin America and the Caribbean, including the PLA's activities, China's involvement in countries' internal security affairs, and China's access to space facilities and other dual-use infrastructure. The fourth panel will examine regional case studies to illustrate China's activities and their implications for the United States.

The hearing will be co-chaired by Chairman Carolyn Bartholomew and Commissioner Derek Scissors. Any interested party may file a written statement by May 20, 2021 by transmitting to the contact above. A portion of the hearing will include a question and answer period between the Commissioners and the witnesses.

Authority: Congress created the U.S.-China Economic and Security Review Commission in 2000 in the National Defense Authorization Act (Pub. L. 106–398), as amended by Division P of the Consolidated Appropriations Resolution, 2003 (Pub L 108–7), as amended by Public Law 109–108 (November 22, 2005), as amended by Public Law 113–291 (December 19, 2014).

Dated: April 30, 2021.

Daniel W. Peck,

Executive Director, U.S.-China Economic and Security Review Commission.

[FR Doc. 2021–09553 Filed 5–4–21; 8:45 am]

BILLING CODE 1137-00-P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900-0319]

Agency Information Collection Activity under OMB Review: Fiduciary Agreement

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 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. Refer to "OMB Control No. 2900–0319.

FOR FURTHER INFORMATION CONTACT:

Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 1717 H Street NW, Washington, DC 20006, (202) 266–4688 or email maribel.aponte@va.gov. Please refer to "OMB Control No. 2900–0319" in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: 38 U.S.C. 5502; 38 CFR 13.140.

Title: Fiduciary Agreement (VA Form 21P–4703).

OMB Control Number: 2900–0319. Type of Review: Reinstatement of a previously approved collection.

previously approved collection.

Abstract: VA Form 21P-4703 is the prescribed form used by VBA as a legal contract between the VA and a federal fiduciary. The form outlines the roles and responsibilities of the fiduciary with respect to the uses of VA funds. Without this agreement, disbursement of funds to the fiduciary would not be possible.

This is a reinstatement only with no substantive changes. The burden remains the same.

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 86 FR 34 on February 23, 2021, pages 11054 and 11055.

Affected Public: Individuals or Households.

Estimated Annual Burden: 3,917. Estimated Average Burden per Respondent: 5 minutes.

Frequency of Response: One time. Estimated Number of Respondents: 47,000.

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. 2021–09414 Filed 5–4–21; 8:45 am]

BILLING CODE 8320-01-P

DEPARTMENT OF VETERANS AFFAIRS

Solicitation of Nominations for Appointment to the Advisory Committee on Tribal and Indian Affairs

ACTION: Notice.

SUMMARY: The Department of Veterans Affairs (VA), Office of Public and Intergovernmental Affairs (OPIA), Office of Tribal Government Relations (OTGR), is seeking nominations of qualified candidates to be considered for appointment as a member of the Advisory Committee on Tribal and Indian Affairs ("the Committee"). **DATES:** Nominations for membership on the Committee must be received no later than 5:00 p.m. EST on June 1, 2021. **ADDRESSES:** All nomination packages (Application, should be mailed to the Office of Tribal Government Relations. 810 Vermont Ave. NW, Suite 915H (075), Washington, DC 20420 or email us at tribalgovernmentconsultation@ va.gov.

FOR FURTHER INFORMATION CONTACT: Ms. Stephanie Birdwell and David "Clay" Ward, Office of Tribal Government Relations, 810 Vermont Ave. NW, Ste. 915H (075), Washington, DC 20420, Telephone (202) 461–7400. A copy of the Committee charter can be obtained by contacting Mr. David "Clay" Ward or by accessing the website managed by OTGR at https://www.va.gov/TRIBALGOVERNMENT/index.asp.

SUPPLEMENTARY INFORMATION: In carrying out the duties set forth, the Committee responsibilities include, but not limited to:

(1) Identify for the Department evolving issues of relevance to Indian tribes, tribal organizations and Native American Veterans relating to programs and services of the Department;

(2) Propose clarifications, recommendations and solutions to address issues raised at tribal, regional and national levels, especially regarding any tribal consultation reports;

(3) Provide a forum for Indian tribes, tribal organizations, urban Indian organizations, Native Hawaiian organizations and the Department to discuss issues and proposals for changes to Department regulations, policies and procedures;

(4) Identify priorities and provide advice on appropriate strategies for tribal consultation and urban Indian organizations conferring on issues at the tribal, regional, or national levels;

(5) Ensure that pertinent issues are brought to the attention of Indian tribes, tribal organizations, urban Indian organizations and Native Hawaiian organizations in a timely manner, so that feedback can be obtained;

(6) Encourage the Secretary to work with other Federal agencies and Congress so that Native American Veterans are not denied the full benefit of their status as both Native Americans and Veterans;

- (7) Highlight contributions of Native American Veterans in the Armed Forces;
- (8) Make recommendations on the consultation policy of the Department on tribal matters;
- (9) Support a process to develop an urban Indian organization confer policy to ensure the Secretary confers, to the maximum extent practicable, with urban Indian organizations; and
- (10) With the Secretary's written approval, conduct other duties as recommended by the Committee.

Authority: The Committee was established in accordance with section 7002 of Public Law 116-315 (H.R. 7105-Johnny Isakson and David P. Roe, M.D. Veterans Health Care and Benefits Improvement Act of 2020). In accordance with Public Law 116-315, the Committee provides advice and guidance to the Secretary of Veterans Affairs on all matters relating to Indian tribes, tribal organizations, Native Hawaiian organizations and Native American Veterans. The Committee serves in an advisory capacity and advises the Secretary on ways the Department can improve the programs and services of the Department to better serve Native American Veterans. Committee members make recommendations to the Secretary regarding such activities.

Membership Criteria: OTGR is requesting nominations for upcoming vacancies on the Committee. The Committee will be composed of 15 members. As required by statute, the members of the Committee are appointed by the Secretary from the general public, including:

- (1) At least one member of each of the 12 service areas of the Indian Health Service is represented in the membership of the Committee nominated by Indian tribes or tribal organization.
- (2) At least one member of the Committee represents the Native Hawaiian Veteran community nominated by a Native Hawaiian Organization.
- (3) At least one member of the Committee represents urban Indian organizations nominated by a national urban Indian organization.
- (4) Not fewer than half of the members are Veterans, unless the Secretary determines that an insufficient number of qualified Veterans were nominated.
- (5) No member of the Committee may be an employee of the Federal Government.

In accordance with Public Law 116–315, the Secretary determines the number and terms of service for members of the Committee, which are appointed by the Secretary, except that a term of service of any such member may not exceed a term of two years.

Additionally, a member may be reappointed for one additional term at the Secretary's discretion.

Professional Qualifications: In addition to the criteria above, VA seeks—

(1) Diversity in professional and personal qualifications;

(2) Experience in military service and military deployments (please identify your Branch of Service and Rank);

(3) Current work with Veterans;

(4) Committee subject matter expertise; and

(5) Experience working in large and

complex organizations.

Requirements for Nomination Submission: Nominations should be typewritten (one nomination per nominator). Nomination package should include: (1) A letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination (i.e., specific attributes which qualify the nominee for service in this capacity), and a statement from the nominee indicating a willingness to serve as a member of the Committee; (2) the nominee's contact information, including name, mailing address, telephone numbers, and email address; (3) the nominee's curriculum vitae or resume, not to exceed five pages and (4) a summary of the nominee's experience and qualification relative to the professional qualifications criteria listed above.

Individuals selected for appointment to the Committee shall be invited to serve a two-year term. All members will receive travel expenses and a per diem allowance in accordance with the Federal Travel Regulations for any travel made in connection with their duties as members of the Committee.

The Department makes every effort to ensure that the membership of its Federal advisory committees is fairly balanced in terms of points of view represented and the Committee's function. Every effort is made to ensure

that a broad representation of geographic areas, males & females, racial and ethnic minority groups, and Veterans with disabilities are given consideration for membership. Appointment to this Committee shall be made without discrimination because of a person's race, color, religion, sex (including gender identity, transgender status, sexual orientation, and pregnancy), national origin, age, disability, or genetic information. Nominations must state that the nominee is willing to serve as a member of the Committee and appears to have no conflict of interest that would preclude membership. An ethics review is conducted for each selected nominee.

Dated: April 29, 2021.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2021-09412 Filed 5-4-21; 8:45 am]

BILLING CODE P



FEDERAL REGISTER

Vol. 86 Wednesday,

No. 85 May 5, 2021

Part II

Department of Health and Human Services

45 CFR Parts 147, 150, 153, et al.

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 147, 150, 153, 155, 156, 158, and 184

[CMS-9914-F2]

RIN 0938-AU18

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health & Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule sets forth payment parameters and provisions related to the risk adjustment program and cost-sharing parameters. It includes changes related to special enrollment periods; direct enrollment entities; the administrative appeals processes with respect to health insurance issuers and non-federal governmental group health plans; the medical loss ratio program; income verification by Exchanges; and other related topics. It also revises the regulation requiring the reporting of certain prescription drug information by qualified health plans or their pharmacy benefit managers.

DATES: These regulations are effective on July 6, 2021, with the exception of the amendments to §§ 155.320(c) and 158.221(b) which are effective May 5, 2021.

FOR FURTHER INFORMATION CONTACT:

Jeff Wu, (301) 492–4305, Rogelyn McLean, (301) 492–4229, Grace Bristol, (410) 786–8437, Kiahana Brooks, (301) 492–5229, or Sara Rosta, (301) 492–4223 for general information.

Cam Clemmons, (206) 615–2338, for matters related to health insurance reform requirements for the group and individual insurance markets and administrative appeals for health insurance issuers and non-federal governmental group health plans.

Allison Yadsko, (410) 786–1740, or Jacquelyn Rudich, (301) 492–5211, for matters related to risk adjustment.

Isadora Gil, (410) 786–4532, or Colleen Gravens, (301) 492–4107, for matters related to EDGE discrepancies.

Joshua Paul, (301) 492–4347, for matters related to risk adjustment data validation.

Dan Brown, (301) 492–5146, for matters related to web-brokers or direct enrollment, other than the direct enrollment option for Federallyfacilitated and State Exchanges.

Nicholas Eckart, (301) 492–4452, for matters related to termination notices.

Amanda Brander, (202) 690–7892, for matters related to income inconsistencies.

Marisa Beatley, (301) 492–4307, for matters related to employer-sponsored coverage verification.

Carolyn Kraemer, (301) 492–4197, for matters related to special enrollment periods for Exchange enrollment under part 155.

Katherine Bentley, (301) 492–5209, for matters related to special enrollment period verification.

Rebecca Bucchieri, (301) 492–4400, for matters related to EHB-benchmark plans and defrayal of state-required benefits.

Aaron Franz, (410) 786–8027, for matters related to user fees.

Joshua Paul, (301) 492–4347 or Nora Simmons, (410–786–1981), for matters related to the premium adjustment percentage.

Ken Buerger, (410) 786–1190, for matters related to PBM transparency reporting requirements.

Nora Simmons, (410–786–1981), Adrianne Carter, (303) 844–5810, or Amber Bellsdale, (301) 492–4411, for matters related to disputes under 45 CFR 156.1210.

Nidhi Singh Shah, (301) 492–5110, for matters related to the Quality Rating System and the Qualified Health Plan Enrollee Experience Survey.

Alper Ozinal, (301) 492–4178, or Jacquelyn Rudich, (301) 492–5211, for matters related to financial program audits and civil money penalties.

Adrianne Patterson, 410–786–0696, or Nora Simmons, (410–786–1981), for matters related to netting of payments under 45 CFR 156.1215 and administrative appeals under 45 CFR 156.1220.

Christina Whitefield, (301) 492–4172, for matters related to the MLR program.

SUPPLEMENTARY INFORMATION:

Future Rulemaking on Benefit and Payment Parameters for the 2022 Plan Year

In the December 4, 2020 Federal **Register**, we published the "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards; Updates to State Innovation Waiver (Section 1332 Waiver) Implementing Regulations" proposed rule (85 FR 78572) (hereinafter referred to as the "proposed rule" or "proposed 2022 Payment Notice") that proposed to reduce fiscal and regulatory burdens across different program areas and to provide stakeholders with greater flexibility. In the January 19, 2021 Federal Register (86 FR 6138), we published a final rule that addressed a

subset of the policies proposed in the proposed rule. That final rule, among other things, finalized the user fee rates for issuers offering qualified health plans through the Federally-facilitated Exchanges (FFEs) at 2.25 percent of total monthly premiums, and the user fee rate for issuers offering qualified health plans (QHPs) through State-based Exchanges on the Federal platform ((SBE-FPs) at 1.75 percent of total monthly premiums. The final rule also codified a new direct enrollment option for states served by any Exchange model to use direct enrollment technology and non-Exchange websites developed by approved web brokers, issuers and other direct enrollment partners to enroll qualified individuals in QHPs offered through the Exchange. The final rule also finalized changes to regulations governing State Innovation Waivers under section 1332 of the Affordable Care Act (ACA) that specifically incorporate policies announced in guidance in 2018.

On January 28, 2021, President Biden issued Executive Order 14009, "Strengthening Medicaid and the Affordable Care Act," 1 directing HHS, and the heads of all other executive departments and agencies with authorities and responsibilities related to the ACA, to review all existing regulations, orders, guidance documents, policies, and any other similar agency actions to determine whether such agency actions are inconsistent with this Administration's policy to protect and strengthen the ACA and to make high-quality health care accessible and affordable for every American. As part of this review, HHS examined policies and requirements under the proposed 2022 Payment Notice and the January 19, 2021 final 2022 Payment Notice to analyze whether the policies under these rulemakings might undermine the Health Benefits Exchanges or the health insurance markets, and whether they may present unnecessary barriers to individuals and families attempting to access health coverage. HHS also considered whether to suspend, revise, or rescind any such actions through appropriate administrative action.

In compliance with Executive Order (E.O.) 14009 and as a result of HHS's review of the proposed 2022 Payment Notice and the January 19, 2021 final 2022 Payment Notice, HHS intends to issue rulemaking this spring to address policies finalized in the final 2022 Payment Notice published on January 19, 2021. Specifically, in future rulemaking, HHS intends to propose

¹86 FR 7793 (February 2, 2021).

new OHP issuer user fees rates for the 2022 plan year: A new FFE user fee rate of 2.75 percent of total monthly premiums; and a new SBE-FP user fee rate of 2.25 percent of monthly premiums. We also intend to revisit the Exchange Direct Enrollment (DE) option for states and the changes to regulations governing State Innovation Waivers under section 1332 of the ACA. HHS is of the view that pursuit of these proposals is consistent with E.O. 14009, and this Administration's goal of protecting and strengthening the ACA and making high-quality health care accessible and affordable for every American.

Table of Contents

- I. Executive Summary
- II. Background
 - A. Legislative and Regulatory Overview
 - B. Stakeholder Consultation and Input
- C. Structure of Proposed Rule
- III. Summary of the Proposed Provisions to the HHS Notice of Benefit and Payment Parameters for 2022, Analysis of and Responses to Public Comments, and Provisions of the Final Rule
 - A. Part 147—Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets
 - B. Part 150—CMS Enforcement in Group and Individual Markets
 - C. Part 153—Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment
 - D. Part 155—Exchange Establishment Standards and Other Related Standards Under the Affordable Care Act
 - E. Part 156—Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges
 - F. Part 158—Issuer Use of Premium Revenue: Reporting and Rebate Requirements
- G. Part 184—Pharmacy Benefit Manager Standards Under the Affordable Care Act
- IV. Implementation of the Decision in *City of Columbus, et al.* v. *Cochran*
- V. Collection of Information Requirements
- A. Wage Estimates
- B. ICRs Regarding Submission of Adjusted Premium Amounts for Risk Adjustment
- C. ICRs Regarding Direct Enrollment Agents and Brokers
- D. IČRs Regarding Prescription Drug Distribution and Cost Reporting by QHP Issuers and PBMs
- E. ICRs Regarding Medical Loss Ratio
- F. Summary of Annual Burden Estimates for Proposed Requirements
- G. Submission of PRA Related Comments VI. Waiver of Proposed Rulemaking and
- Delay in Effective Date VII. Regulatory Impact Analysis
- A Statement of Mood
 - A. Statement of Need
 - B. Overall ImpactC. Impact Estimates of the Payment Notice Provisions and Accounting Table
 - D. Regulatory Alternatives Considered
 - E. Regulatory Flexibility Act
 - F. Unfunded Mandates

- G. Federalism
- H. Congressional Review Act

I. Executive Summary

American Health Benefit Exchanges, or "Exchanges," are entities established under the Affordable Care Act (ACA)² through which qualified individuals and qualified employers can purchase health insurance coverage in OHPs. Many individuals who enroll in QHPs through individual market Exchanges are eligible to receive a premium tax credit (PTC) to reduce their costs for health insurance premiums and to receive reductions in required costsharing payments to reduce out-ofpocket expenses for health care services. The ACA also established the risk adjustment program, which is intended to increase the workability of the ACA regulatory changes in the individual and small group markets, both on- and off-Exchange.

In the December 4, 2020 Federal Register, we published the "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards; Updates to State Innovation Waiver (Section 1332 Waiver) Implementing Regulations" proposed rule (85 FR 78572) (hereinafter referred to as the "proposed rule" or 'proposed 2022 Payment Notice'') that proposed to reduce fiscal and regulatory burdens across different program areas and to provide stakeholders with greater flexibility. In the proposed rule, we proposed to amend provisions and parameters to implement many ACA programs and requirements, with a focus on maintaining a stable regulatory environment. As proposed, the changes would provide issuers with greater predictability for upcoming plan years, while simultaneously enhancing the role of states in these programs. The proposals would also provide states with additional flexibilities, reduce unnecessary regulatory burdens on stakeholders, empower consumers, ensure program integrity, and improve affordability.

Risk adjustment continues to be a core program in the individual and small group markets both on and off Exchanges, and some of the major proposals from the proposed rule included recalibrated parameters for the HHS-operated risk adjustment

methodology. We also proposed changes to the risk adjustment models to include a two-stage specification in the adult and child models, add severity and transplant indicators interacted with hierarchical condition category (HCC) counts factors to the adult and child models, and proposed to modify the enrollment duration factors in the adult models. Additionally, we proposed clarifications to the process for HHS to audit issuers of risk adjustment covered plans and reinsurance-eligible plans and also proposed to establish authority for HHS to conduct compliance review of these issuers.

As we do every year in the HHS notice of benefit and payment parameters, we proposed updated parameters applicable in the individual and small group markets (including merged markets). We proposed the 2022 benefit year user fee rates for issuers offering plans through the Exchanges on the Federal platform. We proposed lowering the Federally-facilitated Exchange (FFE) and State-Exchange on the Federal platform (SBE-FP) user fees rates to 2.25 and 1.75 percent of total monthly premiums, respectively, in order to reflect enrollment, premium and HHS contract estimates for the 2022 plan year. We also proposed user fee rates of 1.5 percent of total monthly premiums for FFE and SBE-FP states that elect the Exchange DE option.3 These user fee proposals were finalized in the final rule published on January 19, 2021 (86 FR 6138).

We proposed the 2022 benefit year premium adjustment percentage, required contribution percentage, and maximum annual limitations on cost sharing, including those for cost-sharing reduction (CSR) plan variations. For the 2023 benefit year and beyond, we proposed to publish these parameters in guidance annually, and if not in guidance, in the annual notice of benefit and payment parameters or another appropriate rulemaking. Additionally, we proposed clarifications to the process under which HHS conducts audits of QHP issuers to ensure compliance with federal requirements related to advance payments of the premium tax credit (APTC), CSRs, and user fees. We also proposed to establish authority for HHS to conduct compliance reviews of QHP issuers to ensure compliance with federal APTC, CSR and user fee requirements.

We proposed changes to the information that FFE-registered web-

² The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), which amended and revised several provisions of the ACA, was enacted on March 30, 2010. In this final rule, we refer to the two statutes collectively as the "Affordable Care Act" or "ACA."

³ As noted below, the proposals to establish the Exchange DE option were finalized, with modifications, in the final rule published on January 19, 2021 (86 FR 6138).

brokers are required to display on their websites. In addition, we proposed amendments to codify more detail describing the operational readiness reviews that must be successfully completed as a prerequisite to a webbroker's non-Exchange website being approved for use by consumers to complete an Exchange eligibility application or a QHP selection. We similarly proposed to add additional detail about the operational readiness reviews applicable to direct enrollment entities

Stable and affordable Exchanges with healthy risk pools are necessary for ensuring consumers maintain stable access to health insurance options. In order to minimize the potential for adverse selection in the Exchanges, we shared our future plans for rulemaking under which we will propose requirements related to Exchange verifications of whether applicants for QHP coverage with APTC or CSR have access to employer sponsored coverage that is affordable and offers minimum value. We proposed to extend our current enforcement posture under which Exchanges may exercise flexibility not to implement risk-based employer sponsored coverage verification and to remove the requirement that Exchanges select a statistically random sample of applicants when no electronic data sources are available.

We proposed new rules related to special enrollment periods. In addition, we proposed to require Exchanges to conduct special enrollment period verification for at least 75 percent of new enrollments through special enrollment periods granted to consumers not already enrolled in coverage through the applicable Exchange.

We also proposed minor procedural changes to provisions regarding administrative hearings in parts 150 and 156 to align with the Departmental Appeals Board's current practices for administrative hearings to appeal civil money penalties (CMPs).

We proposed to release additional data from the QHP Enrollee Experience Survey (QHP Enrollee Survey). We also solicited comments on potential changes to the framework for the Quality Rating System (QRS) to support alignment with other CMS quality reporting programs and to further balance the individual survey and clinical quality measures on the overall quality scores. We noted that we were considering ways to modify the hierarchical structure for the QRS, which is how the measures are organized together for maximum

simplicity and understanding of the quality rating information provided by the QRS.

We proposed revisions to the regulations requiring the collection of certain prescription drug data from QHP issuers, and proposed to implement a requirement for the reporting of this data from pharmacy benefit managers (PBMs) when a QHP issuer contracts with a PBM to administer its prescription drug benefit.

We proposed to further regulate the standards related to QHP issuers' acceptance of payments for premiums and cost sharing. We also proposed to make clarifications to the network adequacy rules to reflect that § 156.230 does not apply to indemnity plans seeking QHP certification. These proposals were finalized in the final rule published on January 19, 2021 (86 FR 6138).

We proposed to establish a new Exchange DE option under which a State Exchange, State-based Exchange on the Federal platform or an FFE state (through an agreement with HHS) can leverage the potential of direct enrollment to offer consumers an enhanced QHP shopping experience. As proposed, instead of operating a centralized enrollment website, states could use direct enrollment technology to establish direct pathways to OHP issuers, web-brokers, and agents and brokers through which consumers would apply for and enroll in a QHP and receive a determination of eligibility for APTC and CSRs. The proposals for the Exchange DE option were finalized, with modifications, in the final rule published on January 19, 2021 (86 FR 6138).

We proposed to establish the definition of prescription drug rebates and other price concessions that issuers must deduct from incurred claims for medical loss ratio (MLR) reporting and rebate calculation purposes. We additionally proposed to explicitly allow issuers the option to prepay a portion or all of the estimated MLR rebate for a given MLR reporting year in advance of the deadlines set forth in §§ 158.240(e) and 158.241(a)(2) and the filing of the MLR Annual Reporting Form, and proposed to establish a safe harbor allowing such issuers, under certain conditions, to defer the payment of any remaining rebates owed after prepayment until the following MLR reporting year. We also proposed to allow issuers to provide MLR rebates in the form of a premium credit prior to the date that the rules previously provided. Lastly, we proposed to clarify MLR reporting and rebate requirements for issuers that choose to offer

temporary premium credits during a public health emergency (PHE) declared by the Secretary of HHS in the 2021 benefit year and beyond, when such credits are permitted by HHS.

In the proposed rule, the Secretaries of HHS and the Department of the Treasury proposed to reference and incorporate specific guidance published in the **Federal Register** in order to give states certainty regarding the requirements to receive and maintain approval by the Departments for State Innovation Waivers under section 1332 of the ACA. This proposal and the accompanying regulatory updates were finalized in the final rule published on January 19, 2021 (86 FR 6138).

II. Background

A. Legislative and Regulatory Overview

Title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) added a new title XXVII to the Public Health Service Act (PHS Act) to establish various reforms to the group and individual health insurance markets.

These provisions of the PHS Act were later augmented by other laws, including the ACA. Subtitles A and C of title I of the ACA reorganized, amended, and added to the provisions of part A of title XXVII of the PHS Act relating to group health plans ⁴ and health insurance issuers in the group and individual markets. The term "group health plan" includes both insured and self-insured group health plans.

Section 2702 of the PHS Act, as added by the ACA, establishes requirements for guaranteed availability of coverage in the group and individual markets, including qualifying events that trigger special enrollment periods under section 2702(b) of the PHS Act.⁵

Section 2718 of the PHS Act, as added by the ACA, generally requires health insurance issuers to submit an annual MLR report to HHS, and provide rebates to enrollees if the issuers do not achieve specified MLR thresholds.

Section 2723(b) of the PHS Act authorizes the Secretary to impose CMPs as a means of enforcing the individual and group insurance market requirements contained in Part A of title XXVII of the PHS Act with respect to health insurance issuers when a state does not have authority to enforce or

⁴The term "group health plan" is used in title XXVII of the PHS Act and is distinct from the term "health plan" as used in other provisions of title I of ACA. The term "health plan" does not include self-insured group health plans.

⁵ Before enactment of the ACA, HIPAA amended the PHS Act (formerly section 2711) to generally require guaranteed availability of coverage for employers in the small group market.

fails to substantially enforce these provisions and with respect to group health plans that are non-federal governmental plans. Section 1301(a)(1)(B) of the ACA directs all issuers of OHPs to cover the Essential Health Benefit (EHB) package described in section 1302(a) of the ACA, including coverage of the services described in section 1302(b) of the ACA, adherence to the cost-sharing limits described in section 1302(c) of the ACA, and meeting the actuarial value (AV) levels established in section 1302(d) of the ACA. Section 2707(a) of the PHS Act, which is effective for plan or policy years beginning on or after January 1, 2014, extends the requirement to cover the EHB package to non-grandfathered individual and small group health insurance coverage, irrespective of whether such coverage is offered through an Exchange. In addition, section 2707(b) of the PHS Act directs non-grandfathered group health plans to ensure that cost sharing under the plan does not exceed the limitations described in sections 1302(c)(1) of the ACA.

Section 1302 of the ACA provides for the establishment of an EHB package that includes coverage of EHBs (as defined by the Secretary), cost-sharing limits, and AV requirements. Section 1302(b) of the ACA directs that EHBs be equal in scope to the benefits provided under a typical employer plan, and that they cover at least the following 10 general categories: Ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care.

To set cost-sharing limits, section 1302(c)(4) of the ACA directs the Secretary to determine an annual premium adjustment percentage, a measure of premium growth that is used to set the rate of increase for three parameters: (1) The maximum annual limitation on cost sharing (section 1302(c)(1) of the ACA); (2) the required contribution percentage used to determine whether an individual can afford minimum essential coverage (MEC) (section 5000A of the Internal Revenue Code of 1986 (the Code), as enacted by section 1501 of the ACA); and (3) the employer shared responsibility payment amounts (section 4980H of the Code, as enacted by section 1513 of the ACA).

Section 1302(d) of the ACA describes the various levels of coverage based on their AV. Consistent with section 1302(d)(2)(A) of the ACA, AV is calculated based on the provision of EHB to a standard population. Section 1302(d)(3) of the ACA directs the Secretary to develop guidelines that allow for *de minimis* variation in AV calculations.

Sections 1311(b) and 1321(b) of the ACA provide that each state has the opportunity to establish an individual market Exchange that facilitates the purchase of insurance coverage by qualified individuals through QHPs and meets other standards specified in the ACA. Section 1321(c)(1) of the ACA directs the Secretary to establish and operate such Exchange within states that do not elect to establish an Exchange or, as determined by the Secretary on or before January 1, 2013, will not have an Exchange operable by January 1, 2014.

Section 1311(c)(1) of the ACA provides the Secretary the authority to issue regulations to establish criteria for the certification of QHPs, including network adequacy standards at section 1311(c)(1)(B) of the ACA. Section 1311(d) of the ACA describes the minimum functions of an Exchange. Section 1311(e)(1) of the ACA grants the Exchange the authority to certify a health plan as a OHP if the health plan meets the Secretary's requirements for certification issued under section 1311(c)(1) of the ACA, and the Exchange determines that making the plan available through the Exchange is in the interests of qualified individuals and qualified employers in the state. Section 1311(c)(6)(C) of the ACA establishes special enrollment periods and section 1311(c)(6)(D) of the ACA establishes the monthly enrollment period for Indians, as defined by section 4 of the Indian Health Care Improvement Act.6

Section 1311(c)(3) of the ACA directs the Secretary to develop a system to rate QHPs offered through an Exchange, based on relative quality and price. Section 1311(c)(4) of the ACA requires the Secretary to establish an enrollee satisfaction survey that evaluates the level of enrollee satisfaction of members with QHPs offered through an Exchange, for each QHP with more than 500 enrollees in the prior year. Further, sections 1311(c)(3) and 1311(c)(4) of the ACA require Exchanges to provide this

quality rating information ⁷ to individuals and employers on the Exchange's website.

Section 1312(c) of the ACA generally requires a health insurance issuer to consider all enrollees in all health plans (except grandfathered health plans) offered by such issuer to be members of a single risk pool for each of its individual and small group markets. States have the option to merge the individual and small group market risk pools under section 1312(c)(3) of the ACA.

Section 1312(e) of the ACA directs the Secretary to establish procedures under which a state may permit agents and brokers to enroll qualified individuals and qualified employers in QHPs through an Exchange and to assist individuals in applying for financial assistance for QHPs sold through an Exchange.

Sections 1313 and 1321 of the ACA provide the Secretary with the authority to oversee the financial integrity of State Exchanges, their compliance with HHS standards, and the efficient and non-discriminatory administration of State Exchange activities. Section 1321 of the ACA provides for state flexibility in the operation and enforcement of Exchanges and related requirements.

Section 1321(a) of the ACA provides broad authority for the Secretary to establish standards and regulations to implement the statutory requirements related to Exchanges, QHPs and other components of title I of the ACA. Section 1321(a)(1) of the ACA directs the Secretary to issue regulations that set standards for meeting the requirements of title I of the ACA for, among other things, the establishment and operation of Exchanges. When operating an FFE under section 1321(c)(1) of the ACA, HHS has the authority under sections 1321(c)(1) and 1311(d)(5)(A) of the ACA to collect and spend user fees. Office of Management and Budget (OMB) Circular A-25 establishes federal policy regarding user fees and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from federal activities beyond those received by the general public.

Section 1321(c)(2) of the ACA provides that the provisions of section 2723(b) of the PHS Act shall apply to the enforcement of the Federal Exchange standards and authorizes the Secretary to enforce the Exchange standards using CMPs on the same basis

⁶The Indian Health Care Improvement Act (IHCIA), the cornerstone legal authority for the provision of health care to American Indians and Alaska Natives, was made permanent when President Obama signed the bill on March 23, 2010, as part of the ACA.

⁷ The term "quality rating information" includes the QRS scores and ratings and the results of the enrollee satisfaction survey (which is also known as the "Qualified Health Plan (QHP) Enrollee Experience Survey").

as detailed in section 2723(b) of the PHS Act.

Section 1321(d) of the ACA provides that nothing in title I of the ACA must be construed to preempt any state law that does not prevent the application of title I of the ACA. Section 1311(k) of the ACA specifies that Exchanges may not establish rules that conflict with or prevent the application of regulations issued by the Secretary.

Section 1332 of the ACA provides the Secretary of HHS and the Secretary of the Treasury (collectively, the Secretaries) with the discretion to approve a state's proposal to waive specific provisions of the ACA, provided the state's section 1332 waiver plan meets certain requirements. The Department of Health and Human Services and the Department of the Treasury (collectively, the Departments) finalized implementing regulations on February 27, 2012 (76 FR 13553) and published detailed guidance on the Department's application of section 1332 to proposed state waivers on October 24, 2018 (83 FR 53575).

Section 1341 of the ACA provides for the establishment of a transitional reinsurance program in each state to help pay the cost of treating high-cost enrollees in the individual market in the 2014 through 2016 benefit years.

Section 1343 of the ACA establishes a permanent risk adjustment program to provide payments to health insurance issuers that attract higher-than-average risk populations, such as those with chronic conditions, funded by payments from those that attract lower-than-average risk populations, thereby reducing incentives for issuers to avoid higher-risk enrollees.

Section 1402 of the ACA provides for, among other things, reductions in cost sharing for EHB for qualified low- and moderate-income enrollees in silver level QHPs offered through the individual market Exchanges. This section also provides for reductions in cost sharing for American Indians enrolled in QHPs at any metal level.

Section 1411(c) of the ACA requires the Secretary to submit certain information provided by applicants under section 1411(b) of the ACA to other federal officials for verification, including income and family size information to the Secretary of the Treasury.

Section 1411(d) of the ACA provides that the Secretary must verify the accuracy of information provided by applicants under section 1411(b) of the ACA for which section 1411(c) of the ACA does not prescribe a specific verification procedure, in such manner as the Secretary determines appropriate.

Section 1411(f) of the ACA requires the Secretary, in consultation with the Secretary of the Treasury, the Secretary of Homeland Security, and the Commissioner of Social Security, to establish procedures for hearing and making decisions governing appeals of Exchange eligibility determinations.

Section 1411(f)(1)(B) of the ACA requires the Secretary to establish procedures to redetermine eligibility on a periodic basis, in appropriate circumstances, including eligibility to purchase a QHP through the Exchange and for APTC and CSRs.

Section 1411(g) of the ACA allows the use or disclosure of applicant information only for the limited purposes of, and to the extent necessary to, ensure the efficient operation of the Exchange, including by verifying eligibility to enroll through the Exchange and for APTC and CSRs.

Section 5000A of the Code, as added by section 1501(b) of the ACA, requires individuals to have MEC for each month, qualify for an exemption, or make an individual shared responsibility payment. Under the Tax Cuts and Jobs Act (Pub. L. 115-97, December 22, 2017) the individual shared responsibility payment has been reduced to \$0, effective for months beginning after December 31, 2018. Notwithstanding that reduction, certain exemptions are still relevant to determine whether individuals age 30 and above qualify to enroll in catastrophic coverage under 45 CFR 155.305(h) or 45 CFR 156.155.

Section 1150A(a) of the Social Security Act (the Act) requires a health benefits plan or PBM that manages prescription drug coverage under a contract with a QHP issuer to provide certain prescription drug information to the Secretary at such times, and in such form and manner, as the Secretary shall specify. HHS will limit disclosure of the information disclosed by a health benefits plan or PBM under this section as required by section 1150A of the Act and may only disclose the information in a form which does not disclose the identity of a specific PBM or plan, or prices charged for specific drugs, except that for limited purposes, HHS may disclose the information to states to carry out section 1311 of the ACA. An issuer or PBM that fails to provide the information on a timely basis or that knowingly provides false information may be subject to a civil monetary penalty under section 1927(b)(3)(C) of the Act in the same manner as such provisions apply to a manufacturer with an agreement under that section.

1. Premium Stabilization Programs 8 In the July 15, 2011 Federal Register (76 FR 41929), we published a proposed rule outlining the framework for the premium stabilization programs. We implemented the premium stabilization programs in a final rule published in the March 23, 2012 Federal Register (77 FR 17219) (Premium Stabilization Rule). In the December 7, 2012 Federal Register (77 FR 73117), we published a proposed rule outlining the benefit and payment parameters for the 2014 benefit year to expand the provisions related to the premium stabilization programs and set forth payment parameters in those programs (proposed 2014 Payment Notice). We published the 2014 Payment Notice final rule in the March 11, 2013 Federal Register (78 FR 15409). In the June 19, 2013 Federal Register (78 FR 37032), we proposed a modification to the HHS-operated methodology related to community rating states. In the October 30, 2013 Federal Register (78 FR 65046), we finalized the proposed modification to the HHS-operated methodology related to community rating states. We published a correcting amendment to the 2014 Payment Notice final rule in the November 6, 2013 Federal Register (78 FR 66653) to address how an enrollee's age for the risk score calculation would be determined under the HHS-operated risk adjustment methodology.

In the December 2, 2013 Federal Register (78 FR 72321), we published a proposed rule outlining the benefit and payment parameters for the 2015 benefit year to expand the provisions related to the premium stabilization programs, setting forth certain oversight provisions and establishing the payment parameters in those programs (proposed 2015 Payment Notice). We published the 2015 Payment Notice final rule in the March 11, 2014 Federal Register (79 FR 13743). In the May 27, 2014 **Federal** Register (79 FR 30240), the 2015 fiscal year sequestration rate for the risk adjustment program was announced.

In the November 26, 2014 Federal Register (79 FR 70673), we published a proposed rule outlining the benefit and payment parameters for the 2016 benefit year to expand the provisions related to the premium stabilization programs, setting forth certain oversight provisions and establishing the payment parameters in those programs (proposed 2016 Payment Notice). We published the 2016 Payment Notice final rule in

⁸ The term "premium stabilization programs" refers to the risk adjustment, risk corridors, and reinsurance programs established by the ACA. See 42 U.S.C. 18061, 18062, and 18063.

the February 27, 2015 **Federal Register** (80 FR 10749).

In the December 2, 2015 Federal Register (80 FR 75487), we published a proposed rule outlining the benefit and payment parameters for the 2017 benefit year to expand the provisions related to the premium stabilization programs, setting forth certain oversight provisions and establishing the payment parameters in those programs (proposed 2017 Payment Notice). We published the 2017 Payment Notice final rule in the March 8, 2016 Federal Register (81 FR 12203).

In the September 6, 2016 Federal Register (81 FR 61455), we published a proposed rule outlining the benefit and payment parameters for the 2018 benefit vear and to further promote stable premiums in the individual and small group markets. We proposed updates to the risk adjustment methodology, new policies around the use of external data for recalibration of our risk adjustment models, and amendments to the Department of Health and Human Services' Risk Adjustment Data Validation (HHS–RADV) process (proposed 2018 Payment Notice). We published the 2018 Payment Notice final rule in the December 22, 2016 Federal Register (81 FR 94058)

In the November 2, 2017 Federal Register (82 FR 51042), we published a proposed rule outlining the benefit and payment parameters for the 2019 benefit year, and to further promote stable premiums in the individual and small group markets. We proposed updates to the risk adjustment methodology and amendments to the HHS-RADV process (proposed 2019 Payment Notice). We published the 2019 Payment Notice final rule in the April 17, 2018 Federal Register (83 FR 16930). We published a correction to the 2019 risk adjustment coefficients in the 2019 Payment Notice final rule in the May 11, 2018 Federal Register (83 FR 21925). On July 27, 2018, consistent with 45 CFR 153.320(b)(1)(i), we updated the 2019 benefit year final risk adjustment model coefficients to reflect an additional recalibration related to an update to the 2016 enrollee-level External Data Gathering Environment (EDGE) dataset.9

In the July 30, 2018 **Federal Register** (83 FR 36456), we published a final rule that adopted the 2017 benefit year risk adjustment methodology as established in the final rules published in the March 23, 2012 **Federal Register** (77 FR 17220 through 17252) and in the March 8,

2016 Federal Register (81 FR 12204 through 12352). This final rule set forth additional explanation of the rationale supporting use of statewide average premium in the HHS-operated risk adjustment state payment transfer formula for the 2017 benefit year, including the reasons why the program is operated in a budget-neutral manner. This final rule permitted HHS to resume 2017 benefit year risk adjustment payments and charges. HHS also provided guidance as to the operation of the HHS-operated risk adjustment program for the 2017 benefit year in light of publication of this final rule.10

In the August 10, 2018 **Federal** Register (83 FR 39644), we published a proposed rule seeking comment on adopting the 2018 benefit year risk adjustment methodology in the final rules published in the March 23, 2012 Federal Register (77 FR 17219) and in the December 22, 2016 Federal Register (81 FR 94058). The proposed rule set forth additional explanation of the rationale supporting use of statewide average premium in the HHS-operated risk adjustment state payment transfer formula for the 2018 benefit year, including the reasons why the program is operated in a budget-neutral manner. In the December 10, 2018 Federal Register (83 FR 63419), we issued a final rule adopting the 2018 benefit year HHS-operated risk adjustment methodology as established in the final rules published in the March 23, 2012 Federal Register (77 FR 17219) and the December 22, 2016 Federal Register (81 FR 94058). This final rule sets forth additional explanation of the rationale supporting use of statewide average premium in the HHS-operated risk adjustment state payment transfer formula for the 2018 benefit year, including the reasons why the program is operated in a budget-neutral manner.

In the January 24, 2019 Federal Register (84 FR 227), we published a proposed rule outlining updates to the calibration of the risk adjustment methodology, the use of EDGE data for research purposes, and updates to HHS–RADV audits. We published the 2020 Payment Notice final rule in the April 25, 2019 Federal Register (84 FR 17454).

In the February 6, 2020 **Federal Register** (85 FR 7088), we published a proposed rule that included updates to the risk adjustment models' HCCs and a modification HHS–RADV error rate calculation methodology. We published

the 2021 Payment Notice final rule in the May 14, 2020 **Federal Register** (85 FR 29164).

In the June 2, 2020 Federal Register (85 FR 33595), we published a proposed rule that proposed updates to various aspects of the HHS-RADV methodologies and processes. We published the 2020 HHS-RADV Amendments final rule in the December 1, 2020 Federal Register (85 FR 76979). This final rule made revisions to the HCC failure rate grouping algorithm, finalized a sliding scale adjustment in HHS-RADV error rate calculation, and a constraint on risk score adjustments for low-side failure rate outliers. The final rule also established a transition from the prospective application of HHS-RADV adjustments to apply HHS-RADV results to risk scores from the same benefit year as that being audited.

In the September 2, 2020 **Federal Register** (85 FR 54820), HHS issued an interim final rule containing certain policy and regulatory revisions in response to the COVID–19 PHE, wherein we set forth risk adjustment reporting requirements for issuers offering temporary premium credits in the 2020 benefit year (interim final rule on COVID–19).

In the December 4, 2020 **Federal Register** (85 FR 78572), HHS issued a proposed rule containing certain policy and regulatory revisions related to the risk adjustment program (proposed 2022 Payment Notice).

2. Program Integrity

In the June 19, 2013 Federal Register (78 FR 37031), we published a proposed rule that proposed certain program integrity standards related to Exchanges and the premium stabilization programs (proposed Program Integrity Rule). The provisions of that proposed rule were finalized in two rules, the "first Program Integrity Rule" published in the August 30, 2013 Federal Register (78 FR 54069) and the "second Program Integrity Rule" published in the October 30, 2013 Federal Register (78 FR 65045). In the December 27, 2019 Federal Register (84 FR 71674), we published a final rule that revised standards relating to oversight of Exchanges established by states and periodic data matching frequency.

3. Market Rules

An interim final rule relating to the HIPAA health insurance reforms was published in the April 8, 1997 Federal Register (62 FR 16894). A proposed rule relating to ACA health insurance market reforms that became effective in 2014 was published in the November 26, 2012 Federal Register (77 FR 70584). A

⁹ "Updated 2019 Benefit Year Final HHS Risk Adjustment Model Coefficients," July 27, 2018. Available at https://www.cms.gov/CCIIO/Resources/ Regulations-and-Guidance/Downloads/2019-Updtd-Final-HHS-RA-Model-Coefficients.pdf.

¹⁰ "Update on the HHS-operated Risk Adjustment Program for the 2017 Benefit Year," July 27, 2018. Available at https://www.cms.gov/CCIIO/Resources/ Regulations-and-Guidance/Downloads/2017-RA-Final-Rule-Resumption-RAOps.pdf.

final rule implementing those provisions was published in the February 27, 2013 **Federal Register** (78 FR 13406) (2014 Market Rules).

A proposed rule relating to Exchanges and Insurance Market Standards for 2015 and beyond was published in the March 21, 2014 Federal Register (79 FR 15808) (2015 Market Standards Proposed Rule). A final rule implementing the Exchange and Insurance Market Standards for 2015 and Beyond was published in the May 27, 2014 Federal Register (79 FR 30240) (2015 Market Standards Rule). The 2018 Payment Notice final rule in the December 22, 2016 Federal Register (81 FR 94058) provided additional guidance on guaranteed availability and guaranteed renewability. In the Market Stabilization final rule that was published in the April 18, 2017 Federal Register (82 FR 18346), we released further guidance related to guaranteed availability. In the 2019 Payment Notice final rule in the April 17, 2018 Federal Register (83 FR 17058), we clarified that certain exceptions to the special enrollment periods only apply with respect to coverage offered outside of the Exchange in the individual market.

4. Administrative Appeals Process Related to Federal Enforcement in Group and Individual Health Insurance Markets and Non-Federal Governmental Group Health Plans

On April 8, 1997 an interim final rule with comment period was published in the Federal Register (62 FR 16894) that implemented the HIPAA health insurance reforms by adding 45 CFR parts 144, 146, and 148. Included in those regulations were enforcement provisions. In the June 10, 1997 Federal Register (62 FR 31669), we published technical corrections to these interim final rules. After gaining some experience with direct federal enforcement in some states, we determined that it was necessary to provide more detail on the procedures that will be used to enforce HIPAA when a state does not do so. On August 20, 1999, an interim final rule with comment period was published in the Federal Register (64 FR 45786) that provided more detail on the procedures for enforcing title XXVII of the PHS Act, as added by HIPAA, and as amended by the Mental Health Parity Act of 1996 (Pub. L. 104-204, September 26, 1996), the Newborns' and Mothers' Health Protection Act of 1996 (Pub. L. 104-204, September 26, 1996), and the Women's Health and Cancer Rights Act of 1998 (Pub. L. 105-277, October 21, 1998), when a state does not enforce such laws. We published a final rule on November

25, 2005 in the **Federal Register** (70 FR 71020) that finalized this interim final rule, and made non-substantive amendments to the regulations detailing procedures for enforcing title XXVII of the PHS Act.

5. Exchanges

We published a request for comment relating to Exchanges in the August 3. 2010 Federal Register (75 FR 45584). We issued initial guidance to states on Exchanges on November 18, 2010. In the July 15, 2011 Federal Register (76 FR 41865), we published a proposed rule with proposals to implement components of the Exchanges, and a rule in the August 17, 2011 Federal Register (76 FR 51201) regarding Exchange functions in the individual market and Small Business Health Options Program (SHOP), eligibility determinations, and Exchange standards for employers. A final rule implementing components of the Exchanges and setting forth standards for eligibility for Exchanges was published in the March 27, 2012 Federal Register (77 FR 18309) (Exchange Establishment Rule).

In the 2014 Payment Notice and in the Amendments to the HHS Notice of Benefit and Payment Parameters for 2014 interim final rule, published in the March 11, 2013 **Federal Register** (78 FR 15541), we set forth standards related to Exchange user fees. We established an adjustment to the FFE user fee in the Coverage of Certain Preventive Services under the Affordable Care Act final rule, published in the July 2, 2013 **Federal Register** (78 FR 39869) (Preventive Services Rule).

In the May 11, 2016 Federal Register (81 FR 29146), we published an interim final rule with amendments to the parameters of certain special enrollment periods (2016 Interim Final Rule). We finalized these in the 2018 Payment Notice final rule, published in the December 22, 2016 Federal Register (81 FR 94058). In the March 8, 2016 Federal Register (81 FR 12203), the final 2017 Payment Notice codified State Exchanges on the Federal platform along with relevant requirements. In the April 18, 2017 Market Stabilization final rule Federal Register (82 FR 18346), we amended standards relating to special enrollment periods and QHP certification. In the 2019 Payment Notice final rule, published in the April 17, 2018 Federal Register (83 FR 16930), we modified parameters around certain special enrollment periods. In the April 25, 2019 Federal Register (84 FR 17454), the final 2020 Payment Notice established a new special enrollment period. In the May 14, 2020

Federal Register (85 FR 29204), the 2021 Payment Notice final rule made certain changes to plan category limitations and special enrollment period coverage effective date rules, allowed individuals provided a noncalendar year qualified small employer health reimbursement arrangement (QSEHRA) to qualify for an existing special enrollment period, and discussed plans for future rulemaking for employer-sponsored coverage verification and non-enforcement discretion for Exchanges that do not conduct random sampling until plan year 2021.

In the December 4, 2020 Federal Register (85 FR 78572), HHS issued a proposed rule containing certain policy and regulatory revisions related to user fees, Exchanges, and section 1332 State Innovation Waivers (proposed 2022 Payment Notice). A final rule was published in the Federal Register (86 FR 6138) on January 19, 2021, that addressed a subset of the policies proposed in the proposed rule. That final rule set forth provisions related to user fees for FFEs and SBE-FPs. It finalized the proposed changes related to acceptance of payments by issuers of individual market Qualified Health Plans, and clarifies the regulation imposing network adequacy standards with regard to Qualified Health Plans that do not use provider networks. It also finalized a new direct enrollment option for Federally-facilitated Exchanges and State Exchanges and implemented changes to codify in regulations certain policies related to section 1332 State Innovation Waivers.

6. Essential Health Benefits

On December 16, 2011, HHS released a bulletin 11 that outlined an intended regulatory approach for defining EHB, including a benchmark-based framework. A proposed rule relating to EHBs was published in the November 26, 2012 Federal Register (77 FR 70643). We established requirements relating to EHBs in the Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation Final Rule, which was published in the February 25, 2013 Federal Register (78 FR 12833) (EHB Rule). In the 2019 Payment Notice, published in the April 17, 2018 Federal Register (83 FR 16930), we added § 156.111 to provide states with additional options from which to select an EHB-benchmark plan for plan years 2020 and beyond.

¹¹ "Essential Health Benefits Bulletin," December 16, 2011. Available at https://www.cms.gov/CCIIO/Resources/Files/Downloads/essential_health_benefits_bulletin.pdf.

The 2015 Payment Notice final rule, established a methodology for estimating the average per capita premium for purposes of calculating the premium adjustment percentage. Beginning with the 2015 benefit year, the premium adjustment percentage was calculated based on the estimates and projections of average per enrollee employer-sponsored insurance premiums from the National Health Expenditure Accounts (NHEA), which are calculated by the CMS Office of the Actuary. In the 2020 Payment Notice final rule, we amended the methodology for calculating the premium adjustment percentage by estimating per capita insurance premiums as private health insurance premiums, minus premiums paid for Medigap insurance and property and casualty insurance, divided by the unrounded number of unique private health insurance enrollees, excluding all Medigap enrollees. Additionally, in response to public comments to the proposed 2021 Payment Notice, the 2021 Payment Notice final rule included a policy stating that we will finalize payment parameters that depend on NHEA data, including the premium adjustment percentage, based on the data that are available as of the publication of the proposed rule for that benefit year, even if NHEA data are updated between the proposed and final rules.

In the December 15, 2020 Federal Register (85 FR 81097), HHS published the final rule, along with the Departments of Labor and the Treasury, that finalized using the premium adjustment percentage as one alternative in setting the parameters for permissible increases in fixed-amount cost-sharing requirements for grandfathered group health plans.

7. Medical Loss Ratio (MLR)

We published a request for comment on section 2718 of the PHS Act in the April 14, 2010 Federal Register (75 FR 19297), and published an interim final rule with a 60-day comment period relating to the MLR program on December 1, 2010 (75 FR 74863). A final rule with a 30-day comment period was published in the December 7, 2011 Federal Register (76 FR 76573). An interim final rule with a 60-day comment period was published in the December 7, 2011 Federal Register (76 FR 76595). A final rule was published in the Federal Register on May 16, 2012 (77 FR 28790). The MLR program requirements were amended in final rules published in the March 11, 2014 Federal Register (79 FR 13743), the May 27, 2014 Federal Register (79 FR 30339), the February 27, 2015 Federal

Register (80 FR 10749), the March 8, 2016 Federal Register (81 FR 12203), the December 22, 2016 Federal Register (81 FR 94183), the April 17, 2018 Federal Register (83 FR 16930), the May 14, 2020 Federal Register (85 FR 29164) and an interim final rule was published in the September 2, 2020 Federal Register (85 FR 54820).

8. Quality Rating System and Enrollee Satisfaction Survey

The overall framework and elements of the rating methodology for the QRS were published in the November 19, 2013 **Federal Register** (78 FR 69418). Consistent with statutory provisions, in May 2014, HHS issued regulations at §§ 155.1400 and 155.1405 to establish the QRS and the QHP Enrollee Experience Survey display requirements for Exchanges and has worked towards requiring nationwide the prominent display of quality rating information on Exchange websites. 12 As a condition of certification and participation in the Exchanges, HHS requires that QHP issuers submit QRS clinical measure data and QHP Enrollee Survey response data for their respective QHPs offered through an Exchange in accordance with HHS guidance, which has been issued annually for each forthcoming plan year.13

9. State Innovation Waivers

Section 1332(a)(4)(B) of the ACA requires the Secretaries to issue regulations regarding procedures for State Innovation Waivers. On March 14, 2011, the Departments published the "Application, Review, and Reporting Process for Waivers for State Innovation" proposed rule ¹⁴ in the **Federal Register** (76 FR 13553) to implement section 1332(a)(4)(B) of the ACA. On February 27, 2012, the Departments published the "Application, Review, and Reporting Process for Waivers for State Innovation" final rule ¹⁵ in the **Federal**

Register (77 FR 11700) (hereinafter referred to as the "2012 Final Rule"). On October 24, 2018, the Departments issued the "State Relief and Empowerment Waivers' guidance 16 in the Federal Register (83 FR 53575) (hereinafter referred to as the "2018 Guidance"), which superseded the previous guidance 17 published on December 16, 2015 in the Federal Register (80 FR 78131) and provided additional information about the requirements that states must meet for waiver proposals, the Secretaries' application review procedures, passthrough funding determinations, certain analytical requirements, and operational considerations. On November 6, 2020, the Departments issued an interim final rule 18 in the Federal Register (85 FR 71142), which revises regulations to set forth flexibilities in the public notice requirements and post-award public participation requirements for State Innovation Waivers under section 1332 of the ACA during the COVID-19 PHE.

In the December 4, 2020 Federal Register (85 FR 78572), HHS issued a proposed rule under which policies announced under the 2018 Guidance would be incorporated into regulations governing State Innovation Waivers. A final rule was published in the Federal Register (86 FR 6138) on January 19, 2021, which adopted final regulations to incorporate certain policies announced in the 2018 Guidance regarding State Innovation Waivers.

B. Stakeholder Consultation and Input

HHS has consulted with stakeholders on policies related to the operation of Exchanges and the risk adjustment and HHS–RADV programs. We have held a number of listening sessions with consumers, providers, employers, health plans, advocacy groups and the actuarial community to gather public input. We have solicited input from state representatives on numerous topics, particularly risk adjustment and the direct enrollment option for FFEs and State Exchanges.

We consulted with stakeholders through regular meetings with the National Association of Insurance Commissioners (NAIC), regular contact with states, and health insurance issuers, trade groups, consumer advocates, employers, and other interested parties. We considered all

¹² ACA; Exchange and Insurance Market Standards for 2015 and Beyond, Final Rule, 79 FR 30240 at 30352 (May 27, 2014). Also see the "CMS Bulletin on display of QRS star ratings and QHP Enrollee Survey results for QHPs offered through Exchanges," August 15, 2019. Available at https:// www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/QualityRatingInformation BulletinforPlan Year2020.pdf.

¹³ See, for example, "Center for Clinical Standards & Quality, CMS, The Quality Rating System and Qualified Health Plan Enrollee Experience Survey: Technical Guidance for 2021," September 2020. Available at https://www.cms.gov/files/document/quality-rating-system-and-qualified-health-plan-enrollee-experience-survey-technical-guidance-2021.pdf.

¹⁴ https://www.govinfo.gov/content/pkg/FR-2011-03-14/pdf/2011-5583.pdf.

¹⁵ https://www.govinfo.gov/content/pkg/FR-2012-02-27/pdf/2012-4395.pdf.

 $^{^{16}\,}https://www.govinfo.gov/content/pkg/FR-2018-10-24/pdf/2018-23182.pdf.$

 $^{^{17}\,}https://www.govinfo.gov/content/pkg/FR-2015-12-16/pdf/2015-31563.pdf.$

¹⁸ https://www.federalregister.gov/documents/ 2020/11/06/2020-24332/additional-policy-andregulatory-revisions-in-response-to-the-covid-19public-health-emergency.

public input we received as we developed the policies in this final rule.

C. Structure of Final Rule

The regulations outlined in this final rule are codified in 45 CFR parts 147, 150, 153, 155, 156, 158, and 184.

The changes to 45 CFR part 147 make technical and conforming amendments regarding limited and special enrollment periods in the individual market.

The changes to 45 CFR part 150 make minor procedural changes to the requirements for administrative appeals of CMPs by health insurance issuers and non-federal governmental group health plans to align with current practices for the Departmental Appeals Board. We are finalizing parallel changes to the requirements for administrative appeals of CMPs by QHP issuers under 45 CFR part 156, subpart J.

The changes to 45 CFR part 153 recalibrate the HHS risk adjustment models consistent with the approach outlined in the 2020 Payment Notice to transition away from the use of MarketScan® data. However, we are finalizing the policy to use the 3 most recent consecutive years of enrollee-level EDGE data that are available in time for incorporating into the coefficients in the proposed rule, which would utilize enrollee-level EDGE data from 2016, 2017 and 2018 for the 2022 model recalibration, the same data years used for the 2021 model recalibration.¹⁹

We are clarifying risk adjustment reporting requirements for issuers that choose to offer premium credits, if such credits are permitted by HHS for future benefit years. In this final rule, we are also approving the requests from Alabama to reduce risk adjustment transfers by 50 percent in the individual (including catastrophic and noncatastrophic risk pools) and small group markets for the 2022 benefit year. Additionally, we clarify the process for HHS to audit issuers of risk adjustment covered plans and reinsurance-eligible plans and establish the authority for HHS to conduct compliance reviews of these issuers.

The provisions in part 153 also relate to the risk adjustment user fee for the 2022 benefit year. In this final rule, we revise the schedule for the collection of HHS–RADV charges and disbursement of payments such that these charges and disbursements will occur in the same calendar year in which HHS–RADV results are released. We also finalize

provisions under part 153 to update the applicable regulations to reflect the previously established framework regarding when second validation audit (SVA) findings can be disputed or appealed, expand the conflict of interest standard for initial validation audit (IVA) Entities, and codify two previously established exemptions from the requirement to participate in HHS—RADV.

In part 155, we finalize the required contribution percentage for the 2022 benefit year. We amend the definition of direct enrollment technology provider and add a definition of QHP issuer direct enrollment technology provider in part 155 to recognize that QHP issuers may also use QHP issuer direct enrollment technology providers to facilitate participation in direct enrollment under §§ 155.221 and 156.1230, and make conforming amendments to the definition of webbroker. We also codify more specific operational readiness review requirements for web-brokers and direct enrollment entities. We also amend the marketing and display requirements for direct enrollment entities, and rescind text contained in § 155.320 to implement a federal court order invalidating certain requirements in the section.

We also finalize several amendments to special enrollment period policy. Specifically, we add new flexibility to allow current Exchange enrollees and their dependents to change to a QHP of a lower metal level if they qualify for a special enrollment period due to becoming newly ineligible for APTC; allow a qualified individual, enrollee, or dependent who did not receive timely notice of a triggering event and otherwise was reasonably unaware that a triggering event occurred to select a plan within 60 days of the date that he or she knew, or reasonably should have known, of the occurrence of the triggering event; and clarify that a special enrollment period will be available when a qualified individual or his or her dependent is enrolled in COBRA continuation coverage, and the employer contributions or government subsidies for such coverage completely

In part 156, we set forth the premium adjustment percentage, maximum annual limitation on cost sharing and reduced maximum annual limitation on cost sharing for the 2022 benefit year. We also amend part 156 to establish that for the 2023 benefit year and beyond, we will publish the annual updates to the premium adjustment percentage, maximum annual limitation on cost sharing, reduced maximum annual

limitation on cost sharing and required contribution percentage in guidance in January of the benefit year prior to the applicable benefit year, rather than in the applicable benefit year's annual HHS notice of benefit and payment parameters, as long as no change to the methodologies to calculate these amounts are proposed. We finalize a methodology for analyzing the impact of preliminary values of the reduced annual maximum limitations on cost sharing on the AVs of silver plan variations. Additionally, we clarify the process for HHS to audit QHP issuers related to compliance with federal requirements for APTC, CSRs, and user fees and establish authority for HHS to conduct compliance reviews of QHP issuers to ensure compliance with federal requirements for APTC, CSRs, and user fee standards.

The changes to part 158 establish the definition of prescription drug rebates and other price concessions that issuers must deduct from incurred claims for MLR reporting and rebate calculation purposes. The changes to part 158 also remove the option for issuers to report an amount equal to 0.8 percent of earned premium in the relevant State and market in lieu of reporting the issuer's actual expenditures for activities that improve health care quality for MLR reporting and rebate calculation purposes to implement a federal court order invalidating this provision. The changes to part 158 additionally explicitly allow issuers the option to prepay a portion or all of the estimated MLR rebate for a given MLR reporting year in advance of the deadlines set forth in §§ 158.240(e) and 158.241(a)(2) and filing the MLR Annual Reporting Form, and establish a safe harbor allowing such issuers, under certain conditions, to defer the payment of rebates remaining after prepayment until the following MLR reporting year. In addition, the changes to part 158 allow issuers to provide MLR rebates in the form of a premium credit prior to the date that the rules previously provided. Lastly, we clarify MLR reporting and rebate requirements for issuers that choose to offer temporary premium credits during a PHE declared by the Secretary of HHS in the 2021 benefit year and beyond when such credits are permitted by HHS.

The addition of part 184 requires PBMs under contract with an issuer of QHPs to report prescription drug data required by section 1150A of the Act.

¹⁹ As detailed below, the one exception relates to RXC 09, which involved the use of only 2016 and 2017 enrollee-level data to develop the applicable 2022 benefit year coefficients and interaction terms.

III. Summary of the Proposed Provisions of the HHS Notice of Benefit and Payment Parameters for 2022, Analysis of and Responses to Public Comments, and Provisions of the Final Rule

In the December 4, 2020 Federal Register (86 FR 78572), we published the "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards; Updates To State Innovation Waiver (Section 1332 Waiver) Implementing Regulations" proposed rule. We received a total of 542 comments in response to the proposed 2022 Payment Notice. Comments were received from state entities, such as departments of insurance and State Exchanges, health insurance issuers, providers and provider groups, consumer groups, industry groups, national interest groups, and other stakeholders. The comments ranged from general support of, or opposition to, the proposed provisions to specific questions or comments regarding proposed changes. We received a number of comments and suggestions that were outside the scope of the proposed rule that are not addressed in this final rule.

In this final rule, we provide a summary of proposed provisions, a summary of the public comments received that directly related to those proposals, our responses to these comments, and a description of the provisions we are finalizing.

We first address comments regarding the publication of the proposed rule and the comment period.

Comment: Multiple commenters criticized the length of the comment period, stating that a longer comment period is necessary to allow stakeholders to review the proposed rule and provide thoughtful comments. Some commenters also expressed concern that HHS would not adequately review and consider all comments before issuing a final rule; that HHS appears to be rushing to finalize substantial changes to regulations that would hamper access to access to coverage through the Exchanges; and that HHS should defer any major policy decisions affecting access to Exchange coverage to the incoming Administration.

Response: We disagree that the comment period was not long enough to allow stakeholders to provide meaningful comments. Each year, we generally have set a 30-day comment period to accommodate issuer filing deadlines for the upcoming plan year and to avoid creating significant

challenges for states, Exchanges, issuers, and other entities operating under strict deadlines related to approval of products. Moreover, we found commenters' submissions to be thoughtful and reflective of a detailed review and analysis of the proposed rule.

We further recognize the importance of federal agencies reviewing and considering all relevant comments before issuing a final rule. The comment period for the proposed rule closed on December 30, 2020. HHS has had ample time to review and fully consider comments relevant to the rules and policies finalized under this final rule.

We also disagree that the rules and policies in this final rule will hamper access to Exchange coverage. First, based on a review of the comments as a whole, we believe comments that asserted the policies in the proposed 2022 Payment Notice would hamper access to Exchange coverage were largely relevant to proposals that were finalized in the January 19, 2021 final Payment Notice, including the Exchange DE option finalized under 45 CFR 155.221(j), and the changes to the regulations governing State Innovation Waivers under 31 CFR part 33 and 45 CFR part 155.20 Such comments were not focused on policies that we are finalizing in this final rule, and for reasons more fully reviewed in the preamble discussions related to specific policies in this final rule, we disagree that the rules and policies finalized in this final rule will hamper access to Exchange coverage. Further, as noted above, HHS reviewed the proposed 2022 Payment Notice and the January 19. 2021 final 2022 Payment Notice in compliance with E.O. 14009 and intends to issue a proposed rule this spring to address certain polices, including the Exchange DE option and the changes to the State Innovation Waivers regulations.

A. Part 147—Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets

1. Guaranteed Availability of Coverage (§ 147.104)

Section 147.104(b)(2) incorporates by reference certain Exchange special enrollment periods described in § 155.420, making those special enrollment periods applicable to nongrandfathered coverage offered in the individual market through or outside of an Exchange. We proposed amendments to § 147.104(b)(2) to clarify that

paragraph (b)(2)(ii) does not apply to references in § 155.420(d)(4) (relating to errors of the Exchange), and to make a conforming amendment consistent with the proposal in § 155.420(c)(5) relating to special enrollment period availability for individuals who do not receive timely notice of a triggering event. We are finalizing these amendments as proposed.

Section 155.420(d)(4) establishes an Exchange special enrollment period for a qualified individual or their dependent if his or her enrollment or non-enrollment in a QHP is unintentional, inadvertent, or erroneous and is the result of the error, misrepresentation, misconduct, or inaction of an officer, employee, or agent of the Exchange or HHS, its instrumentalities, or a non-Exchange entity providing enrollment assistance or conducting enrollment activities. Section 147.104(b)(2)(ii) states that, when determining the application of a special enrollment period for individual market coverage offered outside the Exchange, a reference in § 155.420 to a "QHP" is deemed to refer to a plan, a reference to "the Exchange" is deemed to refer to the applicable state authority, and a reference to a "qualified individual" is deemed to refer to an individual in the individual market.

However, this paragraph was not intended to change the application of § 155.420(d)(4), which is specific to errors of the Exchange, not those of the applicable state authority. It would be inappropriate for the triggering event in this case to apply to errors of the applicable state authority because the state does not perform the same functions as the Exchange. For example, the state authority does not perform an enrollment function. Thus, basing the triggering event on errors of the state is inappropriate and could create different special enrollment periods in the individual market on and off of the Exchange.

Therefore, we proposed to clarify that § 147.104(b)(2)(ii) does not apply to references in § 155.420(d)(4). As a result, issuers offering health insurance coverage in the individual market must provide a limited open enrollment period under the same circumstances as described in § 155.420(d)(4).

In addition, we proposed a conforming amendment to § 147.104(b)(4)(ii), consistent with the proposal in § 155.420(c)(5), to establish that if an individual did not receive timely notice of a triggering event described in paragraph (b)(2) or (3) of § 147.104, and otherwise was reasonably unaware that such a triggering event occurred, an issuer of non-grandfathered

²⁰ These comments were addressed in the January 19, 2021 final 2022 Payment Notice. *See* 86 FR 6138.

coverage in the individual market, whether inside or outside an Exchange, must assign the date the individual knew, or reasonably should have known, of the occurrence of the triggering event as the date of the triggering event for a special enrollment period. Consistent with §§ 147.104(b)(5) and 155.420(b), the proposed provision would allow the individual or dependent to choose the earliest effective date that would have been available if he or she had received timely notice of the triggering event or another effective date that would otherwise be available pursuant to § 155.420(b). We solicited comments on this approach. We noted that this provision would not apply for special enrollment periods in the group market, and sought comment on whether we should exclude the reference to the triggering events in § 147.104(b)(3) in the amended § 147.104(b)(4)(ii) to retain alignment of the individual and group market special enrollment periods required under § 147.104(b)(3).

We received public comments on the proposed amendments to § 147.104. Comments related to the proposal in § 155.420(c)(5) regarding when an individual does not receive timely notice of a triggering event and otherwise was reasonably unaware that a triggering event occurred are summarized and addressed in the preamble to § 155.420. The following is a summary of and our response to the comments we received related to the proposal to clarify that paragraph (b)(2)(ii) does not apply to references in § 155.420(d)(4) (relating to errors of the Exchange).

Comment: A commenter generally supported clarifying that the special enrollment period for an error of the Exchange does not extend to errors of the applicable state authority when applied market-wide in the individual market.

Response: We appreciate this comment, and we are finalizing the amendment as proposed.

B. Part 150—CMS Enforcement in Group and Individual Markets

1. Technical Corrections

Part 150 sets forth our enforcement processes for all the requirements of title XXVII of the PHS Act with respect to health insurance issuers and nonfederal governmental group health plans. We proposed to make technical corrections to multiple sections of part 150. Specifically, we proposed to remove all references to "HIPAA" and replacing them with "PHS Act" to clarify that the part 150 processes are

used for enforcing not only the requirements emanating from HIPAA, but also the ACA and other legislation enacted subsequent to HIPAA. These proposed wording changes were made in the February 27, 2013 Federal Register final rule entitled "Patient Protection and Affordable Care Act; Health Insurance Market Rules; Rate Review" (78 FR 13406). However, because of an oversight, some references were not updated at that time. In the proposed rule, we proposed this change to the definition of "Complaint" in § 150.103; the introductory text to § 150.303(a), as well as to §§ 150.205(e)(2); 150.213(b); 150.305(a)(1), (a)(2), (b)(1) and (c)(1); 150.311(g) and 150.313(b).

We received one comment that acknowledged these technical corrections but made no other statement about them, and we are finalizing the clarifying amendments as proposed.

2. Administrative Hearings

Additionally, we proposed certain procedural changes to part 150 sections regarding administrative hearings. The proposed changes are intended to align with the Departmental Appeals Board's (DAB's) current practices for administrative hearings to appeal CMPs. Specifically, we proposed changes to remove requirements to file submissions in triplicate and instead require electronic filing. This change is reflected in the proposed amendments to the definition of "Filing date" in § 150.401, to the introductory text in § 150.427(a), and to the service of submission requirements captured in § 150.427(b). We also proposed amendments to several provisions in part 150 to allow for the option of video conferencing as a form of administrative hearing in part 150 in addition to the forms already allowed. To capture this flexibility, we proposed amendments to the definition of "Hearing" in § 150.401 and to the requirements outlined in § 150.419(a) related to the forms for the hearing, § 150.441(e) related to prehearing conferences, and § 150.447(a) related to the record of the hearing. Finally, we proposed to update § 150.431 to allow the Administrative Law Judge (ALJ) to communicate the next steps for a hearing in either the acknowledgement of a request for hearing or on a later date. We proposed parallel amendments to the administrative hearings requirements under subpart J of part 156.

We received a small number of public comments on the proposed revisions to the administrative hearing requirements captured in part 150—CMS Enforcement in Group and Individual Markets and subpart J—Administrative Review of QHP Issuer Sanctions (§§ 156.901, 156.927, 156.931, 156.947). The following is a summary of the comments we received and our responses.

Comment: All commenters supported the availability of electronic filing for administrative appeals. However, two commenters opposed the elimination of the option to submit paper files. Those commenters specifically noted that consumers might not be comfortable with technology or have access to electronic means to file administrative appeals.

Response: We appreciate the commenters' concerns about eliminating paper filing as an option. However, the administrative appeals procedures in part 150 apply to plans and issuers; they are separate and apart from consumer appeals processes. ²¹ In addition, the proposed changes were intended to update the administrative hearing regulations in order to align with the DAB's current practices and did not make changes to existing practices.

The DAB's Civil Remedies Division, which handles the administrative hearings on CMPs under part 150 and subpart J of part 156, fully transitioned from paper to electronic filing to increase administrative efficiency and provide greater access and convenience to parties. However, a party may request a written waiver from the requirement of using DAB E-File. See Civil Remedies Division Procedures § 6, available at https://www.hhs.gov/about/agencies/ dab/different-appeals-at-dab/appealsto-alj/procedures/filing-and-service-ofwritten-material. If a waiver is granted, the party may file documents by U.S. mail or an express delivery service. Id.

Therefore, because the changes were intended to reflect the DAB's current practices that incorporate a written waiver process, and because these changes do not affect the consumer appeals processes, we are finalizing the revisions as proposed.

Comment: All commenters supported allowing video conferencing as a form of hearing. One commenter also noted that the system should include third party interpreters, whether foreign language or sign language.

Response: We appreciate the commenter's accessibility concerns regarding the video conferencing system. While it is not specifically noted in the administrative hearing regulations in part 150 and subpart J of part 156 language, the DAB complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age,

²¹ See, for example, 45 CFR 155.355.

disability, or sex. The DAB provides free aids and services to people with disabilities, including sign language interpreters, and provides free language services to people whose primary language is not English, including qualified interpreters. Instructions for requesting these services are available here: https://www.hhs.gov/about/agencies/dab/about-dab/nondiscrimination-notice/index.html. The DAB's Civil Remedies Division also provides a written nondiscrimination notice with similar instructions to individual parties in every case.

Because DAB's current system already allows for these means of access and these changes align our regulations with the DAB's current practices, we are finalizing the revisions as proposed.

Comment: Two commenters requested that HHS adopt specific timeframes for the ALJ to communicate next steps for an administrative hearing in order for consumers to better prepare for the hearing and to avoid delays in the process. The regulation, as proposed, allows the ALJ to communicate next steps either in the acknowledgement of a request for a hearing or on a later date.

Response: We understand commenters' concerns that the lack of a specified time period for response from the ALJ may allow for some uncertainty related to the timing for the proceedings. However, as previously noted, the administrative appeals procedures in part 150 and subpart J of part 156 apply to plans and issuers; they are separate and apart from consumer appeals processes. Further, the proposed changes were intended to update the regulations in order to reflect the DAB's current practices and did not make changes to existing practices for administrative appeals by plans and issuers. Therefore, we are finalizing the revisions as proposed.

C. Part 153—Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment

Subparts A, B, D, G, and H of part 153, provide standards for administering the risk adjustment program. The risk adjustment program is a permanent program created by section 1343 of the ACA that transfers funds from lower-than-average risk, risk adjustment covered plans to higher-than-average risk, risk adjustment covered plans in the individual and small group markets (including merged markets), inside and outside the Exchanges.²² In accordance with § 153.310(a), a state that is approved or conditionally approved by the Secretary

to operate an Exchange may establish a risk adjustment program, or have HHS do so on its behalf.²³ We did not receive any requests from states to operate risk adjustment for the 2022 benefit year; therefore, HHS will operate risk adjustment in every state and the District of Columbia for the 2022 benefit year.

We proposed changes to our approach for identifying the 3 benefit years of enrollee-level EDGE data that would be used for purposes of the annual recalibration of the HHS risk adjustment models. We also proposed modeling updates to improve the models' predictive power for certain subgroups of enrollees, as well as proposed changes to the enrollment duration factors for the adult models, and we proposed to continue a pricing adjustment related to Hepatitis C drugs. We proposed to allow states to submit multi-year requests for reductions to transfer calculations under the state payment transfer formula and we outlined the 2022 benefit year reduction requests submitted by Alabama. Additionally, we proposed to clarify risk adjustment reporting requirements for issuers that choose to offer premium credits, if permitted by HHS for future benefit years, and to codify a materiality threshold for EDGE discrepancies. We proposed the risk adjustment user fee for the 2022 benefit year and to codify in regulation the previously established exemptions from HHS-RADV requirements for issuers with only small group market carryover coverage in the benefit year being audited and for sole issuers in a state market risk pool during the benefit year being audited. We also proposed to revise the schedule for the collection of HHS-RADV charges and disbursement of payments such that these charges and disbursements would occur in the same calendar year in which HHS-RADV results are released. Finally, we proposed to shorten the discrepancy reporting windows during HHS-RADV, clarify and expand the conflict of interest standards applicable to initial validation audit (IVA) entities, and update the risk adjustment regulations to more clearly reflect the previously established limitations on the ability to dispute or appeal SVA findings and clarify the timeframe for HHS-RADV appeals.

1. HHS Risk Adjustment (§ 153.320)

The HHS risk adjustment models predict plan liability for an average enrollee based on that person's age, sex, and diagnoses (also referred to as hierarchical condition categories

The enrollment-weighted average risk score of all enrollees in a particular risk adjustment covered plan (also referred to as the plan liability risk score) within a geographic rating area is one of the inputs into the risk adjustment state payment transfer formula, which determines the state transfer payment or charge that an issuer will receive or be required to pay for that plan for the applicable state market risk pool. Thus, the HHS risk adjustment models predict average group costs to account for risk across plans, in keeping with the Actuarial Standards Board's Actuarial Standards of Practice for risk classification.

a. Updates to Data Used for Risk Adjustment Model Recalibration

Consistent with the approach outlined in the 2020 Payment Notice to no longer rely upon MarketScan® data 25 for recalibrating the risk adjustment models, we proposed to continue to recalibrate the risk adjustment models for the 2022 benefit year using only enrollee-level EDGE data. However, rather than using 2017, 2018 and 2019 enrollee-level EDGE data, we proposed to use the 2016, 2017, and 2018 enrollee-level EDGE data (the same years' data used to recalibrate the 2021 risk adjustment models) to recalibrate the risk adjustment models for the 2022 benefit year. We also proposed to continue to use blended, or averaged, coefficients from the 3 years of separately solved models for the 2022

⁽HCCs)), producing a risk score. The HHS risk adjustment methodology utilizes separate models for adults, children, and infants to account for clinical and cost differences in each age group. In the adult and child models, the relative risk assigned to an individual's age, sex, and diagnoses are added together to produce an individual risk score. Additionally, to calculate enrollee risk scores in the adult models, we added enrollment duration factors beginning with the 2017 benefit year, and prescription drug categories (RXCs) beginning with the 2018 benefit year.²⁴ Infant risk scores are determined by inclusion in one of 25 mutually exclusive groups, based on the infant's maturity and the severity of diagnoses. If applicable, the risk score for adults, children, or infants is multiplied by a CSR adjustment that accounts for differences in induced demand at various levels of cost sharing.

²⁴ For the 2018 benefit year, there were 12 RXCs, but starting with the 2019 benefit year, the two severity-only RXCs were removed from the adult risk adjustment models. See, for example, 83 FR 16941.

²⁵ 84 FR 17463 through 17466.

²³ Also see 42 U.S.C. 18041(c)(1).

benefit year model recalibration. We are finalizing these policies as proposed.

Previously, we used the three most recent years of MarketScan® data available to recalibrate the 2016, 2017, and 2018 benefit year risk adjustment models. Then, starting with the 2019 benefit year, we began transitioning from using the MarketScan® data to using the enrollee-level EDGE data to recalibrate the risk adjustment models. The 2021 benefit year was the first year that we recalibrated the risk adjustment models using 3 years of enrollee-level EDGE data.²⁶ Specifically, for the 2021 benefit year, we used the 2016, 2017, and 2018 benefit years of enrollee-level EDGE data to recalibrate the risk adjustment models. During prior recalibrations, we implemented an approach that used blended, or averaged, coefficients from 3 years of separately solved models to provide stability for the risk adjustment coefficients year-to-year, while reflecting the most recent years' claims experience available. In some prior years, this approach resulted in reliance on data that could not be incorporated into the coefficients until after the publication of the applicable benefit year's Payment Notice, because the associated data was not available in time to incorporate into the models in time for publication in the Payment Notice.²⁷ For example, due to the timing of the proposed 2021 Payment Notice, we were unable to incorporate the 2018 benefit year enrollee-level EDGE data into the proposed coefficients in the proposed 2021 Payment Notice, and instead included draft coefficients in the proposed rule reflecting only 2016 and 2017 benefit years' enrollee-level EDGE data.28 We were also unable to incorporate the 2018 benefit year enrollee-level EDGE data in the final coefficients in the 2021 Payment Notice; therefore, consistent with § 153.320(b)(1)(i), we released the final 2021 benefit year coefficients in guidance after publication of the 2021 Payment Notice.29 We followed a similar approach in other benefit years when we were unable to incorporate the most recent year of available data in the

applicable benefit year's Payment Notice.³⁰

Some commenters to the proposed 2021 Payment Notice expressed concern about when the final blended coefficients would be available, asking that final coefficients be made available earlier. Having the risk adjustment coefficients for the upcoming benefit year available earlier allows issuers more time to incorporate this information when pricing their plans for the upcoming benefit year. Commenters offered suggestions for ways HHS could provide final coefficients sooner. Stakeholders submitted similar comments in prior years when the final coefficients were released in guidance after publication of the applicable benefit year's Payment Notice.31 While in the initial years of risk adjustment and implementation of the 2014 federal market reforms (such as guaranteed availability and community rating), the markets underwent rapid changes in which the relative impact of using the most recent available data for recalibrating the risk adjustment models may have been more pronounced. However, in recent years, HHS has shifted from recalibrating the risk adjustment models using a blend of the three most recent years of large group market data to using data collected entirely from the risk adjustment population (enrollee-level EDGE data). This change has resulted in coefficients that better reflect underlying market conditions, and the markets have continued to mature and stabilize in the years following implementation of the risk adjustment program and other 2014 federal ACA reforms, thereby reducing the relative impact of the most recent data year on model coefficients. As a result, we continued to consider these comments and we proposed to change our approach for identifying the 3 most recent years of enrollee-level EDGE data that would be used to recalibrate the risk adjustment models. Previously, we used the 3 most recent years of data that were available in time for publication in the final rule or soon thereafter in guidance. However, beginning with the 2022 benefit year, we proposed to use the 3 most recent consecutive years of enrollee-level EDGE data that are available in time for incorporating the

data in the draft recalibrated coefficients published in the proposed rule and we proposed to not update the coefficients for additional years of data between the proposed and final rules if an additional vear of enrollee-level EDGE data became available for incorporation. The purpose of the proposed change was to respond to stakeholders' request to provide the proposed coefficients in the proposed rule and to release the final coefficients earlier, while continuing to use the 3 most recent consecutive years of enrollee-level EDGE data available to recalibrate the risk adjustment models. We explained that we believe this approach promotes stability and avoids the delays in publication of the coefficients while continuing to develop blended, or averaged, coefficients from the 3 years of separately solved models for model recalibration. As proposed, the approach also would continue to use actual data from issuers' individual and small group (or merged) market populations, as well as maintain year-toyear stability in risk scores as the recalibration would continue to use at least 2 years of enrollee-level EDGE data that were used in the previous year's models.³²

For these reasons, we proposed to use 2016, 2017, and 2018 benefit years enrollee-level EDGE data for the 2022 benefit year model recalibration. We sought comment on our proposal to determine coefficients for the 2022 benefit year based on a blend of separately solved coefficients from the 2016, 2017, and 2018 benefit years enrollee-level EDGE data and our proposed approach to identify the 3 most recent years of data available for the annual recalibration of the risk adjustment models moving forward. Additionally, we sought comment on whether we should instead maintain the approach that would use the 2017, 2018, and 2019 benefit years' data to recalibrate the risk adjustment models for the 2022 benefit year.

We also noted that the coefficients could change if the proposed recalibration policies, or other proposed modeling parameters, were not finalized or were modified in response to comments. In addition, we explained that, consistent with § 153.320(b)(1)(i), if we were unable to finalize the final coefficients in time for the final rule, we would publish the final coefficients for the 2022 benefit year in guidance soon after the publication of the final rule.

 $^{^{26}\,85}$ FR 29173 through 29175.

²⁷ See, for example, the 2018 Payment Notice final rule, 81 FR 94058; and the 2021 Payment Notice final rule, 85 FR 29173 through 29175.

 $^{^{28}\,\}mathrm{See}$ 85 FR 7097 through 7098 and 7104 through 7112.

²⁹ See 85 FR 29173 through 29175. Also see https://www.cms.gov/CCIIO/Resources/Regulationsand-Guidance/Downloads/Final-2021-Benefit-Year-Final-HHS-Risk-Adjustment-Model-Coefficients.pdf. https://www.cms.gov/CCIIO/Resources/Regulationsand-Guidance/Downloads/Final-2021-Benefit-Year-Final-HHS-Risk-Adjustment-Model-Coefficients.pdf.

³⁰ See, for example, the 2018 Payment Notice rule, 81 FR 94084. Also see https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/2018-Benefit-Year-Final-HHS-Risk-Adjustment-Model-Coefficients.pdf. https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/2018-Benefit-Year-Final-HHS-Risk-Adjustment-Model-Coefficients.pdf.

³¹ See, for example, 81 FR 94084 through 94085.

³² As detailed earlier, the 2022 benefit year recalibration would rely on the same 3 years of enrollee-level EDGE data that were used in the 2021 benefit year. For the 2023 benefit year and beyond, the recalibration would rely on 2 years of the enrollee-level data that were used in the prior year.

We received public comments on the proposed updates to data used for risk adjustment model recalibration and the proposed 2022 benefit year model recalibration approach. The following is a summary of these comments and our responses.

Comment: Many commenters supported the inclusion of the actual coefficients that would apply to risk adjustment models for that benefit year in the applicable benefit year's payment notice. Some commenters supported the proposal to use the 3 most recent consecutive years of enrollee-level EDGE data that are available in time for incorporating in the proposed recalibrated coefficients published in the proposed rule and to not update the coefficients for additional years of data between the proposed and final rules if an additional year of enrollee-level EDGE data becomes available for incorporation. Some of these commenters stated that providing the recalibrated coefficients earlier in the process will promote stability, better meet the goals of the risk adjustment program, and more closely align with issuer pricing cycles for individual and small group health insurance coverage.

Other commenters did not support the proposed approach and recommended instead to maintain the approach used in previous years, which would lead to the use of the 2017, 2018, and 2019 benefit years enrollee-level EDGE data for model recalibration for the 2022 benefit year. These commenters stated that incorporating newer data was more important than having the model coefficients earlier, with several commenters expressing concern that the proposed approach would rely on older data that would not include the most up-to-date experience and would not accurately reflect the reality and actuarial risk of the applicable benefit

One commenter that opposed the proposed approach stated that because issuers are required to submit all claims information to their respective EDGE servers by April 30th following the end of a benefit year, there should be enough time to include the most recent year's enrollee-level EDGE data in the applicable benefit year's proposed payment notice. The commenter expressed the view that if the final coefficients are known by the end of March, issuers can properly incorporate risk adjustment coefficients for ratesetting for the following year. However, another commenter stated that they preferred having the final coefficients sooner, by the end of January, and expressed support for the proposed approach if the final coefficients

incorporating the most recent year of data that becomes available are not expected to be ready within that timeframe.

Response: We are finalizing the proposals to use the 3 most recent consecutive years of enrollee-level EDGE data that are available in time for incorporating the data in the recalibrated coefficients published in the proposed rule and that we will not update the coefficients for additional years of data between the proposed and final rules if an additional year of enrollee-level EDGE data becomes available. We agree with commenters that this approach promotes stability and avoids the delays in publication of the coefficients while continuing to develop blended, or averaged, coefficients from the 3 years of separately solved models for model recalibration using actual data from issuers' individual and small group (or merged) market populations.

Additionally, we clarify that while we may collect the most recent plan year's EDGE data prior to the publication of the proposed rule, the data are often not available in time for incorporation into the proposed coefficients until much later. This is because the process to prepare enrollee-level EDGE data for incorporation into risk adjustment model recalibration is rigorous and requires time for analysis and data quality checks. Therefore, we believe utilizing the 3 most recent consecutive years of enrollee-level EDGE data that are available in time for inclusion in the coefficients in the proposed rule promotes stability while ensuring data quality and avoids the delays in publication of the coefficients that stakeholders have continued to raise concerns about in comments on the annual payment notices. This policy will allow HHS to provide proposed coefficients in the proposed rule that reflects the same underlying data as will be utilized for the final rule. This approach will minimize changes between the proposed and final coefficients that result from differences in data years, particularly in cases where the risk adjustment models and any accompanying proposed updates are finalized without changes. As noted earlier, in the initial years of risk adjustment and implementation of the 2014 federal market reforms, the markets underwent rapid changes in which the relative impact of using the most recent data for recalibrating the risk adjustment models may have been more pronounced. However, in recent vears, HHS has shifted from recalibrating the risk adjustment models using a blend of the three most recent

years of large group market data to using data collected entirely from the risk adjustment population (enrollee-level EDGE data). This change has resulted in coefficients that better reflect underlying market conditions, and the markets have continued to mature and stabilize, thereby reducing the relative impact of the most recent data year on model coefficients.

This policy will also allow us to continue to use the 3 most recent consecutive years of enrollee-level EDGE data available to recalibrate the risk adjustment models. It also continues to use actual data from issuers' individual and small group (or merged) market populations and maintains year-to-year stability in risk scores as the recalibration would continue to use at least 2 years of enrollee-level EDGE data that were used in the previous year's models. Finally, since this approach could allow us to finalize the coefficients earlier, it could allow issuers more time to incorporate this information when pricing their plans for the upcoming benefit year.

The proposed coefficients that were published in the proposed rule reflected the other proposed risk adjustment model specification changes (that is, inclusion of a two-stage model specification in the adult and child models; addition of severity and transplant indicators interacted with HCC counts factors in the adult and child models; modification to the enrollment duration factors in the adult models; and removal of the current severity indicator and enrollment duration factors in the adult models). However, based on our decision to not finalize those proposed model specification changes at this time as described below, the proposed coefficients outlined in the proposed rule are not being finalized. Instead, as discussed in more detail below, we will continue to apply the current risk adjustment model specifications (that is, the enrollment duration factors for the adult models and the severity illness indicators in the adult models that were finalized in the 2021 Payment Notice will continue to apply for the 2022 benefit year, with trending adjustments made to project the data used to develop the factors forward to reflect the 2022 benefit year). The final coefficients outlined below reflect the use of the 2016, 2017, and 2018 benefit years enrollee-level EDGE data to develop blended, or averaged, coefficients from the 3 years of separately solved models, as proposed, and the maintenance of the current adult model severity indicators and enrollment duration factors, with trending adjustments made to reflect the 2022 benefit year.33 In response to comments expressing concern about the use of older years of data, we note that, similar to previous years, we used 3 years of blended data to develop the 2022 risk adjustment models with certain adjustments to that data, such as trending the data to reflect the applicable benefit year.34 These adjustments are necessary because recalibration efforts have always used data from prior benefit years to project a future benefit year. As such, even if we adopted the alternative approach suggested by some commenters and used the 2017, 2018 and 2019 data for the 2022 benefit year recalibration, the recalibration data would still need to be trended forward to project for the applicable benefit year. We believe this approach of incorporating adjustments to the enrollee-level EDGE data to project the coefficients for the applicable benefit year is appropriate and consistent with the use of prior benefit years data for model recalibration, and strikes the appropriate balance between the policy desire to provide the coefficients earlier in the pricing cycle for the upcoming plan year and the concerns about recalibration data not reflecting the most up-to-date experience. After our continued consideration of stakeholder requests for earlier release of the risk adjustment coefficients, along with the comments on the proposed 2022 Payment Notice, we are finalizing the proposals to use the 3 most recent consecutive years of enrollee-level EDGE data available in time for incorporating the data in the recalibrated coefficients published in the proposed rule and that we will not update the coefficients for additional vears of data between the proposed and final rules if an additional year of enrollee-level EDGE data becomes available. The final coefficients outlined below for the 2022 benefit year reflect the use of the 2016, 2017, and 2018 benefit years enrollee-level EDGE data for recalibration purposes.³⁵

Comment: One commenter sought clarification on the reasoning and implications for using the 2016, 2017, and 2018 enrollee-level EDGE data.

Response: We proposed changes to how we identify the 3 most recent consecutive years of enrollee-level EDGE data for the annual recalibration of the HHS risk adjustment models to respond to stakeholders' request to provide the coefficients earlier. This approach allows HHS to avoid delays in publication of the coefficients, which will allow issuers more time to incorporate this information when pricing their plans for the upcoming benefit years. While this approach will utilize a set of data that is one year older than what we have used in previous years, we will continue to project the coefficients to reflect estimated costs for the applicable benefit year. We believe that this approach will promote stability while ensuring data quality and avoid the delays in publication of the coefficients. It also continues to use actual data from issuers' individual and small group (or merged) market populations and maintains year-to-year stability in risk scores as the recalibration would continue to use at least 2 years of enrollee-level EDGE data that were used in the previous year's models. Therefore, we are finalizing the use of the 3 most recent consecutive years of enrollee-level EDGE data that is available to HHS in time for incorporation in the proposed coefficients in the annual proposed payment notice.

Comment: One commenter noted that the stated advantages for publishing final coefficients earlier has similarly applied in prior years as well, and HHS could always publish the final Payment Notice earlier. This commenter also stated that the changed approach in the proposed rule disrupts issuers' settled expectations, namely, that issuers had assumed a continuation of past practice, through which the proposed rule's coefficients are updated in the final rule to include new data.

Response: As stated in the proposed rule, we proposed changes to our approach to identify the 3 most recent consecutive years of enrollee-level EDGE data that would be used for the annual recalibration of the risk adjustment models in response to stakeholder feedback. HHS has continued to receive numerous comments from stakeholders that expressed concerns about the timing for release of the model coefficients and asked that final coefficients be made available earlier. The approach we used in previous benefit years sometimes resulted in delays in publication of the

final coefficients until after the publication of the applicable benefit year's Payment Notice, ³⁶ because the associated data was not available in time to incorporate into the models in time for publication in the Payment Notice

We considered the potential disruption to issuers' settled expectations and we explicitly sought comments from stakeholders on whether to finalize the proposed approach, or whether we should instead maintain the approach of using the 2017, 2018, and 2019 benefit years' data to recalibrate the risk adjustment models for the 2022 benefit year. As part of our analysis, we considered that it is appropriate for HHS to consider changes to program parameters through noticeand-comment rulemaking, including the proposed changes to the approach for the annual model recalibration. We further note that even if we were to maintain the approach suggested by commenters to utilize the 2017, 2018, and 2019 benefit years, changes in the underlying data would attenuate the relative impact of the most recent benefit year data on risk adjustment coefficients. This is because the coefficients also incorporate changes to the risk adjustment methodology for the applicable benefit year, updated plan design parameters, and certain other adjustments to the data, such as trending the data to reflect the applicable benefit year. Finally, as noted above, in the initial years of risk adjustment and implementation of the 2014 federal market reforms, the markets underwent rapid changes, however, in recent years the markets have continued to mature and stabilize. We believe the approach finalized in this rule will provide stability and easier price prediction for issuers for the 2022 benefit year and beyond. It is an appropriate and reasonable response to comments submitted by stakeholders over the years asking HHS to reevaluate these issues and find a way to release the coefficients earlier to align with issuer pricing cycles.

Comment: One commenter who supported the proposed approach noted that there may be circumstances that result in changes to the risk adjustment models between the date the proposed rule is published and the date the final rule is published, and recommended that if HHS makes any final

³³ As detailed later in the preamble, the one exception relates to RXC 09, which involved the use of only 2016 and 2017 enrollee-level data to develop the applicable 2022 benefit year coefficients and interaction terms.

³⁴ We previously discussed trending and standardized benefit design parameters in the risk adjustment models in the "March 31, 2016, HHS-Operated Risk Adjustment Methodology Meeting Discussion Paper," March 24, 2016, available at https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/RA-March-31-White-Paper-032416.pdf.

³⁵ As detailed later in the preamble, the one exception relates to RXC 09, which involved the use of only 2016 and 2017 enrollee-level data to develop the applicable 2022 benefit year coefficients and interaction terms.

³⁶ For example, the final 2021 benefit year risk adjustment model coefficients were published in guidance after the final annual benefit and payment parameters. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2021-Benefit-Year-Final-HHS-Risk-Adjustment-Model-Coefficients.pdf.

modifications to the coefficients, they should be issued no later than the release of the final payment notice for the applicable benefit year.

Response: We agree that the coefficients could still change between the proposed and final rules. There are various reasons that this could happen, such as the proposed recalibration policies (or other proposed modeling parameters) not being finalized, or those parameters are modified in response to comments. As stated above and described more fully below, our decision not to finalize the proposed changes to the risk adjustment model specifications and other proposed model updates demonstrates how changes between the proposed and final rule can impact the risk adjustment coefficients.

While we intend to make the proposed and final coefficients available as early as possible, we did not propose to delete and are still retaining the flexibility under § 153.320(b)(1)(i) that permits HHS to release the final coefficients in guidance after publication of the final rule. Consistent with prior years where we have invoked this flexibility, we intend any subsequent publication of final coefficients would occur either in the final rule or in guidance published soon after the publication of the final rule.

Comment: Several commenters recommended that we consider whether utilizing the 2020 benefit year enrolleelevel EDGE data for future years' risk adjustment model calibration would be appropriate in light of the COVID–19 pandemic.

Response: We did not propose to use 2020 benefit year enrollee-level EDGE data as part of the annual recalibration of the risk adjustment models for the 2022 benefit year. However, we understand commenters' questions about the 2020 benefit year enrolleelevel EDGE data and its use for recalibration of future benefit years' risk adjustment models. We intend to carefully review the 2020 benefit year enrollee-level EDGE data as it becomes available to assess the potential impact of the COVID-19 pandemic and consider whether it should be used for recalibration of the HHS risk adjustment models in future benefit years. Additionally, we note that our decision to use the 2016, 2017, and 2018 benefit years data for the 2022 benefit year model recalibration provides an additional year to evaluate the 2020 benefit year enrollee-level EDGE data and assess the implications for using 2020 benefit year enrollee-level EDGE data for risk adjustment model

recalibration.³⁷ If necessary, we will propose any needed changes related to risk adjustment model recalibration through rulemaking published in advance of the applicable benefit year.

After consideration of the comments on these proposals, we are finalizing the approach to use the 3 most recent consecutive years of enrollee-level EDGE data that are available in time for incorporating the data in the recalibrated coefficients published in the proposed rule and to not update the coefficients for additional years of data between the proposed and final rules if an additional year of enrollee-level EDGE data becomes available. As a result, we will use 2016, 2017, and 2018 enrollee-level EDGE data to recalibrate the 2022 risk adjustment models.³⁸

b. Risk Adjustment Model Updates

Beginning with the 2022 benefit year, we proposed several updates to the risk adjustment models. These proposed updates include changes to the specifications for the adult and child models and updates to the enrollment duration factors in the adult models to improve the models' predictions. We also proposed to continue the market pricing adjustment for Hepatitis C drugs that has been in place since the 2020 benefit year.

We are not finalizing the proposed model specification changes and enrollment duration factor updates or the accompanying removal of the current severity illness indicators and enrollment duration factors in the adult models at this time. Therefore, the current adult model severity illness indicators and enrollment duration factors, with trending adjustments made to reflect the 2022 benefit year, will apply for the 2022 benefit year without the proposed specification changes. We are finalizing and will continue the market pricing adjustment for the Hepatitis C drugs that has been in place since the 2020 benefit year.

(1) Changes to the Model Specifications

Beginning with the 2022 benefit year, we proposed to modify the adult and child models specifications to improve prediction for enrollees at both the low and highest ends of expected expenditures. The current HHS–HCC models are estimated by a weighted

least squares regression.³⁹ The dependent variable is annualized simulated plan liability expenditures, and the weight is the person-specific sample eligibility fraction. The effective outcome is that the models predict per member per month (PMPM) expenditures.

As described in the 2021 Payment Notice, the current HHS-HCC models, which are linear models, underpredict plan liability for enrollees without HCCs (enrollees with low expected expenditures) and underpredict plan liability for enrollees with the highest HCC counts (enrollees with high expected expenditures).40 In the 2021 Payment Notice, we described options that we were considering to address these issues, such as adding a non-linear term or HCC counts factors to the risk adjustment models.41 For the non-linear model option, we considered adding a coefficient-weighted sum of payment HCCs raised to a power that could be interpreted as a measure of overall disease burden. For the HCC counts model option, we considered adding eight indicator variables corresponding to 1 to 8-or-more payment HCCs, similar to the CMS-HCC risk adjustment counts models used for Medicare Advantage.42 We have further evaluated the performance of these options, their potential for improved prediction, and considered other alternatives to improve the HHS risk adjustment models' prediction.

Our initial analyses showed that the non-linear and HCC counts models would yield considerable gains in predictive accuracy in the adult models across several subgroups when compared to the current linear models.43 We tested both the HCC counts and non-linear models' impact on the adult silver risk adjustment models and found that the enrollees in the lowest cost deciles had better predictive ratios under either the HCC counts or non-linear model specification than under the current linear model specification. However, both models had shortcomings that prompted us to

³⁷Consistent with the approach finalized in this rulemaking, the earliest the 2020 enrollee-level EDGE data would be used for model recalibration is the 2024 benefit year.

³⁸ As detailed later in the preamble, the one exception relates to RXC 09, which involved the use of only 2016 and 2017 enrollee-level data to develop the applicable 2022 benefit year coefficients and interaction terms.

³⁹ See, for example, 78 FR 15420 and Section 3.7 of the "March 31, 2016 HHS-Operated Risk Adjustment Methodology Meeting Discussion Paper," March 24, 2016. Available at https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/RA-March-31-White-Paper-032416.pdf.

⁴⁰ 85 FR 29188 and 29189.

⁴¹ Ibid.

^{42 &}quot;Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for the Medicare Advantage (MA) CMS—HCC Risk Adjustment Model," December 20, 2018. Available at https:// www.cms.gov/Medicare/Health-Plans/ MedicareAdvtgSpecRateStats/Downloads/ Advance2020Part1.pdf.

⁴³ 85 FR 7101 through 7104.

consider alternate model options to improve the predictive power of the current HHS risk adjustment models. For the HCC counts model, we noted that we were concerned that the presence of counts across all HCCs may promote gaming in coding practices. We explored ways to assure modeling convergence across all metals and data years, and found that the non-linear models did not consistently converge in all testing scenarios, and that convergence could not reliably be assured without constraining model factors and revising those techniques with each metal and data year model run. Therefore, we continued to explore additional types of model specifications refinements that could balance the goals of improving the models' prediction with mitigating modeling complexity and gaming concerns. Specifically, as described later in this section, we explored a two-stage specification with additional weighting in the second stage based on the inverse capped prediction from the first stage ("two-stage specification"), a specification with HCC counts included for a small number of severity and transplant HCCs ("interacted HCC counts factors"), and an approach combining the two-stage specification with the interacted HCC counts factors.

For the two-stage specification, we explored calibrating the adult and child models in two stages: In the first-stage estimation, the model coefficients would be estimated using the current model specifications; and in the second stage, we would re-estimate the model weighted by the reciprocal of the predicted values of relative expenditures from the first step estimation with the same model specification.44 The first stage of the weighted estimation method involved a linear regression (weighted by the person-specific eligibility fraction of the number of months enrolled divided by 12) of simulated plan liability on agesex factors, payment HCC factors, the enrollment duration factors,45 and RXCs for the adult models. For the child

models, the first stage of the weighted estimation method involved a linear regression of simulated plan liability on age-sex factors and payment HCC factors. The second stage involved using the reciprocal of first-stage predictions as weights for a second linear regression.46 To stabilize the weights for the second stage estimation, we imposed lower and upper bound caps on the first-stage predictions at the 2.5th and 97.5th percentiles in the adult models, and the 2.5th and 99.5th percentiles in the child models. We tested various caps for the weights based on the distribution of costs, and found these lower and upper bound caps achieved better prediction on average. This approach has the material effect of weighting the healthier enrollees, who represent a majority of enrollees in the individual and small group (including merged) markets but who are underpredicted by the current models, more heavily so that the statistical model predicts their expenditures more accurately. On the other hand, this approach systematically underweights, and therefore underpredicts, very expensive enrollees. However, the capped weighting approach would mitigate the potential to underpredict at the high end for expensive enrollees, as well as any possible low-end overprediction. In our consideration of this option, we tested various weights, including reciprocals of the square root of prediction, log of prediction, and residuals from first step estimation, but the reciprocal of the capped predictions resulted in better predictive ratios for low-cost enrollees compared to any of these alternative weighting functions.

We also explored how the addition of severity and transplant indicators interacted with HCC counts, wherein an indicator flagging the presence of at least one severity or transplant payment HCC is being interacted with counts of the enrollee's payment HCCs.⁴⁷ The goals for this approach were to: (1) Address the non-linearity in costs between enrollees with no or very low

costs and enrollees with high costs; (2) empirically incorporate the cost impact of multiple complex diseases; and (3) mitigate the gaming concerns with the HCC counts model. We tested different types of severity and transplant indicators interacted with HCC counts with the goal of improving prediction for enrollees with the highest costs and multiple HCCs to counter balance the reciprocal prediction weights that relatively underpredicted costs for these enrollees. For this approach, we assessed the HCCs for enrollees with extremely high costs, and HCCs that were being underpredicted in the current risk adjustment models. We found that many of the HCCs that were flagged as being under-predicted were those HCCs that indicated severe illness, such as the transplant HCCs, and other HCCs related to severity of disease: therefore, we considered dropping the current severity illness indicators in the adult models and replacing them with severity and transplant indicators interacted with HCC counts factors in the adult and child models. Table 3 in the proposed rule 48 listed the HCCs that were selected for the severity and transplant indicators for the adult and child models for purposes of exploring this option. The severity and transplant indicators were then interacted with HCC counts factors, which are described below.

The purpose of adding severity and transplant indicators interacted with HCC counts factors is to account for the fact that costs of certain HCCs rise significantly when they occur with multiple other HCCs. To mitigate the incentive to upcode multiple HCCs, we only increased incremental risk scores in the presence of at least one of the selected HCCs in the severity or transplant indicator groups in Table 3 in the proposed rule. That is, an adult or child enrollee would have to have at least one HCC in the "severity" or "transplant" indicator groups in Table 3 in the proposed rule to receive the interacted HCC counts coefficient toward their risk score.

Under this approach, when an adult or child enrollee has a severity indicator HCC in Table 3 in the proposed rule, the enrollee's risk score would include the sum of: (1) Severity HCC variable coefficient; ⁴⁹ and (2) applicable severity HCC counts variable coefficient. The HCC counts factors, which indicate the

⁴⁴This weighted approach is similar to the weighted least squares approach with the weight equal to the reciprocal of the estimated variance that is often used to correct for heteroskedasticity. However, in our proposed approach, we would use the reciprocal of predictions from the first step as weights to correct for underprediction of low-valued coefficients.

⁴⁵We proposed to remove and replace the enrollment duration factors in the adult models in the proposed rule, but we are not finalizing the proposed changes to the enrollment duration factors in this final rule and will apply the current enrollment duration factors of up to 11 months, with trending adjustments made to reflect the 2022 benefit year, in the adult models for the 2022 benefit year.

⁴⁶ Under the proposed two-stage specification and interacted HCC counts model described later in this section, we proposed to remove and replace the severity illness indicators in the adult risk adjustment models with the proposed interacted HCC counts factors in the adult and child models. However, we not are finalizing these proposed model specification changes in this final rule and will continue to apply the current severity illness indicators in the adult models for the 2022 benefit year.

⁴⁷ For HCCs in a group, the group is counted at most once. These groups of HCCs in the risk adjustment models are typically detailed in the Tables 6 and 7 of the HHS-Developed Risk Adjustment Model Algorithm "Do It Yourself (DIY)" Software.

⁴⁸ See 85 FR at 78593.

⁴⁹ This is in addition to the HCC coefficients for any other HCCs that the enrollee has, as well other risk adjustment factors that the enrollee has (such as demographic factors). If an enrollee has no severity HCCs the severity count interaction term coefficients are not applicable.

counts of all payment HCCs for an enrollee with at least one HCC, interacted with the severity indicator in Table 3 in the proposed rule, range from one, two, to 10+ payment HCCs (1, 2, . . . , 10+) for the adult models, and from one, two, to 5, then 6 or 7, and 8+ payment HCCs for the child models. To implement the severity indicator HCC counts factors and further explore this option, we removed the current severity illness indicators in the adult models, and added severity indicator interacted HCC counts variables for the adult and child models.

For the transplant-related HCCs within the severity indicator HCC counts in Table 3 in the proposed rule, we found separating out transplant HCCs into their own additional indicator to interact HCC counts factors improved prediction for these high-cost enrollees. Therefore, for the transplant HCCs, we created a separate transplant indicator to interact with payment HCC counts of 4, 5, 6, 7, or 8+ for the adult models, and a single indicator variable of payment HCC counts of 4+ for the child models. For example, an adult enrollee with a transplant HCC 34 "Liver Transplant Status/ Complications" in the transplant indicator group and three other payment HCCs received the following factors toward their risk score in the adult models: (1) The four coefficients for their individual HCCs (the three nontransplant HCCs and the HCC 34 transplant HCC coefficient), (2) severity interacted HCC counts of 4 coefficient, and (3) transplant interacted HCC counts of 4 coefficient.50 The child model operated similarly. For a child enrollee with a transplant HCC in the transplant indicator group and three other payment HCCs, the following was used to calculate the enrollee's risk score: (1) Coefficients for all four HCCs, (including the transplant HCC coefficient), (2) severity interacted HCC counts of 4 coefficient, and (3) transplant interacted HCC counts of 4 coefficient.

As an alternative, we explored interacting the HCC counts factors with each selected severity and transplant HCC, but found it was sufficient to interact the HCC counts factors with a variable indicating the presence of at least one of the selected HCCs in each group to improve prediction for enrollees with these HCCs. We also explored different combinations of HCC counts to identify the counts factors for both indicator groups in the adult and

child models that provided the best balance of reasonable sample sizes and relative cost differences between each counts factor. More specifically, in the adult models, we found that starting with 4+ HCCs for the transplant interacted factors improved predictions of enrollees at the very high end in terms of risk and cost and ending at 8+ HCCs instead of 10+ HCCs addressed the small sample sizes of enrollees with a transplant and 9 or more payment HCCs. For the child models, we found having one variable for 4+ payment HCCs provided more stable estimates as compared to separate variable for each payment HCC above that number, given the smaller sample sizes for children than those for adults.

Lastly, we tested combining these specifications into an alternative approach that incorporated both the two-stage specification and the severity and transplant indicators interacted HCC counts factors described above for the HHS adult and child models. We found this combined approach generally improved prediction for enrollees at both the low and highest ends of expected expenditures. Specifically, even though we found that the age-sex factors and some HCCs might have slightly worse predictive ratios under the proposed combined approach than the current linear models, we found that this combined approach improves predictive ratios in comparison to the current models in each decile of predicted plan liability. We also found that this combined approach improves R-squared in comparison to the current model and that even though the coefficients for the model factors that are most impacted by the combined approach (the age-sex factors and the severity and transplant HCCs) would be changing under the 2022 benefit year models compared to the 2021 benefit year models, the average enrollee's adult risk score in the recalibration sample in the silver metal level only increased slightly between 2021 benefit year models to 2022 benefit year models. Therefore, we proposed to modify the HHS risk adjustment model specifications for the adult and child models by combining a two-stage specification and adding interacted HCC counts factors beginning with the 2022 benefit year. For the two-stage specification, we proposed calibrating the adult and child models in two stages. The first stage of the weighted estimation method would involve a linear regression of simulated plan liability on age-sex factors and payment HCC factors for the adult and child models, with the addition of the

enrollment duration and RXCs factors for the adult models. The second stage would use the reciprocal of prediction as weights from the first step as a second stage linear regression. To stabilize the weights from the first stage predictions, we proposed lower and upper bound caps on the predictions at the 2.5th and 97.5th percentiles in the adult models, and the 2.5th and 99.5th percentiles in the child models. This two-stage specification would be combined with the severity and transplant indicators from the interacted HCC counts factors. For the severity indicator group, we proposed to add separate count factors for one to 10+ payment HCCs counts factors (1, 2, . . ., 10+) for the adult models and one to 5, 6 or 7, and 8+ payment HCCs (1, 2, . . . 5, 6 or 7, 8+) for the child models. The proposed HCCs that would flag the severity indicator are listed in Table 3 of the proposed rule.⁵¹ For the transplant HCCs, we proposed to incorporate variables for 4 to 8+ payment HCCs (4, 5, 6, 7, 8+) for the adult models and one variable for 4+ payment HCCs for the child models. All variables, including the severity and transplant indicators interacted in the interacted HCC counts factors, would be included in both stages of the regressions. We proposed to incorporate these model specification updates beginning with the 2022 benefit year HHS risk adjustment adult and child models. We also proposed to remove the current severity illness indicators in the adult models beginning with the 2022 benefit vear.

We sought comment on these proposals, including on the HCCs selected for flagging as severity and transplant indicators listed in Table 3 of the proposed rule such as whether we should include HCC 18 Pancreas Transplant in the transplant indicator group, and the alternatives described above. We also requested comment on whether we should pursue both the interacted HCC counts factors and the two-stage specification beginning with the 2022 benefit year (as proposed), if we should implement one of the two approaches beginning with the 2022 benefit year (and if so, which one), or if we should wait to implement the proposed changes that combines the proposed model specification updates until the 2023 benefit year.

We are not finalizing the risk adjustment model specification changes as proposed at this time, but will further consider potential changes that could increase the predictive power of the HHS risk adjustment models. We also

⁵⁰ This is in addition to other risk adjustment factors that the enrollee has (such as demographic factors)

⁵¹ See 85 FR at 78593.

are not finalizing the accompanying proposals to remove the current severity illness indicators in the adult models; those factors, as finalized in the 2021 Payment Notice, will continue to apply to the 2022 benefit year adult models with trending adjustments made to project the data used to develop the factors forward to reflect the 2022 benefit year.52

We received public comments on the proposed updates to the model specification changes. The following is a summary of these comments and our

responses.

Comment: Many commenters opposed the proposed risk adjustment model specification changes and wanted to know more about the specific impacts of the proposed risk adjustment model specification changes. Many of these commenters were concerned that HHS did not give stakeholders adequate information or time to assess the model specification changes, while some stated that the model specification changes were unexpected and not fully reviewed with stakeholders in advance of them being proposed for implementation. These commenters suggested that, consistent with recent efforts to update risk adjustment data validation, HHS should release a White Paper and conduct listening sessions to provide stakeholders with the opportunity to evaluate the impact of the changes and provide HHS with feedback in advance of pursuing such changes through rulemaking. Some commenters generally wanted additional analyses or more specificity about the model changes while others requested specific types of analyses.

Some commenters that opposed the proposed model specification changes were concerned the changes added complexity to the models and would hinder issuers' ability to price accurately, resulting in higher premiums. Other commenters recommended that HHS collect data to estimate the impact of the proposed model specification changes on risk adjustment transfers before finalizing them. Another commenter recommended evaluating model performance at the plan level instead of the enrollee level using the plan liability risk score predictive ratios because the transfer formula operates at the plan and rating level, wanting HHS to collect data

to do this type of analysis.

A few commenters were concerned that the proposed model specification changes would reduce the quality of coverage available to consumers and would threaten the market's ability to

support robust competition. One of these commenters recommended that we reconsider the goal of reducing under prediction for enrollees with low spending, because this commenter believed that plans that disproportionately attract sick enrollees tend to attract enrollees who are higherthan-average risk based on characteristics not captured in risk adjustment, and that therefore risk adjustment should underpay for low spending enrollees relative to payment for higher-risk enrollees.

However, other commenters supported our proposed model specifications changes. These commenters tended to support improving the predictive power of the risk adjustment models and were concerned about the potential for plans to lose money on enrollees with no HCCs under the current model specifications, discouraging issuers from enrolling healthier enrollees and resulting in excessive risk adjustment payments. One of these commenters reported engaging in their own analysis of the proposed model specification changes and found that they achieved HHS's goals of improving the models' prediction while mitigating modeling complexity and gaming concerns.

Response: After consideration of comments on these proposals, we are not finalizing the proposed model specifications changes at this time and will retain the existing severity illness indicators in the adult models. We intend to continue to consider potential changes that could increase the predictive power of the HHS risk adjustment models in future rulemaking for future benefit years. While we believe stakeholders had sufficient time and adequate information to evaluate these model specifications, as reflected in the detailed comments received on these proposals, we understand stakeholders' desire for additional analyses on these types of model specification changes prior to implementing them in the risk adjustment models. We also appreciate issuers' desire for additional time to prepare for these types of model specification changes and to consider how to price for these model specification changes. While we are limited in our ability to evaluate model performance at the plan level because the enrollee-level EDGE data does not include plan level information, to test the performance of the risk adjustment models for subgroups, we calculate the expenditure ratio of predicted to actual weighted mean plan liability expenditures by subgroup, also referred

as the predictive ratios. 53 Regardless, we agree that more time, and some additional analysis, would help stakeholders further review these changes, help issuers price more accurately, and prevent the introduction of inadvertent volatility in the market(s) as a result of new model specifications. It will also help inform whether refinements to these proposals or other options would be appropriate to meet the overall policy goal of improving the models' predictive power for the lowest cost and highest cost enrollees and developing a model that most accurately captures risk for those with and without HCCs. For these reasons, we are considering releasing a technical paper to provide further assessment of potential changes to the risk adjustment models and additional analysis of options to improve the prediction of the risk adjustment models. In addition, if we decide to pursue these changes, or other options, to improve the predictive power of the models for future benefit years, we would propose such updates through notice-and-comment

rulemaking.

Comment: Some commenters were concerned that the two-stage specification would over-fit the model or would worsen the fit along other dimensions. One of these commenters questioned the basis for the weighting function chosen in the two-stage specification noting that it appeared to be arbitrary and recommended that HHS consider using industry-standard methods to test modeling choices for overfitting and then publish the results of these tests when explaining modeling decisions. This commenter cautioned against an overemphasis on improving model performance in the absence of both a sound theoretical basis for changes and an independent data set to confirm an increase in accuracy. Another commenter recommended that HHS not finalize the proposed risk adjustment model specifications since the two-stage specification does not mitigate the under-prediction of health care costs for enrollees with the highest number of HCCs. One commenter was concerned that the proposed two-stage specification would not predict future

Response: We are not implementing the proposed model specifications at this time. However, in response to comments, we note that as part of our assessment of the proposed model specification changes we tested for

⁵² See the Severity Factors listed in Table 1.

⁵³ March 31, 2016, HHS-Operated Risk Adjustment Methodology Meeting. Discussion Paper. March 24, 2016. https://www.cms.gov/CCIIO/ Resources/Forms-Reports-and-Other-Resources/ Downloads/RA-March-31-White-Paper-032416.pdf.

overfitting of the models by running predictive ratios on the separate validation samples for both the child and adult models. While the sample sizes are smaller in the child models than the adult models, leading to greater fluctuations for the child models, we found that the predictive ratios in the separate validation samples showed no material difference relative to predictive ratios in the estimation sample. Thus, we did not find empirical concerns with respect to overfitting of the models with the proposed model specification changes.

As previously mentioned, we believe it is appropriate to continue to analyze the two-stage specification and interacted HCG counts factors and are considering releasing a technical paper to provide our further assessment of potential changes to the risk adjustment models that could include these model specification changes or other options. In addition, we would pursue adoption of any of these model specification changes, or other options, for future benefit years through notice-and-comment rulemaking.

Comment: Some commenters were concerned about the potential for small sample sizes for the interacted HCC counts model specification. These commenters tended to be concerned that the number of enrollees could drop significantly as the interacted HCC counts go up, which could lead to erratic interacted HCC counts factors coefficients, and had concerns that the proposed rule had some large changes between coefficients and coefficients going from negative to positive for a given count across metal levels. One commenter was concerned that the low sample sizes at higher HCC counts associated with larger coefficients could increase the models' volatility, making it more difficult for issuers to price coverage. Other commenters were concerned that the interacted HCC counts model specification could incentivize unwanted gaming in coding practices by issuers. One commenter that supported the adoption of the interacted HCC counts model specification was concerned that the interacted HCC count model change would encourage issuers to invest additional resources in diagnosis coding. Another commenter did not believe that using interacted HCC counts factors would create an opportunity for gaming, and did not understand how using a full HCC counts model specification would result in gaming opportunities either.

Response: As noted previously, after consideration of comments, we are not finalizing the proposed model

specification updates, including the interacted HCC counts factors, at this time. While we believe that the proposed rule provided stakeholders with adequate information to evaluate these model specifications, we recognize that stakeholders could benefit from further analysis and additional time to analyze the structure of the proposed interacted HCC counts factors. In response to the commenters expressing concerns about negative coefficients under the proposed interacted HCC counts factors, we note that when an enrollee has a severity indicator HCC, the enrollee's risk score would include the sum of: (1) Severity HCC variable coefficient; 54 and (2) applicable severity HCC counts variable coefficient. This means that even though many of the interacted HCC counts factors outlined in the proposed rule were negative coefficients, the net combined impact of the HCC coefficients and the interacted "severity" or "transplant" HCC counts coefficient, to the enrollee's risk score would be positive.55

In developing the proposed interacted HCC counts factors, we also considered sample sizes of the various interacted HCC counts factors. We analyzed multiple years of enrollee-level EDGE data and we chose the model specifications that grouped all of the HCC counts interacted with individual severity and transplant HCCs into two sets of aggregated factors to maximize sample size, reduce concerns of overfitting the model, and reduce the number of factors being added to the

models. The resulting sample size for the proposed interacted HCC counts factors were consistent with the sample size for individual HCCs in the risk adjustment models. Furthermore, by limiting the proposed interacted HCC counts factors to certain severity and transplant HCCs, we believe that the interacted HCC counts factors would restrict the scope for coding proliferation in accordance with the principles of risk adjustment.⁵⁶

As discussed in the 2021 Payment Notice, we considered using a counts model specification where all HCCs were subject to the counts model specifications, but, as stated in the proposed rule, we were concerned that the presence of counts across all HCCs may promote gaming in coding practices. This was our reasoning for investigating an interacted HCC counts model specification to find a way to get the benefits afforded by the HCC counts model while mitigating the potential for gaming. The proposed interacted HCC counts factors would have made changes primarily to the HCCs most associated with underprediction of high-cost cases in the model and would have only applied to less than two percent of the population thereby reducing the concern about additional coding incentives in comparison to a general HCC counts model.

We agree that stakeholders will benefit from additional time to analyze the proposed factors that we presented in the proposed rule to understand the incremental effects of the interacted HCC counts factors and consider the associated coding incentives. After consideration of comments received on these proposals, we are not finalizing the proposed model specification changes or the removal of the current severity illness indicator factors in the adult models at this time. However, we intend to continue to consider changes that can increase the predictive power of the HHS risk adjustment models in rulemaking for future benefit years and also intend to provide stakeholders with further information and additional analysis on potential model specifications changes.

Comment: One commenter believed that inclusion of the interacted HCC counts factors appears to be a discriminatory practice.

⁵⁴ This is in addition to the HCC coefficients for any other HCCs that the enrollee has, as well other risk adjustment factors that the enrollee has (such as demographic factors). If an enrollee has no severity HCCs the severity count interaction term coefficients would not be applicable.

⁵⁵ To further illustrate, we can consider a male enrollee age 63 in silver metal level who has diabetes but no other risk markers. Using the proposed coefficients in the proposed rule, his proposed model predicted cost would be: 0.343 (age-sex estimate) + 0.262 (diabetes HCC estimate) = 0.605.

If he develops sepsis, which is an interacted "severity" HCC, his predicted cost would be: 0.605 + 9.394 (sepsis HCC) + -5.824 (interacted severity HCC counts factor for 2 total HCCs estimate) = 4.175.

If this enrollee also develops heart failure, his predicted cost would further rises: 0.605 + 9.394 + 1.874 (heart failure HCC) + -4.526 (interacted severity HCC counts factor for 3 total HCCs) = 7.347. As can be seen in these illustrative examples, although the interacted "severity" HCC counts factors are negative, the interacted "severity" HCC counts factor rise with the enrollee's total number of HCCs, increasing the enrollee's total predicted cost as his number of HCC diagnoses increases. In fact, the increasing risk scores with each additional HCC is consistent with the current models and predictions are higher for enrollees with many HCCs under the interacted counts specification than under the current model specification.

⁵⁶ We have described our principles for risk adjustment in various documents, but a complete list of them is available in the March 31, 2016, HHS-Operated Risk Adjustment Methodology Meeting Discussion Paper. March 24, 2016. Pages 12–13, https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/RA-March-31-White-Paper-032416.pdf.

Response: We are not finalizing the policy at this time, but we disagree. The interacted HCC counts factors proposed to be added to the HHS risk adjustment models are not discriminatory. HHS takes very seriously our obligation to protect individuals from discrimination. Consistent with section 1343 of ACA, the HHS-operated risk adjustment program reduces the incentives for issuers to avoid higher-than-average risk enrollees, such as those with chronic conditions, by using charges collected from issuers that attract lower-thanaverage risk enrollees to provide payments to health insurance issuers that attract higher-than-average risk enrollees. The proposed interacted HCC counts factors would help predict enrollee risk better for certain subpopulations. Therefore, we do not believe the inclusion of the interacted HCC counts factors is a discriminatory practice and as stated above, the proposed inclusion of interacted HCC counts would reduce the underprediction of the highest cost cases and the under-prediction of the low-risk enrollees, thereby helping to mitigate the potential for adverse selection by improving the predictive power of the HHS risk adjustment models for these enrollees.

Comment: One commenter wanted HHS to consider using more metrics than R-squared statistics to assess the proposed model specification changes, such as mean absolute prediction error or predictive ratios for subsets of the population. Another commenter was concerned that the proposed revisions to incorporate interacted HCC counts factors and modify the enrollment duration factors alone would result in worse model performance among lowercost deciles even if they result in higher R-squared values overall. Another commenter wanted to ensure that HHS's modeling was taking into account the high-cost risk pool component of the HHS risk adjustment methodology.

Response: While we did assess Rsquared statistics for the performance of our proposed model specification changes, our primary metric to evaluate performance and the proposed changes was predictive ratios by subgroup. We found that the proposed interacted HCC counts and the proposed revised enrollment duration factors (discussed in the below section) improved the model performance for the low-end deciles even without the inclusion of the proposed two-stage specifications. We intend to continue to assess model performance in future benefit years, and we will also consider assessing the mean absolute prediction error along with predictive ratios and R-squared

statistics as we continue to assess potential model specification changes in the future. We also confirm that the annual recalibration of the HHS risk adjustment models, including both the development of final coefficients listed in this rule and the proposed coefficients reflecting the proposed model specification changes in the proposed rule, accounts for the costs covered by the high-cost risk pool component of the HHS risk adjustment methodology.^{57 58}

Comment: Some commenters focused on the proposed timeline for implementation of the proposed model specification changes. Some of these comments were opposed to implementing the model specification changes in 2022 and some supported delaying implementation to the 2023 benefit year (or beyond). One commenter wanted all model specification changes completed within one benefit year and then recommended limiting model changes in future benefit years to provide year-to-year stability. Another commenter supported applying the proposed model specification changes beginning with the 2022 benefit year risk adjustment models.

Response: As noted previously in this rule, after consideration of comments on these proposals, we are not finalizing the proposed model specifications at this time and are retaining the current severity illness indicator factors in the adult models. We agree that stakeholders would benefit from having additional analysis and time to consider these changes. Therefore, we intend to provide stakeholders with additional analysis and further information about potential model specification changes and will continue to consider changes that can increase the predictive power of the HHS risk adjustment models. Any such changes would be pursued through rulemaking for future benefit years. As part of our continued analysis of potential future changes, we intend to consider ways to balance the desire to adopt refinements to improve the predictive power of the models with the need to promote stability.

c. Changes to the Enrollment Duration Factors

In the proposed rule, we proposed changes to the enrollment duration factors in the adult risk adjustment models to improve the prediction for partial year enrollees with HCCs. After consideration of comments received, we are not finalizing the proposal to remove the current 11 enrollment duration factors of up to 11 months for all enrollees in the adult models, or the addition of new monthly enrollment duration factors of up to 6 months that would only apply for enrollees with payment HCCs in the adult models. For the 2022 benefit year, we will continue to apply the current 11 enrollment duration factors of up to 11 months for all enrollees in the adult models, with trending adjustments made to project the data used to develop the factors forward to reflect the 2022 benefit year. See Table 1. Similar to the other proposed model specification changes outlined elsewhere in this rule that we are not finalizing in this rule, we intend to continue to analyze potential changes to the enrollment duration factors to improve model prediction for partial year enrollees with HCCs.

As described in the proposed 2021 Payment Notice, we have been considering potential adjustments to the enrollment duration factors and previously analyzed the current factors using the 2016 and 2017 enrollee-level EDGE data.⁵⁹ We explored heterogeneity (variations) of costs for partial year enrollees in the presence of certain diagnosis codes, by market (individual or small group),60 and under various enrollment circumstances, such as enrollment beginning later in the year or ending before the end of the year. Our preliminary analysis of 2017 enrolleelevel EDGE data found that the current enrollment duration factors are driven by enrollees with HCCs. That is, partial vear enrollees with HCCs had higher PMPM expenditures on average as compared to full year enrollees with HCCs. On the other hand, partial year enrollees without HCCs were not significantly different in PMPM expenditures compared to full year enrollees without HCCs. In the 2021 Payment Notice, we also explained that our preliminary analysis found that, in comparison to the effect of the presence of HCCs on enrollment duration factors, enrollment timing (for example, enrollment at the beginning of the year compared to enrollment after open

⁵⁷ Beginning with the 2018 benefit year risk adjustment recalibration, we incorporated the high-cost risk pool parameters in our recalibration of the models by truncating 40 percent of costs above \$1 million in our dataset used to simulate plan liability. See, for example, 81 FR 94058 at 94082.

⁵⁸ See, for example, the proposed 2022 Payment Notice, 85 FR at 78586 (In announcing the proposed coefficients, noting that "(t)he adult, child, and infant models have been truncated to account for the high-cost risk pool payment parameters by removing 60 percent of costs above the \$1 million threshold.")

⁵⁹ See 85 FR 7103 and 7104.

 $^{^{60}}$ In the enrollee-level EDGE data, merged market enrollees are assigned to the individual or small group market indicator based on their plan.

enrollment period, or drop in enrollment before the end of the year) did not appear to affect PMPM expenditures on average. While we did not make changes to the enrollment duration factors in the 2021 Payment Notice, we stated that we were considering eliminating the monthly enrollment duration factors up to 11 months and replacing them with monthly enrollment duration factors up to 6 months for enrollees with HCCs. We also stated that we intended to review the trends observed in our preliminary analysis using an additional year's data before proposing changes.

Since the publication of the 2021 Payment Notice, we have reassessed enrollment duration factors for adults using the 2018 benefit year enrolleelevel EDGE data. The additional data year's findings were consistent with our prior finding that partial year enrollees without HCCs do not have PMPM expenditures that are significantly different compared to full year enrollees without HCCs. Therefore, beginning with the 2022 benefit year, we proposed to remove the current 11 enrollment duration factors of up to 11 months for all enrollees in the adult models, and add new monthly enrollment duration factors of up to 6 months to the adult models that would only apply for enrollees with payment HCCs. Under the proposal, there would be no enrollment duration factors for adult enrollees without payment HCCs starting with the 2022 benefit year adult models. As part of this analysis, we also considered adoption of enrollment duration factors by market, but we did not find a meaningful distinction in relative costs between markets on average once we implemented the proposed enrollment duration factors of up to 6 months for adult enrollees with payment HCCs. Therefore, we did not propose enrollment duration factors for the adult models by market type at this time. We also proposed to continue to incorporate enrollment duration factors only in the adult models. 61 We solicited comment on the changes to the enrollment duration factors for the adult models. We also sought comment on

whether we should implement these model changes starting with the 2022 benefit year, whether we should delay implementation until the 2023 benefit year, or whether we should create the enrollment duration factors for different lengths, such as up to 9 months of enrollment, instead of up to 6 months.

We are not finalizing the proposal to remove the current 11 enrollment duration factors of up to 11 months for all enrollees in the adult models, or to add new monthly enrollment duration factors of up to 6 months that would only apply for enrollees with payment HCCs in the adult models. We intend to consider proposing changes that increase the predictive power of the HHS risk adjustment models model in the future, including with respect to improving model prediction for partial year enrollees with HCCs. We received public comments on the proposed changes to the adult model enrollment duration factors. The following is a summary of the comments we received on these proposals and our responses.

Comment: Many commenters were opposed to the new enrollment duration factors for up to 6 months for adult enrollees with a payment HCC. These commenters wanted additional analysis on the new enrollment duration factors, such as further evaluation of the new enrollment duration factors in a White Paper or dialogue during stakeholder listening sessions. Other commenters supported the new enrollment duration factors (of up to 6 months for adult enrollees with a payment HCC). These commenters believed that the new enrollment duration factors would capture adverse selection related to partial year enrollment and were concerned that plans are unable to recover premiums for the foreseeable additional costs that result from partial year enrollees.

A few commenters opposed the new enrollment duration factors because they believed that the current enrollment duration factors that apply to all adult enrollees help to offset under-prediction of healthy enrollees in the risk adjustment models and that the proposed enrollment duration factors would undermine this offset by only applying to adult enrollees with an HCC. Other commenters believed that the current enrollment duration factors helped mitigate some potential underprediction issues in the small group market.

Some commenters wanted HHS to implement the proposed enrollment duration factors changes beginning with the 2022 benefit year. Other commenters recommended delaying implementation of the proposed enrollment duration

factor changes to the 2023 benefit year, asking that HHS provide additional analysis on the enrollment duration factor changes in the interim to assist issuers with pricing their plans to reflect these changes. One commenter wanted HHS to implement the proposed enrollment duration factor changes now so that carriers are not deterred from enrolling people seeking coverage during special enrollment periods with millions of people losing employer-sponsored insurance due to COVID–19.

Response: Similar to the other proposed model specification changes, we are not finalizing the revisions to the enrollment duration factors at this time and will consider proposing changes that increase the predictive power of the HHS risk adjustment models in the future. For the 2022 benefit year, we will continue to apply the current 11 enrollment duration factors of up to 11 months for all enrollees in the adult models with trending adjustments made to project the data used to develop the factors forward to reflect the 2022 benefit year. We recognize that stakeholders would benefit from additional analysis and time to assess these or other potential changes to the enrollment duration factors. We also see value in making any changes to the enrollment duration factors at the same time as other model specification changes under consideration to address the under-prediction of no HCC enrollees. This approach to aligning the enrollment duration factors changes with the timing of other potential model specification changes targeted to improve the predictive power of the models would support a balanced approach to addressing the overprediction of no HCC enrollees with partial year enrollment at the same time that we address the under-prediction of no HCC enrollees (with full or close to full year enrollment) in the risk adjustment models. We note that the current enrollment duration factors still compensate plans for partial year enrollees, and therefore, already help mitigate any disincentive to enroll partial-year enrollees.

Therefore, we are also not finalizing the proposed changes to the enrollment duration factors at this time and will continue to apply the current 11 enrollment duration factors of up to 11 months, with trending adjustments made to reflect the 2022 benefit year, for all enrollees in the adult models. In addition, we are considering releasing a further analysis of potential changes to the risk adjustment models that could include updates to the adult model enrollment duration factors.

⁶¹ As explained in the 2021 Payment Notice proposed rule, we found that partial year enrollees in the child models did not have the same risk differences as partial year enrollees in the adult models and they tended to have similar risk to full year enrollees in the child models. In the infant models, we found that partial year infants had higher expenditures on average compared to their full year counterparts; however, the incorporation of enrollment duration factors created interaction issues with the current severity and maturity factors and did not have a meaningful impact on the general predictive power of the infant models. See 85 FR 7103 and 7104.

Comment: Some commenters wanted HHS to consider whether enrollment duration factors should be tied to certain HCCs, believing that not all HCCs contribute equally to the coefficient for enrollees with the one month enrollment duration factor and wanting us to constrain the enrollment duration factor to a subset of HCCs driving the high one-month enrollment duration factor coefficient value. One commenter recommended HCC specific enrollment duration factors for maternity HCCs be finalized for the 2022 benefit year. Another commenter recommended the creation of enrollment duration factors up to 9 months of enrollment for adult enrollees with HCCs (instead of up to 6 months for enrollees with HCCs, as proposed).

Response: While we are not finalizing changes to the adult model enrollment duration factors at this time, as part of our analysis of the enrollment duration factors, we did review the most common HCCs in the 2018 enrollee-level EDGE data for one month enrollees. We found that the most common HCCs for one month adult enrollees are also common HCCs in the enrollee-level EDGE data. However, our main concern with the suggestion to tie enrollment duration factors to certain HCCs or specific to maternity HCCs is that many new factors would have to be added to the models to create HCC-specific enrollment duration factors, adding an additional level of complexity and potential instability to the models.

We also note that as part of our analysis of potential changes to the adult model enrollment duration factors, we considered creating factors for adult enrollees with HCCs for up to 9 months and tested this alternative model specification using 2018 enrolleelevel EDGE data. We found that the estimated coefficients for the factors between 6 and 9 months were small and in some cases negative. We also did not find meaningful improvement in the predictive ratios when using enrollment duration factors up to 9 months. For these reasons, we proposed using enrollment duration factors of up to 6 months for enrollees with HCCs. However, as detailed above, we are not finalizing the proposed changes to the enrollment duration factors or the accompanying removal of the current enrollment duration factors in the adult models at this time.

Comment: Some commenters wanted enrollment duration factors by market type or wanted HHS to consider whether the individual and small group markets should have market specific risk adjustment model coefficients. Some of these commenters were

concerned that the proposed enrollment duration factors were created to address a partial year enrollment issue that primarily exists in the individual market and had concerns about making changes to the enrollment duration factors in the small group market which has non-calendar coverage that can somewhat artificially create partial year enrollees. Other commenters had concerns about removing the previous enrollment duration factors for the small group market, believing that the previous enrollment duration factors mitigate the disconnect between the calendar year for EDGE claims and the renewal year for the small group market, which is often not on the calendar year. One commenter was concerned that eliminating the existing enrollment duration factors would be destabilizing for any market where an issuer may obtain a higher percentage of new small employer business relative to other competitors. Other commenters were concerned about issuers' ability to capture HCCs in the small group market, especially when plan renewal can occur in December, limiting the amount of time that issuers would have to collect diagnosis codes for the applicable benefit year of risk adjustment even though the issuer would have claims for December. Another commenter was concerned about small issuers and Medicaid issuers being able to effectively capture HCCs from churning enrollees.

Response: As discussed in the proposed rule, we considered adoption of enrollment duration factors by market, but we did not find a meaningful distinction in relative costs between markets on average once we implemented the proposed enrollment duration factors of up to 6 months for adult enrollees with payment HCCs. Therefore, we did not propose and are not finalizing market-specific enrollment duration factors. Furthermore, we are not aware of any evidence that would indicate that various types of issuers (for example, issuers of various sizes, Medicaid issuers, private market issuers) are unable to capture HCCs for partial year enrollees.

After consideration of the comments received, we are not finalizing the proposed revisions to the enrollment duration factors at this time. For the 2022 benefit year, we will continue to apply the current 11 enrollment duration factors of up to 11 months, with trending adjustments made to reflect the 2022 benefit year, for all enrollees in the adult models.

d. Pricing Adjustment for the Hepatitis C Drugs

For the 2022 benefit year models, we proposed to continue applying the market pricing adjustment to the plan liability associated with Hepatitis C drugs that has been in place beginning with the 2020 benefit year final risk adjustment models.⁶² We are finalizing the pricing adjustment for Hepatitis C drugs as proposed.

As explained in the proposed rule, we continue to believe this market pricing adjustment is necessary and appropriate to account for the significant pricing changes associated with the introduction of new and generic Hepatitis C drugs between the data years used for recalibrating the models and the applicable recalibration benefit year. We also continue to be cognizant that issuers might seek to influence provider prescribing patterns if a drug claim can trigger a large increase in an enrollee's risk score that is higher than the actual plan liability of the drug claim, and therefore, make the risk adjustment transfer results more favorable for the issuer. We previously stated that we intended to reassess this pricing adjustment with future benefit years' enrollee-level EDGE data.⁶³ However, in alignment with the proposal to use the same 3 years of enrollee-level EDGE data for the 2022 benefit year model recalibration as those used for the 2021 benefit year, we proposed to continue making a market pricing adjustment to the plan liability associated with Hepatitis C drugs to reflect future market pricing prior to solving for coefficients for the 2022 benefit year models.64 We noted that we intend to reassess this pricing adjustment in future recalibrations with additional years of enrollee-level EDGE data. We sought comment on this proposal.

We received public comments on the proposed continuation of the market pricing adjustment for Hepatitis C drugs for the 2022 benefit year. The following is a summary of the comments we received and our responses.

Comment: Most commenters supported the continuation of the pricing adjustment for Hepatitis C drugs stating that it would more accurately reflect the average cost of treatment in the risk adjustment models, ensure enrollees can continue to receive incremental credit for having both the Hepatitis C RXC and HCC, and account

^{62 84} FR 17463 through 17466.

^{63 85} FR 29185.

⁶⁴ The Hepatitis C drugs market pricing adjustment to plan liability is applied for all enrollees taking Hepatitis C drugs in the data used for recalibration.

for the introduction of new Hepatitis C drugs. One commenter recommended HHS clarify the data source and approach used to constrain the Hepatitis C RXC coefficient, and cautioned against reducing the coefficient more than the expected decrease in cost. One commenter similarly recommended HHS reassess this adjustment on an ongoing basis to ensure the coefficient is not constrained beyond the expected decrease in the cost of the drugs.

Response: In response to comments, we note that we continue to assess trends in the enrollee-level EDGE data as well as monitor for developments that would impact expectations for pricing for Hepatitis C drugs to ensure that the adjustments are reasonable and are not reduced below the expected decrease in cost. We reassessed the pricing adjustment for Hepatitis C drugs for the 2022 benefit year model recalibration using the most recent year of data (2019 enrollee-level EDGE data) and found the costs for Hepatitis C drugs continued to show a significant decline when compared to the costs in the 2018 enrollee-level EDGE data. Therefore, we continue to believe that it is necessary and appropriate to use a pricing adjustment for Hepatitis C drugs for the 2022 benefit year since the data used to recalibrate the risk adjustment models, which does not include the 2019 enrollee-level EDGE data, does not reflect the average cost of Hepatitis C treatments applicable to the 2022 benefit year when newer and cheaper Hepatitis C drugs will be available. Because the cost of these drugs were reflected in the 2016, 2017 and 2018 enrollee-level EDGE datasets without a pricing adjustment to plan liability, the Hepatitis C RXC in the 2022 benefit year based on this data could overcompensate issuers and incentivize them to encourage overprescribing practices to favorably impact their risk adjustment transfers (increase their payment or decrease their charge). The pricing adjustment finalized here helps avoid perverse incentives, and leads to Hepatitis C RXC coefficients that better reflect anticipated actual 2022 benefit year plan liability associated with Hepatitis C drugs. We intend to continue to reassess this pricing adjustment in future benefit years' model recalibrations using additional vears of available enrollee-level EDGE

Comment: One commenter agreed with HHS's stated concern that issuers might seek to influence provider prescribing patterns if a drug claim can trigger a large increase in an enrollee's risk score that is higher than the actual plan liability of the drug claim. In

contrast, another commenter questioned the view that issuers are gaming risk adjustment by encouraging providers to prescribe particular treatments when they are unnecessary.

Response: Due to the changing cost of these drugs reflected in the data used for recalibration purposes (that is, the 2016, 2017 and 2018 enrollee-level EDGE data), without a pricing adjustment to plan liability, issuers could be overcompensated for the Hepatitis C RXC in the 2022 benefit year and could be incentivized to "game" risk adjustment or encourage overprescribing practices. More specifically, the absence of a pricing adjustment could incentivize some issuers to influence provider prescribing patterns because the drug claim could trigger a large increase in an enrollee's risk score that is higher than the actual plan liability of the drug claim. This would lead to the calculation of inflated risk scores and would make the risk adjustment transfer results more favorable for the issuer (that is, increase a payment or decrease a charge). To avoid perverse incentives to influence overprescribing behavior, we are finalizing a market pricing adjustment for Hepatitis C drugs. It is an appropriate and necessary adjustment in light of the cost of the drugs reflected in the 2016 through 2018 enrollee-level EDGE data and the introduction of newer and lower cost Hepatitis C drugs that will be available in the 2022 benefit year. We intend to continue to reassess whether this pricing adjustment is needed for future benefit years.

Comment: One commenter expressed concern about issuers potentially gaming risk adjustment based on when the Hepatitis C drug prescription is filled. The commenter noted that because HHS-operated risk adjustment operates on a calendar year basis an issuer could receive credit for a prescription filled in December of Year 1 and receive credit for the same individual for a prescription filled in January of Year 2, potentially doubledipping in risk adjustment. The commenter recommended we modify the EDGE server requirements to mandate the tracking of the days supply of each prescription fill and scale the coefficient by the percentage of a recommended therapeutic regime supplied over the course of the year to reduce the possibility of gaming.

Response: While some stakeholders have expressed concern about timing for filling Hepatitis C prescriptions, we have previously analyzed the potential for issuers to game HHS-operated risk adjustment by encouraging consumers to refill prescriptions for the treatment

for Hepatitis C in December and January and have not found clear evidence that this type of behavior is occurring. However, as part of our consideration of the comments received on this proposal, we revisited this analysis using more recent data and found similar results. Therefore, based on our analysis and continued study of this issue, we do not believe modifications to HHS-operated risk adjustment program or EDGE server requirements are needed at this time. However, we will continue to monitor usage trends to assess whether modifications to the Hepatitis C pricing adjustment or the adoption of other safeguards to prevent potential doubledipping are warranted in the future. We further note that the proposed suggestions by the commenter—to modify EDGE server requirements or scale the coefficient—would introduce burden and complexity to the HHSoperated risk adjustment program. If we determine pursuit of these types of measures is warranted for future benefit years, we would need to weigh these disadvantages against any potential benefits.

Comment: Some commenters asked HHS to monitor the market and introduction of new expensive therapies and treatments, such as gene therapy drugs, and incorporate them into the risk adjustment model factors due to the anticipated high costs of these drugs and associated services. The comments noted that the costs of very new, high cost treatments will not be reflected in prior year enrollee-level EDGE data. One commenter noted that that while the high-cost risk pool, which compensates plans for enrollees with claims over \$1 million, is helpful, there may be a need for something more specific in the risk adjustment model to account for these costs.

Response: We did not propose to update the risk adjustment model factors to reflect the costs of gene therapy drugs in the proposed rule and are not finalizing such updates in this rule. We recognize that the data used to recalibrate the risk adjustment models are lagged by several benefit years and cannot account for the costs of new, expensive gene therapy drugs that are expected to be available by the 2022 benefit year. Thus, we considered whether to include any gene therapy drugs in the risk adjustment models for the 2022 benefit year as a separate RXC or an additive HCC. In considering these options, our primary concern was that we do not have adequate data on these drugs to create a separate RXC or an additive HCC for the 2022 benefit year and we are concerned with the ability

to obtain data of an adequate population size given the limited use of these drugs.

We note that if an enrollee in an issuer's risk adjustment covered plan has claims for gene therapy or other expensive treatments, that enrollee would be eligible for the high-cost risk pool payments if claims for that enrollee are over \$1 million. We intend to assess the use of gene therapy drugs as additional data become available and consider whether model updates are warranted to address their anticipated costs in the future.

Comment: One commenter wanted to ensure the required ancillary services associated with pre-exposure prophylaxis (PrEP) use were being incorporated into risk adjustment. Another commenter expressed concern that some prescription drug codes (Descovy®) that are used for PrEP would map to an RXC in the risk adjustment models while others prescription drug codes used for PrEP would not.

Response: In the 2021 Payment Notice, we incorporated PrEP as a preventive service in the simulation of plan liability in the risk adjustment adult and child models with zero cost sharing after careful analysis of preventive drugs that are recommended at grade A or B by the United States Preventive Services Task Force (USPSTF). We are again incorporating the costs of PrEP in this same manner in the 2022 risk adjustment models to give issuers credit at the preventive services level for the costs of these drugs. We also considered treating ancillary services for PrEP as preventive services in risk adjustment model recalibration. However, we found that many of the recommended PrEP

ancillary services (such as, HIV screenings) already qualify as preventive services and as such are already calibrated at 100 percent plan liability; therefore, no updates were made to capture these services in the simulation of plan liability in the adult and child models. However, we will continue to consider whether additional PrEP ancillary services should be treated as preventive services for risk adjustment model recalibration for future benefit years.

We further note that we also continuously assess the availability of drugs in the market and the associated mapping of those drugs to RXCs in the adult risk adjustment models. As a result of this on-going assessment, we make quarterly updates to the RXC Crosswalk to ensure drugs are being mapped to RXCs where appropriate, including adding and removing new and old drugs. In response to the comments regarding the potential different treatment of PrEP drugs in risk adjustment, we note that in January 2021, we announced that consistent with our treatment of other PrEP drugs, Descovy® would be removed from RXC 1 in the final Benefit Year (BY) 2020 Do it Yourself (DIY) update, released in April 2021, since it can be used as a preventive drug.⁶⁵ Enrollees that use Descovy® (or other PrEP drugs) in combination with other HIV treatment drugs will still receive credit for RXC 1. We will continue these types of reviews in the future.

After consideration of the comments we received on this proposal, we are finalizing the proposal to continue the market pricing adjustment for Hepatitis C drugs.

e. List of Factors To Be Employed in the Risk Adjustment Models (§ 153.320)

The final 2022 benefit year risk adjustment model factors resulting from the equally weighted (averaged) blended factors from separately solved models using the 2016, 2017, and 2018 enrolleelevel EDGE data, consistent with the policies finalized in this rulemaking, are shown in Tables 1 through 6.66 The adult, child, and infant models have been truncated to account for the highcost risk pool payment parameters by removing 60 percent of costs above the \$1 million threshold.⁶⁷ Table 1 contains factors for each adult model, including the age-sex, HCCs, RXCs, RXC-HCC interactions, severity interactions, and enrollment duration coefficients. Table 2 contains the HCCs in the severity illness indicator variable. Table 3 contains the factors for each child model. Table 4 contains the factors for each infant model. Tables 5 and 6 contain the HCCs included in the infant models' maturity and severity categories, respectively.

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⁶⁵ HHS-Developed Risk Adjustment Model Algorithm "Do It Yourself (DIY)" Software Instructions for the 2020 Benefit Year (April 15, 2021 Update), available at https://www.cms.gov/ files/document/cy2020-diyinstructions04132021.pdf.

⁶⁶ As detailed below, the one exception relates to RXC 09, which involved the use of only 2016 and 2017 enrollee-level data to develop the applicable 2022 benefit year coefficients and interaction terms.

⁶⁷ As detailed below, we did not propose and are finalizing any changes to the high-cost risk pool parameters for the 2022 benefit year. Therefore, we are maintaining the \$1 million threshold and 60 percent coinsurance rate.

TABLE 1: Adult Risk Adjustment Model Factors for 2022 Benefit Year

HCC or	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
RXC No.	Don	nographic Fa	ctors			
	Age 21-24, Male	0.128	0.086	0.049	0.020	0.019
	Age 25-29, Male	0.128	0.086	0.049	0.020	0.017
	Age 30-34, Male	0.159	0.109	0.065	0.019	0.027
	Age 35-39, Male	0.187	0.129	0.077	0.034	0.033
	Age 40-44, Male	0.222	0.157	0.099	0.051	0.049
	Age 45-49, Male	0.251	0.181	0.117	0.062	0.060
	Age 50-54, Male	0.333	0.253	0.181	0.119	0.117
	Age 55-59, Male	0.372	0.283	0.204	0.135	0.132
	Age 60-64, Male	0.418	0.320	0.232	0.155	0.152
	Age 21-24, Female	0.217	0.151	0.093	0.047	0.045
	Age 25-29, Female	0.236	0.165	0.103	0.053	0.051
	Age 30-34, Female	0.306	0.226	0.155	0.097	0.095
	Age 35-39, Female	0.372	0.283	0.204	0.139	0.136
	Age 40-44, Female	0.425	0.326	0.238	0.163	0.160
	Age 45-49, Female	0.433	0.329	0.234	0.153	0.149
	Age 50-54, Female	0.470	0.366	0.269	0.185	0.181
	Age 55-59, Female	0.445	0.339	0.241	0.156	0.152
	Age 60-64, Female	0.446	0.337	0.235	0.147	0.144
		iagnosis Fact				
HCC001	HIV/AIDS	1.520	1.379	1.282	1.212	1.210
110001	Septicemia, Sepsis, Systemic	1.320	1.379	1.282	1,212	1.210
	Inflammatory Response					
HCC002	Syndrome/Shock	7.045	6.891	6.847	6.864	6.867
110002	Central Nervous System Infections,	7.043	0.071	0.047	0.004	0.007
HCC003	Except Viral Meningitis	5.927	5.857	5.833	5.835	5.835
HCC004	Viral or Unspecified Meningitis	5.072	4.918	4.820	4.718	4.716
HCC006	Opportunistic Infections	6.319	6.275	6.237	6.187	6.185
HCC008	Metastatic Cancer	22.979	22.560	22.379	22.335	22.336
110000	Lung, Brain, and Other Severe	22.717	22.300	22.31)	22.333	22.330
	Cancers, Including Pediatric Acute					
HCC009	Lymphoid Leukemia	13.282	12.979	12.825	12.743	12.742
110000	Non-Hodgkin Lymphomas and Other	13.202	12.575	12.023	12.713	12.7 12
HCC010	Cancers and Tumors	5.575	5.376	5.248	5.144	5.141
1100010	Colorectal, Breast (Age < 50), Kidney,	3.373	3.370	3.270	3.144	3.171
HCC011	and Other Cancers	3.845	3.648	3.517	3.409	3.405
1100011	Breast (Age 50+) and Prostate Cancer,	3.013	3.010	3.317	3.103	3.103
	Benign/Uncertain Brain Tumors, and					
HCC012	Other Cancers and Tumors	2.604	2.457	2.350	2.254	2.251
1100012	Thyroid Cancer, Melanoma,	2.001	2	2.550	2.20	2.201
	Neurofibromatosis, and Other Cancers					
HCC013	and Tumors	1.132	1.017	0.903	0.779	0.775
HCC018	Pancreas Transplant Status	2.006	1.955	1.933	1.932	1.933
HCC019	Diabetes with Acute Complications	0.427	0.359	0.299	0.243	0.240
HCC020	Diabetes with Chronic Complications	0.427	0.359	0.299	0.243	0.240
HCC021	Diabetes without Complication	0.427	0.359	0.299	0.243	0.240
1100021	Type 1 Diabetes Mellitus, add-on to	5.727	0.557	0.277	0.273	U.2TU
HCC022	Diabetes HCCs 19-21	0.384	0.350	0.319	0.257	0.255
HCC023	Protein-Calorie Malnutrition	10.719	10.711	10.746	10.828	10.831
HCC026	Mucopolysaccharidosis	29.195	29.017	28.940	28.930	28.931
HCC027	Lipidoses and Glycogenosis	29.195	29.017	28.940	28.930	28.931
1100021	Amyloidosis, Porphyria, and Other	27.173	<i>△</i> J.01/	20.770	20.730	20.731
	Metabolic Disorders	7.748	7.653	7.595	7.554	7.553
HCC029						
HCC029	Adrenal, Pituitary, and Other	7.746	7.055	7.575	7.551	7.555

HCC034	HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Acute Liver Failure/Disease, Infections/Necrositis 9,532 9,480 9,468 9,490 9,489		Liver Transplant Status/Complications	9.695	9.633	9.608	9.605	9.604
Chronic Liver Failure/End-Stage Liver Disorders 3.107 2.965 2.901 2.873 2.872							
HCC035 2 Liver Disorders 3.107 2.965 2.901 2.873 2.872 HCC037 1 Chronic Viral Hepatitis C 0.871 0.785 0.717 0.653 0.651 HCC037 2 Chronic Ilepatitis, Except Chronic Chronic Ilepatitis, Except Chronic Intestine Transplant 0.871 0.785 0.717 0.653 0.651 HCC041 Intestine Transplant 0.871 0.785 0.717 0.653 0.651 HCC041 Extracrocity and transplant 0.871 0.785 0.717 0.653 0.651 HCC042 Perforation Necrotizing Enterocolitis 8.835 8.633 8.577 8.561 8.562 HCC043 Intestinal Obstruction 5.241 5.066 4.982 4.928 4.927 HCC044 Chronic Pancreatitis 3.546 3.407 3.355 3.341 3.342 HCC047 Acute Pancreatitis 3.344 2.855 2.755 2.665 2.664 HCC048 Inflammatory Bowel Disease 0.532 0.444 0.356 0.249 0.245 HCC049 Recrotizing Eascitis 9.981 9.883 9.868 9.923 9.925 HCC055 Bono-Dinit/Muscle Infections/Necrosis 5.231 5.080 5.019 5.016 5.016 HCC056 Reumatoid Arthritis and Specified 1.372 1.265 1.169 1.076 1.072 HCC061 Systemic Lupus Erythematosus and Other Autoimmune Disorders 0.658 0.562 0.457 0.334 0.330 HCC062 Autoimmune Disorders 0.658 0.562 0.457 0.334 0.330 HCC063 Congenital/Developmental Skeletal and Connective Fissue Disorders 2.433 2.281 2.177 2.083 2.080 HCC064 Hemophilia 70.009 69.723 69.594 69.568 69.568 HCC065 Hemophilia 70.009 69.723 69.594 69.568 69.568 HCC066 Hemophilia 70.009 69.723 69.594 69.568 69.568 HCC067 Myelofibrosis 14.086 13.994 13.949 13.929 13.928 HCC07 Disorders of the Immune Mechanism 14.086 13.994 13.949 13.929 13.928 HCC07 Disorders of the Immune Mechanism 14.086 13.994 13.949 13.929 13.928 HCC07 Disorders of the Immune Mechanism 14.086 2.537 2.486 2.442 2.441 HCC07 Disorders of the Immune Mechanism 4.770 4.683 4.639 4.615 4.614	HCC035_1*	Including Neonatal Hepatitis	9.532	9.480	9.468	9.490	9.489
HCC036		Chronic Liver Failure/End-Stage					
HCC037 Chronic Viral Hepatitis C		Liver Disorders					
Chronic Hepatitis, Except Chronic 0.871 0.785 0.717 0.653 0.651 Intestine Transplant Status/Complications 33.660 33.619 33.587 33.545 Perforation/Necrotizing Enterocolitis 8.835 8.653 8.577 8.561 8.562 HCC042 Perforation/Necrotizing Enterocolitis 8.835 8.653 8.577 8.561 8.562 HCC043 Intestinal Obstruction 5.241 5.066 4.982 4.928 4.927 HCC046 Chronic Pancreatitis 3.546 3.407 3.355 3.341 3.342 HCC047 Acute Pancreatitis 3.034 2.855 2.755 2.665 2.664 HCC048 Inflammatory Bowel Disease 0.532 0.444 0.356 0.249 0.245 HCC054 Necrotizing Fascitits 9.981 9.883 9.868 9.923 9.925 HCC055 Infections/Necrosis 5.231 5.080 5.019 5.016 5.016 HCC056 Autoimmune Disorders 1.372 1.265 1.169 1.076 1.072 HCC061 Other Autoimmune Disorders 0.658 0.562 0.457 0.334 0.330 HCC062 Autoimmune Disorders 0.658 0.562 0.457 0.334 0.330 HCC063 Other Autoimmune Disorders 0.658 0.562 0.457 0.334 0.330 HCC064 Hemophilia 0.000 0.000 0.000 0.000 HCC065 Hemophilia 0.000 0.000 0.000 0.000 0.000 HCC066 Hemophilia 0.000 0.000 0.000 0.000 0.000 HCC066 Hemophilia 0.000 0.000 0.000 0.000 0.000 HCC067 Sickle Cell Anemia (Hb-SS) 2.795 2.679 2.593 2.514 2.511 HCC074 Disorders of the Immune Mechanism 0.000 0.000 0.000 0.000 0.000 0.000 HCC075 Disorders of the Immune Mechanism 0.000 0.0							
IICC031 2 Viral Hepatitis C	HCC037_1		0.871	0.785	0.717	0.653	0.651
Intestine Transplant Satatus Complications Peritoritis Castrointestinal Perforation/Necrotizing Enterocolitis R.835 R.653 R.577 R.561 R.562 Intestinal Obstruction S.241 S.066 4.982 4.928 4.927 R.504 R.504							
HCC041 Status/Complications 33.660 33.619 33.587 33.545 33.545 HCC042 Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis 8.835 8.653 8.577 8.561 8.562 HCC045 Intestinal Obstruction 5.241 5.066 4.982 4.928 4.927 HCC046 Intestinal Obstruction 5.241 5.066 4.982 4.928 4.927 HCC047 Acute Pancreatitis 3.344 2.855 2.755 2.665 2.664 HCC048 Inflammatory Bowel Disease 0.532 0.444 0.356 0.249 0.245 HCC054 Necrotizing Fasciitis 9.981 9.883 9.868 9.923 9.925 HCC055 Rheumatoid Arthritis and Specified Autoimmune Disorders 0.582 0.562 0.457 0.334 0.330 HCC056 Autoimmune Disorders 0.658 0.562 0.457 0.334 0.330 HCC057 Osteogenesis Imperfecta and Other Osteodystrophics 2.433 2.281 2.177 2.083 2.080 HCC063 Cleft Lip/Cleft Palate 1.904 1.780 1.690 1.604 1.601 HCC066 HcC066 Myelofibrosis 14.086 13.994 13.949 13.929 13.928 HCC067 Myelofibrosis 14.086 13.994 13.949 13.929 13.928 HCC069 Newborn 14.086 13.994 13.949 13.929 13.928 HCC070 Sickle Cell Anemia HbcSs) 2.795 2.679 2.593 2.514 2.511 HCC071 Disorders Merita Me	HCC037_2	Viral Hepatitis C	0.871	0.785	0.717	0.653	0.651
Pertionitis/Gastrointestinal Pertionitis/Gastrointestinal Pertonitis/Gastrointestinal Pertonitis/Gastrointestinal Pertonitis/Castrointestinal Obstruction S.241 S.066 4.982 4.928 4.927 HCC046							
HCC042 Perforation/Necrotizing Enterocolitis 8.835 8.653 8.577 8.561 8.562 HCC045 Intestinal Obstruction 5.241 5.066 4.982 4.928 4.927 HCC046 Chronic Pancreatitis 3.546 3.407 3.355 3.341 3.342 HCC047 Acute Pancreatitis 3.034 2.855 2.755 2.665 2.664 HCC048 Inflammatory Bowel Disease 0.532 0.444 0.356 0.249 0.245 HCC048 Necrotizing Fasciitis 9.981 9.883 9.868 9.923 9.925 HCC054 Necrotizing Fasciitis 9.981 9.883 9.868 9.923 9.925 HCC055 Infections/Necrosis 5.231 5.080 5.019 5.016 5.016 HCC056 Autoimmune Disorders 1.372 1.265 1.169 1.076 1.072 Systemic Lupus Erythematosus and Other Autoimmune Disorders 0.658 0.562 0.457 0.334 0.330 0.360 Osteogenesis Imperfecta and Other Osteodystrophics 2.433 2.281 2.177 2.083 2.080 HCC061 Osteodystrophics 2.433 2.281 2.177 2.083 2.080 HCC063 Cleft Lip/Cleft Palate 1.904 1.780 1.690 1.604 1.601 HCC066 Hemophilia 70.009 69.723 69.594 69.568 69.568 4.0206 Myelodysplastic Syndromes and HCC067 Myelodysplastic Syndromes and HCC068 Aplastic Anemia Hcluding Hemolytic Anemia, Including Hemolytic Disease of Newborn 14.086 13.994 13.949 13.929 13.928 HCC069 Newborn 14.086 13.994 13.949 13.929 13.928 HCC073 Sickle Cell Anemia (Hb-SS) 2.795 2.679 2.593 2.514 2.511 Combined and Other Severe HCC073 Immunodeficiencies 4.770 4.683 4.639 4.615 4.614 HCC074 Disorders of the Immune Mechanism 4.770 4.683 4.639 4.615 4.614 HCC075 Specified Hematological Disorders 2.602 2.446 2.303 2.144 2.138 HCC082 Complications 2.622 2.446 2.303 2.144 2.138 HCC083 Complications 2.622 2.446 2.303 2.144 2.138 HCC084 Disorders Onderate/Severe, or Alcohol Use with Psychotic Complications 4.24 4.095 0.995 0.891 0.887 HCC084 HCC084 HCC084 Complications 4.24 4.095 0.995 0.891 0.887	HCC041		33.660	33.619	33.587	33.545	33.545
HCC045 Intestinal Obstruction 5,241 5,066 4,982 4,928 4,927 HCC046 Chronic Pancreatitis 3,546 3,407 3,355 3,341 3,342 4,000 3,335 3,341 3,342 3,342 3,342 3,342 3,342 3,342 3,342 3,342 3,342 3,342 3,342 3,343 2,285 2,755 2,665 2,664 11CC048 Inflammatory Bowel Disease 0,532 0,444 0,356 0,249 0,245 4,000 0,245 4,0	1100010		0.005	0.650	0.555	0.561	0.500
HCC046							
HCC047 Acute Pancreatitis 3.034 2.855 2.755 2.665 2.664 HCC048 Inflammatory Bowel Disease 0.532 0.444 0.356 0.249 0.245 HCC054 Inflammatory Bowel Disease 9.981 9.883 9.868 9.923 9.925 9.925 HCC055 Infections/Necrosis 5.231 5.080 5.019 5.016 5.016 HCC056 Infections/Necrosis 5.231 5.080 5.019 5.016 5.016 HCC056 Autoimmune Disorders 1.372 1.265 1.169 1.076 1.072 HCC057 Other Autoimmune Disorders 0.658 0.562 0.457 0.334 0.330 Other Autoimmune Disorders 0.458 0.562 0.457 0.334 0.330 Other Disorders 0.458 0.562 0.457 0.334 0.330 Other Disorders 0.458 0.562 0.457 0.334 0.330 0.330 Other Disorders 0.458 0.562 0.457 0.334 0.330 0.330 Other Disorders 0.458 0.45							
HCC048 Inflammatory Bowel Disease 0.532 0.444 0.356 0.249 0.245 HCC054 Necrotizing Fascititis 9.981 9.883 9.868 9.923 9.925 Bone/Joint/Muscle							
HCC054 Necrotizing Fascilits 9.981 9.883 9.868 9.923 9.925 HCC055 Infections/Necrosis 5.231 5.080 5.019 5.016 Rheumatoid Arthritis and Specified Autoimmune Disorders 1.372 1.265 1.169 1.076 HCC056 Autoimmune Disorders 0.658 0.562 0.457 0.334 0.330 HCC057 Osteodystrophies 0.658 0.562 0.457 0.334 0.330 HCC061 Osteodystrophies 2.433 2.281 2.177 2.083 2.080 HCC062 Congenital/Developmental Skeletal and Connective Tissue Disorders 2.433 2.281 2.177 2.083 2.080 HCC063 Cleft Lip/Cleft Palate 1.904 1.780 1.690 1.604 1.601 HCC066 Hemophilia 70.009 69.723 69.594 69.568 69.568 HCC067 Myelofibrosis 14.086 13.994 13.949 13.929 13.928 HCC068 Aplastic Anemia 14.086 13.994 13.949 13.929 13.928 HCC060 Aplastic Anemia 14.086 13.994 13.949 13.929 13.928 HCC070 Sickle Cell Anemia (Hb-SS) 2.795 2.679 2.593 2.514 2.511 HCC071 Beta Thalassemia Major 2.795 2.679 2.593 2.514 2.511 HCC072 Combined and Other Severe Immunodeficiencies 4.770 4.683 4.639 4.615 4.614 HCC074 Disorders of the Immune Mechanism 4.770 4.683 4.639 4.615 4.614 HCC075 Specified Hematological Disorders 2.622 2.446 2.303 2.144 2.138 HCC081 Complications 2.622 2.446 2.303 2.144 2.138 HCC082 Complications 2.622 2.446 2.303 2.144 2.138 HCC083 Alcohol Use with Psychotic Complications 2.622 2.446 2.303 2.144 2.138 HCC084 Complications 2.622 2.446 2.303							
Bone/Joint/Muscle Infections/Necrosis 5.231 5.080 5.019 5.016 5.016		Inflammatory Bowel Disease					
HCC055 Infections/Necrosis S.231 S.080 S.019 S.016 S.016 Rheumatoid Arthritis and Specified Autoimmune Disorders 1.372 1.265 1.169 1.076 1.072	HCC054		9.981	9.883	9.868	9.923	9.925
Rheumatoid Arthritis and Specified Autoimmune Disorders 1.372 1.265 1.169 1.076 1.072	HCCOSS		5 221	<i>5</i> 000	5.010	5.016	5.016
HCC056	HCC033		3.231	3.080	3.019	3.016	3.016
HCC057	UCC056		1 272	1 265	1 160	1.076	1.072
HCC057 Other Autoimmune Disorders O.658 O.562 O.457 O.334 O.330 HCC061 Osteogenesis Imperfecta and Other Osteodystrophies O.562 O.457 O.334 O.330 HCC062 Congenital/Developmental Skeletal Autoin Congenital/Developmental Skeletal O.562 O.457 O.563 O.562 O.457 O.563 HCC063 Cleft Lip/Cleft Palate D.904 D.604 D.604 D.604 D.601 HCC066 Hemophilia T0.009 O.69.723 O.69.508 O.69.508 HCC067 Myelofibrosis D.4.086 D.4.094 D.4.094 D.4.094 D.4.094 D.4.094 HCC068 Aplastic Anemia D.4.086 D.4.094 D.4.094 D.4.094 D.4.094 D.4.094 D.4.094 HCC069 Newborn D.4.086 D.4.094 D.4.094 D.4.094 D.4.094 D.4.094 D.4.094 HCC070 Sickle Cell Anemia (Hb-SS) D.795 D.679 D.593 D.514 D.511 HCC071 Beta Thalassemia Major D.795 D.679 D.593 D.514 D.511 HCC073 Immunodeficiencies D.795 D.679 D.593 D.401 D.401 HCC074 Disorders of the Immune Mechanism D.794 D.402 D.401 D.40	HCC030		1.372	1.203	1.109	1.076	1.072
HCC061	HCC057		0.658	0.562	0.457	0.334	0.330
HCC061 Osteodystrophies 2.433 2.281 2.177 2.083 2.080	1100037		0.036	0.302	0.437	0.554	0.550
Congenital/Developmental Skeletal and Connective Tissue Disorders 2.433 2.281 2.177 2.083 2.080 HCC063 Cleft Lip/Cleft Palate 1.904 1.780 1.690 1.604 1.601 HCC066 Hemophilia 70.009 69.723 69.594 69.568 69.568 Myelodysplastic Syndromes and Myelofibrosis 14.086 13.994 13.949 13.929 13.928 HCC067 Myelofibrosis 14.086 13.994 13.949 13.929 13.928 HCC068 Aplastic Anemia 14.086 13.994 13.949 13.929 13.928 HCC069 Newborn 14.086 13.994 13.949 13.929 13.928 HCC070 Sickle Cell Anemia (Hb-SS) 2.795 2.679 2.593 2.514 2.511 HCC071 Beta Thalassemia Major 2.795 2.679 2.593 2.514 2.511 HCC073 Immunodeficiencies 4.770 4.683 4.639 4.615 4.614 HCC074 Disorders of the Immune Mechanism 4.770 4.683 4.639 4.615 4.614 HCC075 Specified Hematological Disorders 2.606 2.537 2.486 2.442 2.441 Drug Use with Psychotic Complications 2.622 2.446 2.303 2.144 2.138 HCC081 Complications 2.622 2.446 2.303 2.144 2.138 HCC082 Complications 2.622 2.446 2.303 2.144 2.138 HCC083 Complications 1.224 1.095 0.995 0.891 0.887 HCC084 Complications 1.224 1.095 0.995 0.891 0.887	HCC061		2 433	2 281	2 177	2 083	2 080
HCC062	1100001		2.133	2.201	2.177	2.003	2.000
HCC063 Cleft Lip/Cleft Palate 1.904 1.780 1.690 1.604 1.601 HCC066 Hemophilia 70.009 69.723 69.594 69.568 69.568 Myelodysplastic Syndromes and HCC067 Myelofibrosis 14.086 13.994 13.949 13.929 13.928 HCC068 Aplastic Anemia 14.086 13.994 13.949 13.929 13.928 HCC069 Newborn 14.086 13.994 13.949 13.929 13.928 HCC070 Sickle Cell Anemia (Hb-SS) 2.795 2.679 2.593 2.514 2.511 HCC071 Beta Thalassemia Major 2.795 2.679 2.593 2.514 2.511 HCC073 Immunodeficiencies 4.770 4.683 4.639 4.615 4.614 HCC074 Disorders of the Immune Mechanism 4.770 4.683 4.639 4.615 4.614 HCC075 Specified Hematological Disorders 2.606 2.537 2.486 2.442 2.441 Drug Use with Psychotic Complications 2.622 2.446 2.303 2.144 2.138 HCC081 Complications 2.622 2.446 2.303 2.144 2.138 HCC082 Complications 2.622 2.446 2.303 2.144 2.138 Alcohol Use with Psychotic Complications 1.224 1.095 0.995 0.891 0.887 HCC084 Complications 1.224 1.095 0.995 0.891 0.887	HCC062		2.433	2.281	2.177	2.083	2.080
HCC066 Hemophilia T0.009 69.723 69.594 69.568 69.568 HCC067 Myelodysplastic Syndromes and Myelodysplastic Syndromes and Myelofibrosis 14.086 13.994 13.949 13.929 13.928 HCC068 Aplastic Anemia 14.086 13.994 13.949 13.929 13.928 Acquired Hemolytic Disease of Newborn 14.086 13.994 13.949 13.929 13.928 HCC069 Newborn 14.086 13.994 13.949 13.929 13.928 HCC070 Sickle Cell Anemia (Hb-SS) 2.795 2.679 2.593 2.514 2.511 HCC071 Beta Thalassemia Major 2.795 2.679 2.593 2.514 2.511 HCC073 Immunodeficiencies 4.770 4.683 4.639 4.615 4.614 HCC074 Disorders of the Immune Mechanism 4.770 4.683 4.639 4.615 4.614 HCC075 Specified Hematological Disorders 2.606 2.537 2.486 2.442 2.441 HCC076 Drug Use with Psychotic Complications 2.622 2.446 2.303 2.144 2.138 HCC081 Complications 2.622 2.446 2.303 2.144 2.138 HCC082 Complications 2.622 2.446 2.303 2.144 2.138 HCC083 Complications 2.622 2.446 2.303 2.144 2.138 HCC084 Complications 1.224 1.095 0.995 0.891 0.887 HCC084 Complications 1.224 1.095 0.995 0.891 0.887							
HCC067 Myelodysplastic Syndromes and Myelofibrosis 14.086 13.994 13.949 13.929 13.928 HCC068 Aplastic Anemia 14.086 13.994 13.949 13.929 13.928 Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn 14.086 13.994 13.949 13.929 13.928 HCC069 Newborn 14.086 13.994 13.949 13.929 13.928 HCC070 Sickle Cell Anemia (Hb-SS) 2.795 2.679 2.593 2.514 2.511 HCC071 Beta Thalassemia Major 2.795 2.679 2.593 2.514 2.511 Combined and Other Severe Immunodeficiencies 4.770 4.683 4.639 4.615 4.614 HCC074 Disorders of the Immune Mechanism 4.770 4.683 4.639 4.615 4.614 HCC074 Disorders of the Immune Mechanism 4.770 4.683 4.639 4.615 4.614 HCC075 Specified Hematological Disorders 2.606 2.537 2.486 2.442 2.441 HCC081 Complications 2.622 2.446 2.303 2.144 2.138 Drug Use with Psychotic 2.622 2.446 2.303 2.144 2.138 HCC082 Complications 2.622 2.446 2.303 2.144 2.138 HCC083 Complications 2.622 2.446 2.303 2.144 2.138 HCC084 Complications 1.224 1.095 0.995 0.891 0.887 HCC084 Complications 1.224 1.095 0.995 0.891 0.887							
HCC067 Myelofibrosis 14.086 13.994 13.949 13.929 13.928 HCC068 Aplastic Anemia 14.086 13.994 13.949 13.929 13.928 Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn 14.086 13.994 13.949 13.929 13.928 HCC070 Sickle Cell Anemia (Hb-SS) 2.795 2.679 2.593 2.514 2.511 HCC071 Beta Thalassemia Major 2.795 2.679 2.593 2.514 2.511 HCC073 Immunodeficiencies 4.770 4.683 4.639 4.615 4.614 HCC074 Disorders of the Immune Mechanism 4.770 4.683 4.639 4.615 4.614 HCC075 Specified Hematological Disorders 2.606 2.537 2.486 2.442 2.441 HCC081 Complications 2.622 2.446 2.303 2.144 2.138 HCC082 Complications 2.622 2.446 2.303 2.144 2.138 HCC083 Complications 2.622 2.446 2.303 2.144 2.138 HCC084 Complications 1.224 1.095 0.995 0.891 0.887 HCC084							
Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	HCC067		14.086	13.994	13.949	13.929	13.928
Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	HCC068	Aplastic Anemia	14.086	13.994	13.949	13.929	13.928
HCC069 Newborn 14.086 13.994 13.949 13.929 13.928 HCC070 Sickle Cell Anemia (Hb-SS) 2.795 2.679 2.593 2.514 2.511 HCC071 Beta Thalassemia Major 2.795 2.679 2.593 2.514 2.511 Combined and Other Severe Immunodeficiencies 4.770 4.683 4.639 4.615 4.614 HCC074 Disorders of the Immune Mechanism 4.770 4.683 4.639 4.615 4.614 HCC075 Specified Hematological Disorders 2.606 2.537 2.486 2.442 2.441 Drug Use with Psychotic 2.622 2.446 2.303 2.144 2.138 HCC081 Complications 2.622 2.446 2.303 2.144 2.138 HCC082 Complications 1.224 1.095 0.995 0.891 0.887 HCC084 Complications 1.224 1.095 0.995 0.891 0.887		Acquired Hemolytic Anemia,					
HCC070 Sickle Cell Anemia (Hb-SS) 2.795 2.679 2.593 2.514 2.511 HCC071 Beta Thalassemia Major 2.795 2.679 2.593 2.514 2.511 Combined and Other Severe Immunodeficiencies 4.770 4.683 4.639 4.615 4.614 HCC074 Disorders of the Immune Mechanism 4.770 4.683 4.639 4.615 4.614 HCC075 Specified Hematological Disorders 2.606 2.537 2.486 2.442 2.441 Drug Use with Psychotic Complications 2.622 2.446 2.303 2.144 2.138 HCC082 Complications 2.622 2.446 2.303 2.144 2.138 HCC083 Alcohol Use with Psychotic 2.622 2.446 2.303 2.144 2.138 HCC084 Complications 1.224 1.095 0.995 0.891 0.887		Including Hemolytic Disease of					
HCC071 Beta Thalassemia Major 2.795 2.679 2.593 2.514 2.511						1	
Combined and Other Severe HCC073 Immunodeficiencies 4.770 4.683 4.639 4.615 4.614 HCC074 Disorders of the Immune Mechanism 4.770 4.683 4.639 4.615 4.614 Coagulation Defects and Other Specified Hematological Disorders 2.606 2.537 2.486 2.442 2.441 Drug Use with Psychotic Drug Use with Psychotic Complications 2.622 2.446 2.303 2.144 2.138 Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic HCC082 Complications 2.622 2.446 2.303 2.144 2.138 Alcohol Use with Psychotic HCC083 Complications 1.224 1.095 0.995 0.891 0.887 Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic HCC084 Complications 1.224 1.095 0.995 0.891 0.887 HCC084 Complications 1.224 1.095 0.995 0.891 0.887	HCC070	Sickle Cell Anemia (Hb-SS)	2.795	2.679	2.593	2.514	2.511
HCC073 Immunodeficiencies 4.770 4.683 4.639 4.615 4.614 HCC074 Disorders of the Immune Mechanism 4.770 4.683 4.639 4.615 4.614 Coagulation Defects and Other Specified Hematological Disorders 2.606 2.537 2.486 2.442 2.441 Drug Use with Psychotic Complications 2.622 2.446 2.303 2.144 2.138 Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic 2.622 2.446 2.303 2.144 2.138 HCC082 Complications 2.622 2.446 2.303 2.144 2.138 HCC083 Complications 1.224 1.095 0.995 0.891 0.887 HCC084 Complications 1.224 1.095 0.995 0.891 0.887	HCC071		2.795	2.679	2.593	2.514	2.511
HCC074 Disorders of the Immune Mechanism 4.770 4.683 4.639 4.615 4.614							
Coagulation Defects and Other Specified Hematological Disorders 2.606 2.537 2.486 2.442 2.441							
HCC075 Specified Hematological Disorders 2.606 2.537 2.486 2.442 2.441	HCC074		4.770	4.683	4.639	4.615	4.614
Drug Use with Psychotic Complications 2.622 2.446 2.303 2.144 2.138							
HCC081 Complications 2.622 2.446 2.303 2.144 2.138 Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications 2.622 2.446 2.303 2.144 2.138 HCC082 Complications 2.622 2.446 2.303 2.144 2.138 Alcohol Use with Psychotic Complications 1.224 1.095 0.995 0.891 0.887 Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications 1.224 1.095 0.995 0.891 0.887 HCC084 Complications 1.224 1.095 0.995 0.891 0.887	HCC075		2.606	2.537	2.486	2.442	2.441
Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications 2.622 2.446 2.303 2.144 2.138 HCC082	Hecos		0.505	2 4 4 5	2 2 2 2		2.122
HCC082 Or Drug Use with Non-Psychotic Complications 2.622 2.446 2.303 2.144 2.138 HCC083 Alcohol Use with Psychotic Complications 1.224 1.095 0.995 0.891 0.887 Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications 1.224 1.095 0.995 0.891 0.887 HCC084 Complications 1.224 1.095 0.995 0.891 0.887	HCC081		2.622	2.446	2.303	2.144	2.138
HCC082 Complications 2.622 2.446 2.303 2.144 2.138 HCC083 Alcohol Use with Psychotic Complications 1.224 1.095 0.995 0.891 0.887 Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications 1.224 1.095 0.995 0.891 0.887							
Alcohol Use with Psychotic Complications 1.224 1.095 0.995 0.891 0.887	1100000		2.622	2.446	2 202	2 144	2 120
HCC083 Complications 1.224 1.095 0.995 0.891 0.887	HCCU82		2.022	2.446	2.303	2.144	2.138
Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic HCC084 Complications 1.224 1.095 0.995 0.891 0.887	HCC082		1 224	1.005	0.005	0.001	0.007
Moderate/Severe, or Alcohol Use with Specified Non-Psychotic HCC084 Complications 1.224 1.095 0.995 0.891 0.887	пссовз		1.224	1.093	0.993	0.091	0.88/
Specified Non-Psychotic							
HCC084 Complications 1.224 1.095 0.995 0.891 0.887							
	HCC084		1 224	1.095	0.995	0.891	0.887
	HCC087 1	Schizophrenia	2.622	2.445	2.323	2.205	2.202

Major Depressive Disorder, Severe, and Bipolar Disorders 1.379 1.249 1.132 1.003 Company	astrophic
Psychotic Disorders, Unspecified 2.622 2.445 2.323 2.205 2 2 2 2 2 2 2 2 2	
HCC087 2 Psychosis	
Major Depressive Disorder, Severe, and Bipolar Disorders 1.379 1.249 1.132 1.003 Company	2.202
HCC098	
HCC090	0.999
HCC094	0.712
HCC096	2.106
Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes 1.448 1.371 1.307 1.243 1.107 1.108	
Chromosomal Anomalies, and Congenital Malformation Syndromes 1.448 1.371 1.307 1.243 1	5.715
HCC102	
HCC102	
HCC103 Except Autistic Disorder 1.072 0.962 0.846 0.717	1.241
HCC103 Except Autistic Disorder 1.072 0.962 0.846 0.717	0.895
HCC106 Spinal Cord 11.562 11.447 11.385 11.344 1 HCC107 Quadriplegia 11.562 11.447 11.385 11.344 1 HCC108 Spinal Cord 7.825 7.689 7.610 7.549 7 7 7 7 7 7 7 7 7	
HCC106 Spinal Cord 11.562 11.447 11.385 11.344 1 HCC107 Quadriplegia 11.562 11.447 11.385 11.344 1 Traumatic Complete Lesion Dorsal Spinal Cord 7.825 7.689 7.610 7.549 7 7 7 7 7 7 7 7 7	0.712
HCC107	
Traumatic Complete Lesion Dorsal Spinal Cord 7.825 7.689 7.610 7.549 7.610 7.620 7.6	1.343
HCC108 Spinal Cord 7.825 7.689 7.610 7.549 7.610 HCC109 Paraplegia 7.825 7.689 7.610 7.549 7.610 7.610 7.549 7.610 7.610 7.549 7.610	1.343
HCC109	
HCC110 Spinal Cord Disorders/Injuries 5.342 5.158 5.057 4.987 4.	7.547
Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease 3.336 3.164 3.042 2.918 2.918 1.238 1.070 0.963 0.872 0.000	7.547
HCC111	4.984
HCC112 Quadriplegic Cerebral Palsy 1.238 1.070 0.963 0.872 Cerebral Palsy, Except Quadriplegic 0.790 0.708 0.633 0.547 Cerebral Palsy, Except Quadriplegic 0.790 0.708 0.631 0.547 0.5	
HCC113 Cerebral Palsy, Except Quadriplegic 0.790 0.708 0.633 0.547 0.633 0.633 0.547 0.633 0.547 0.633 0.547 0.633 0.633 0.547 0.633 0.547 0.633 0.633 0.547 0.633 0.633 0.547 0.633 0.633 0.547 0.634 0.633 0.547 0.634 0.633 0.633 0.547 0.634 0.633 0.633 0.547 0.634 0.633 0.633 0.633 0.547 0.634 0.633 0.633 0.633 0.633 0.633 0.633 0.633 0.633 0.633 0.633 0.633 0.633 0.633 0.633 0.633 0.633 0.633 0.633 0.633 0.634	2.913
Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies 1.374 1.273 1.197 1.120 1	0.870
HCC114 Congenital Anomalies 1.374 1.273 1.197 1.120 1	0.544
HCC114 Congenital Anomalies 1.374 1.273 1.197 1.120 1	
Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic	
Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic	1.117
Syndrome/Inflammatory and Toxic HCC115 Neuropathy 5.075 4.987 4.942 4.916 4.91	
HCC115 Neuropathy 5.075 4.987 4.942 4.916 4.947 4.942 4.916 4.947 4.942 4.916 4.947	
HCC117 Muscular Dystrophy 1.763 1.654 1.559 1.447 1	4.016
HCC118 Multiple Sclerosis 2.962 2.806 2.695 2.592 2 2 2 2 2 2 2 2 2	4.916
Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders 1.763 1.654 1.559 1.447 1.608 1.06	1.442
Spinocerebellar Disease, and Other HCC119 Neurodegenerative Disorders 1.763 1.654 1.559 1.447 1.59 HCC120 Seizure Disorders and Convulsions 1.068 0.955 0.861 0.763 0.76	2.589
HCC119 Neurodegenerative Disorders 1.763 1.654 1.559 1.447 1 HCC120 Seizure Disorders and Convulsions 1.068 0.955 0.861 0.763 0 HCC121 Hydrocephalus 8.307 8.209 8.151 8.116 8 Coma, Brain Compression/Anoxic Coma, Brain Compression/Anoxic 7.874 7.753 7.697 7.679 7 HCC123 Narcolepsy and Cataplexy 5.839 5.684 5.563 5.448 5 Respirator Dependence/Tracheostomy Respirator Dependence/Tracheostomy 7 7 7	
HCC120 Seizure Disorders and Convulsions 1.068 0.955 0.861 0.763 0 HCC121 Hydrocephalus 8.307 8.209 8.151 8.116 8 Coma, Brain Compression/Anoxic T.874 7.753 7.697 7.679 7 HCC123 Narcolepsy and Cataplexy 5.839 5.684 5.563 5.448 5 Respirator Dependence/Tracheostomy Respirator Dependence/Tracheostomy 7 8 8 8 8 8 8 8 8 8	1.442
HCC121 Hydrocephalus 8.307 8.209 8.151 8.116 8 Coma, Brain Compression/Anoxic Tomage 7.874 7.753 7.697 7.679 7 HCC123 Narcolepsy and Cataplexy 5.839 5.684 5.563 5.448 5 Respirator Dependence/Tracheostomy 8.307 8.209 8.151 8.116 8	0.759
Coma, Brain Compression/Anoxic Damage 7.874 7.753 7.697 7.679 7.	8.116
HCC122 Damage 7.874 7.753 7.697 7.679 7.753 HCC123 Narcolepsy and Cataplexy 5.839 5.684 5.563 5.448 5 Respirator Dependence/Tracheostomy 5.684 5.563 5.448 5	3.110
HCC123Narcolepsy and Cataplexy5.8395.6845.5635.4485Respirator Dependence/Tracheostomy5.8395.6845.5635.448	7.679
Respirator Dependence/Tracheostomy	5.444
) ,111
HCC125 Status 21.892 21.866 21.900 21.994 2	1.997
	6.585
Cardio-Respiratory Failure and Shock,	,,,,,,,,
Including Respiratory Distress	
	6.585
Heart Assistive Device/Artificial	
	6.708
	6.708
	2.303
	6.163
Unstable Angina and Other Acute	
	4.441

HCC or	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
RXC No.	Heart Infection/Inflammation, Except					
HCC135	Rheumatic	5.740	5.651	5.598	5.557	5.557
	Hypoplastic Left Heart Syndrome and					
	Other Severe Congenital Heart					
HCC137	Disorders	2.586	2.489	2.409	2.341	2.338
	Major Congenital Heart/Circulatory					
HCC138	Disorders	2.586	2.489	2.409	2.341	2.338
	Atrial and Ventricular Septal Defects,					
	Patent Ductus Arteriosus, and Other					
1100120	Congenital Heart/Circulatory	2.506	2.400	2 400	0.241	2.220
HCC139	Disorders	2.586	2.489	2.409	2.341	2.338
HCC142	Specified Heart Arrhythmias	2.265	2.157	2.070	1.983	1.983
HCC145	Intracranial Hemorrhage	6.694	6.498 1.484	6.395	6.327	6.327 1.372
HCC146	Ischemic or Unspecified Stroke Cerebral Aneurysm and Arteriovenous	1.586	1.484	1.427	1.373	1.372
HCC149	Malformation	2.546	2.415	2.323	2.233	2.230
HCC150	Hemiplegia/Hemiparesis	4.176	4.091	4.072	4.095	4.097
1100130	Monoplegia, Other Paralytic	4.170	4.071	4.072	4.093	4.097
HCC151	Syndromes	2.985	2.887	2.823	2.764	2.762
1100131	Atherosclerosis of the Extremities	2.703	2.007	2.023	2.704	2.702
HCC153	with Ulceration or Gangrene	8.710	8.634	8.643	8.727	8.731
HCC154	Vascular Disease with Complications	6.654	6.542	6.492	6.474	6.474
	Pulmonary Embolism and Deep Vein	0.00		*****	0.11.1	
HCC156	Thrombosis	3.510	3.396	3.316	3.234	3.232
HCC158	Lung Transplant Status/Complications	22.123	22.027	22.002	22.028	22.028
HCC159	Cystic Fibrosis	4.871	4.653	4.513	4.410	4.407
	Chronic Obstructive Pulmonary					
HCC160	Disease, Including Bronchiectasis	0.771	0.673	0.576	0.472	0.468
HCC161_1	Severe Asthma	0.771	0.673	0.576	0.472	0.468
HCC161_2	Asthma, Except Severe	0.771	0.673	0.576	0.472	0.468
	Fibrosis of Lung and Other Lung					
HCC162	Disorders	1.934	1.853	1.793	1.729	1.727
	Aspiration and Specified Bacterial					
********	Pneumonias and Other Severe Lung	6.500	c = 0.1			6.701
HCC163	Infections	6.528	6.521	6.538	6.580	6.581
HCC174	Exudative Macular Degeneration	1.570	1.440	1.327	1.197	1.193
1100102	Kidney Transplant	6.027	<i>5</i> 969	5.765	5 (71	5 (72
HCC183	Status/Complications	6.027	5.868	5.765 23.237	5.671	5.673 23.397
HCC184 HCC187	End Stage Renal Disease Chronic Kidney Disease, Stage 5	23.533 0.953	23.284 0.912	0.900	23.356 0.910	0.911
HCC187	Chronic Kidney Disease, Stage 5 Chronic Kidney Disease, Severe	0.955	0.912	0.900	0.910	0.911
HCC188	(Stage 4)	0.953	0.912	0.900	0.910	0.911
HCC203	Ectopic and Molar Pregnancy	2.088	1.879	1.688	1.430	1.421
HCC204	Miscarriage with Complications	0.848	0.732	0.579	0.375	0.365
1100201	Miscarriage with No or Minor	0.010	0.732	0.577	0.575	0.505
HCC205	Complications	0.848	0.732	0.579	0.375	0.365
110000	Pregnancy with Delivery with Major	0.00.0	*****	0.073	0.070	0.000
HCC207	Complications	4.049	3.741	3.498	3.132	3.123
	Pregnancy with Delivery with	-				
HCC208	Complications	4.049	3.741	3.498	3.132	3.123
	Pregnancy with Delivery with No or					
HCC209	Minor Complications	2.881	2.650	2.411	1.973	1.956
	(Ongoing) Pregnancy without					
HCC210	Delivery with Major Complications	1.240	1.074	0.871	0.634	0.623
	(Ongoing) Pregnancy without					
HCC211	Delivery with Complications	0.834	0.699	0.523	0.348	0.340

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
RAC NO.	(Ongoing) Pregnancy without					
	Delivery with No or Minor					
HCC212	Complications	0.365	0.274	0.172	0.103	0.100
1100217	Chronic Ulcer of Skin, Except	1.070	1.705	1.740	1 715	1.715
HCC217 HCC218	Pressure Extensive Third Degree Burns	1.879 18.976	1.795 18.728	1.748 18.594	1.715 18.523	1.715 18.521
HCC218	Major Skin Burn or Condition	2.884	2.767	2.683	2.612	2.609
HCC223	Severe Head Injury	15.439	15.331	15.260	15.212	15.210
HCC226	Hip and Pelvic Fractures	8.537	8.317	8.230	8.224	8.225
	Vertebral Fractures without Spinal					
HCC228	Cord Injury	4.959	4.798	4.692	4.599	4.596
	Traumatic Amputations and					
HCC234	Amputation Complications	5.447	5.311	5.259	5.255	5.256
	Stem Cell, Including Bone Marrow,					
HCC251	Transplant Status/Complications	25.813	25.812	25.822	25.845	25.846
1100252	Artificial Openings for Feeding or	7.205	7.240	7 220	7.250	7.250
HCC253	Elimination Amputation Status, Upper Limb or	7.305	7.240	7.229	7.258	7.259
HCC254	Lower Limb	1.987	1.884	1.830	1.795	1.795
1100234		verity Factor	CONTRACTOR STATE AND ADDRESS OF THE PARTY OF	1.030	1.793	1.795
SEVERE x	Severe illness x Opportunistic	verity ractor	3			
HCC006	Infections	6.236	6.388	6.514	6.663	6.667
SEVERE x	micetions	0.230	0.500	0.511	0.005	0.007
HCC008	Severe illness x Metastatic Cancer	6.236	6.388	6.514	6.663	6.667
	Severe illness x Lung, Brain, and					
SEVERE x	Other Severe Cancers, Including					
HCC009	Pediatric Acute Lymphoid Leukemia	6.236	6.388	6.514	6.663	6.667
	Severe illness x Non-Hodgkin					
SEVERE x	Lymphomas and Other Cancers and	6.226	C 200	6.514	6.662	6.667
HCC010	Tumors Severe illness x Myasthenia	6.236	6.388	6.514	6.663	6.667
	Gravis/Myoneural Disorders and					
	Guillain-Barre					
SEVERE x	Syndrome/Inflammatory and Toxic					
HCC115	Neuropathy	6.236	6.388	6.514	6.663	6.667
	Severe illness x Heart					
SEVERE x	Infection/Inflammation, Except					
HCC135	Rheumatic	6.236	6.388	6.514	6.663	6.667
SEVERE x	Severe illness x Intracranial	(22 (<i>(</i> 200	6.514		6.667
HCC145	Hemorrhage Severe illness x HCC group G06A	6.236	6.388	6.514	6.663	6.667
	(HCC 67 Myelodysplastic Syndromes					
	and Myelofibrosis or HCC 68 Aplastic					
	Anemia or HCC 69 Acquired					
SEVERE x	Hemolytic Anemia, Including					
G06A	Hemolytic Disease of Newborn)	6.236	6.388	6.514	6.663	6.667
	Severe illness x HCC group G08					
	(HCC 73 Combined and Other Severe					
SEVERE x	Immunodeficiencies or HCC 74	(22 ((200	(514	(((2)	
G08	Disorders of the Immune Mechanism)	6.236	6.388	6.514	6.663	6.667
		ent Duration		0.007	L 0.100	0.100
	1 month of enrollment	0.275	0.226	0.207	0.188	0.188
	2 months of enrollment 3 months of enrollment	0.260 0.277	0.210 0.224	0.190 0.199	0.175 0.184	0.175
	4 months of enrollment	0.277	0.224	0.199	0.184	0.183 0.136
	5 months of enrollment	0.217	0.171	0.148	0.136	0.136
	6 months of enrollment	0.203	0.102	0.113	0.102	0.127
<u> </u>	5 mondo of emornion	V.170	V.12 I	0.115	0.102	0.101

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
	7 months of enrollment	0.128	0.101	0.084	0.074	0.074
	8 months of enrollment	0.088	0.069	0.055	0.048	0.048
	9 months of enrollment	0.049	0.036	0.027	0.021	0.021
	10 months of enrollment	0.004	0.001	0.000	0.000	0.000
	11 months of enrollment	0.001	0.000	0.000	0.000	0.000
	Presci	iption Drug	Factors			
RXC 01	Anti-HIV Agents	8.719	8.138	7.742	7.323	7.313
RXC 02	Anti-Hepatitis C (HCV) Agents,					
	Direct Acting Agents	6.743	6.306	6.111	6.038	6.042
RXC 03	Antiarrhythmics	0.113	0.103	0.100	0.067	0.049
RXC 04	Phosphate Binders	2.045	2.052	2.043	1.988	1.911
RXC 05	Inflammatory Bowel Disease Agents	1.805	1.670	1.528	1.322	1.314
RXC 06	Insulin	1.626	1.437	1.238	1.043	1.035
RXC 07	Anti-Diabetic Agents, Except Insulin					
	and Metformin Only	0.785	0.676	0.555	0.397	0.391
RXC 08	Multiple Sclerosis Agents	23.781	22.923	22.485	22.214	22.215
RXC 09	Immune Suppressants and					
	Immunomodulators **	17.156	16.639	16.445	16.445	16.448
RXC 10	Cystic Fibrosis Agents	17.920	17.605	17.496	17.496	17.499
RXC 01 x	Additional effect for enrollees with					
HCC001	RXC 01 and HCC 001	2.213	2.397	2.671	3.133	3.148
RXC 02 x						
HCC037 1,	Additional effect for enrollees with					
036, 035 2,	RXC 02 and (HCC 037_1 or 036 or					
035_1, 34	035_2 or 035_1 or 034)	-0.658	-0.550	-0.444	-0.312	-0.308
RXC 03 x	Additional effect for enrollees with					
HCC142	RXC 03 and HCC 142	0.000	0.000	0.000	0.000	0.000
RXC 04 x						
HCC184,	Additional effect for enrollees with					
183, 187,	RXC 04 and (HCC 184 or 183 or 187					
188	or 188)	0.000	0.000	0.000	0.000	0.000
RXC 05 x						
HCC048,	Additional effect for enrollees with					
041	RXC 05 and (HCC 048 or 041)	-0.374	-0.313	-0.248	-0.170	-0.167
RXC 06 x						
HCC018,	Additional effect for enrollees with					
019, 020,	RXC 06 and (HCC 018 or 019 or 020					
021	or 021)	0.214	0.281	0.371	0.401	0.404
RXC 07 x						
HCC018,	Additional effect for enrollees with					
019, 020,	RXC 07 and (HCC 018 or 019 or 020	0.427	0.250	0.200	0.242	0.240
021	or 021)	-0.427	-0.359	-0.299	-0.243	-0.240
RXC 08 x	Additional effect for enrollees with	0.256	0.207	0.550	0.020	0.044
HCC118	RXC 08 and HCC 118	-0.256	0.207	0.550	0.938	0.944
RXC 09 x	A 11:4: 1 - CC 4 C					
HCC056 or 057 and 048	Additional effect for enrollees with RXC 09 and (HCC 048 or 041) and					
	· · · · · · · · · · · · · · · · · · ·	0.850	0.080	1.000	1 220	1 224
or 041 RXC 09 x	(HCC 056 or 057) Additional effect for enrollees with	0.859	0.989	1.098	1.229	1.234
HCC056	RXC 09 and HCC 056	-1.372	-1.265	-1.169	-1.076	1.072
RXC 09 x	Additional effect for enrollees with	-1.3/4	-1.203	-1.109	-1.070	-1.072
HCC057	RXC 09 and HCC 057	-0.658	-0.562	-0.457	-0.334	-0.330
RXC 09 x	KAC 09 and field 03/	-0.038	-0.362	-0.43/	-0.334	-0.330
HCC048,	Additional effect for enrollees with					
041	RXC 09 and (HCC 048 or 041)	-0.250	-0.202	-0.156	-0.098	-0.096
V 4 1	KAC 03 and (TICC 048 01 041)	-0.230	-0.202	-0.130	-0.098	-0.090

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
RXC 10 x						
HCC159,	Additional effect for enrollees with					
158	RXC 10 and (HCC 159 or 158)	47.572	47.627	47.694	47.819	47.822

^{*} HCC numbers that appear with an underscore in this document will appear without the underscore in the DIY software. For example, HCC 35_1 in this table will appear as HCC 351 in the DIY software.

TABLE 2: HHS HCCs in the Adult Model Severity Illness Indicator Variables

HCC No.	Factor
HCC002	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock
HCC042	Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis
HCC120	Seizure Disorders and Convulsions
HCC122	Coma, Brain Compression/Anoxic Damage
HCC125	Respirator Dependence/Tracheostomy Status
HCC126	Respiratory Arrest
HCC127	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes
HCC156	Pulmonary Embolism and Deep Vein Thrombosis

^{*} This table contains the same list of HCCs that applied to the severity factors in the 2020 and 2021 benefit years. See, for example, Table 2 in the 2020 Payment Notice, 84 FR 17454 at 17474. The table was inadvertently not published in the final 2021 benefit year risk adjustment model coefficients document. As such, the same list of HCCs that will apply to the severity factors for the 2022 benefit year applied in the 2020 and 2021 benefit years.

^{**} The coefficients for RXC 09 Immune Suppressants and Immunomodulators, the HCC factors relevant for RXC 09 (HCC041, HCC048, HCC056, HCC057), and the related RXC 09 interactions (RXC 09 x HCC056 or 057 and 048 or 041; RXC 09 x HCC056; RXC 09 x HCC057; RXC 09 x HCC048, 041) result from the equally weighted (averaged) blended factors from separately solved models using only the 2016 and 2017 enrollee-level EDGE data and are otherwise consistent with the policies finalized in this rulemaking. See the preamble discussion that follows for more details.

TABLE 3: Child Risk Adjustment Model Factors for 2022 Benefit Year

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Pactor			Silver	Bronze	Catastropine
	Demographic	Factors			
Age 2-4, Male	0.230	0.162	0.112	0.073	0.072
Age 5-9, Male	0.170	0.112	0.071	0.045	0.044
Age 10-14, Male	0.203	0.143	0.099	0.072	0.071
Age 15-20, Male	0.243	0.179	0.126	0.087	0.086
Age 2-4, Female	0.177	0.118	0.079	0.051	0.050
Age 5-9, Female	0.122	0.070	0.037	0.016	0.015
Age 10-14, Female	0.191	0.134	0.092	0.068	0.067
Age 15-20, Female	0.265	0.187	0.122	0.073	0.071
	Diagnosis Fac	ctors			
HIV/AIDS	5.846	5.446	5.222	5.058	5.054
Septicemia, Sepsis, Systemic Inflammatory					
Response Syndrome/Shock	13.076	12.930	12.869	12.835	12.836
Central Nervous System Infections, Except					
Viral Meningitis	8.033	7.897	7.841	7.828	7.829
Viral or Unspecified Meningitis	2.626	2.467	2.337	2.169	2.164
Opportunistic Infections	14.919	14.904	14.887	14.864	14.863
Metastatic Cancer	35.966	35.740	35.635	35.613	35.613
Lung, Brain, and Other Severe Cancers,					
Including Pediatric Acute Lymphoid					
Leukemia	9.220	8.990	8.841	8.727	8.723
Non-Hodgkin Lymphomas and Other Cancers					
and Tumors	7.178	6.963	6.810	6.674	6.670
Colorectal, Breast (Age < 50), Kidney, and					
Other Cancers	4.342	4.197	4.079	3.955	3.950
Breast (Age 50+) and Prostate Cancer,					
Benign/Uncertain Brain Tumors, and Other	1 242	4.105	4.050	2.055	2.050
Cancers and Tumors	4.342	4.197	4.079	3.955	3.950
Thyroid Cancer, Melanoma,					
Neurofibromatosis, and Other Cancers and	0.024	0.000	0.700	0.570	0.575
Tumors Panaman Transplant Status	0.924 8.841	0.809	0.700	0.579	0.575
Pancreas Transplant Status Diabetes with Acute Complications	2.612	8.686	8.586	8.485 1.805	8.483
Diabetes with Acute Complications Diabetes with Chronic Complications		2.363	2.134		1.795
Diabetes with Chrome Complications Diabetes without Complication	2.612 2.612	2.363 2.363	2.134 2.134	1.805 1.805	1.795 1.795
Protein-Calorie Malnutrition	13.566	13.485	13.464	13.485	13.486
Mucopolysaccharidosis	39.839	39.617	39.513	39.472	39.471
Lipidoses and Glycogenosis	39.839	39.617	39.513	1	39.471
Congenital Metabolic Disorders, Not	39.839	39.017	39.313	39.472	39.471
Elsewhere Classified	5.822	5.719	5.642	5.576	5.573
Amyloidosis, Porphyria, and Other Metabolic	3.622	3.719	3.042	3.370	3.373
Disorders	5.822	5.719	5.642	5.576	5.573
Adrenal, Pituitary, and Other Significant	3.022	3.719	3.042	3.370	3.373
Endocrine Disorders	6.837	6.621	6.500	6.442	6.440
Liver Transplant Status/Complications	8.841	8.686	8.586	8.485	8.483
Acute Liver Failure/Disease, Including	0.041	0.000	0.500	0.403	0.405
Neonatal Hepatitis	17.574	17.546	17.579	17.664	17.668
Chronic Liver Failure/End-Stage Liver	1,.5,1	17.510	11.517	17.007	17.000
Disorders	13.757	13.669	13.631	13.602	13.601
Cirrhosis of Liver	4.121	4.067	4.026	3.972	3.974
Chronic Viral Hepatitis C	2.621	2.479	2.402	2.390	2.391
Chronic Hepatitis, Except Chronic Viral	2.021	2.112	2.102	2.570	2.571
Hepatitis C	0.132	0.091	0.054	0.016	0.015
Intestine Transplant Status/Complications	16.842	16.819	16.822	16.830	16.829

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Peritonitis/Gastrointestinal					
Perforation/Necrotizing Enterocolitis	11.679	11.439	11.329	11.294	11.295
Intestinal Obstruction	5.173	5.010	4.892	4.779	4.775
Chronic Pancreatitis	12.085	11.919	11.851	11.844	11.845
Acute Pancreatitis	7.147	6.966	6.850	6.733	6.731
Inflammatory Bowel Disease	9.151	8.799	8.595	8.441	8.437
Necrotizing Fasciitis	3.587	3.403	3.278	3.181	3.178
Bone/Joint/Muscle Infections/Necrosis	3.587	3.403	3.278	3.181	3.178
Rheumatoid Arthritis and Specified					
Autoimmune Disorders	5.087	4.860	4.711	4.609	4.606
Systemic Lupus Erythematosus and Other					
Autoimmune Disorders	0.678	0.566	0.450	0.321	0.316
Osteogenesis Imperfecta and Other					
Osteodystrophies	1.313	1.210	1.124	1.042	1.039
Congenital/Developmental Skeletal and					
Connective Tissue Disorders	1.313	1.210	1.124	1.042	1.039
Cleft Lip/Cleft Palate	1.185	1.042	0.922	0.789	0.784
Hemophilia	71.879	71.450	71.242	71.155	71.154
Myelodysplastic Syndromes and					
Myelofibrosis	15.280	15.144	15.071	15.026	15.025
Aplastic Anemia	15.280	15.144	15.071	15.026	15.025
Acquired Hemolytic Anemia, Including					
Hemolytic Disease of Newborn	15.280	15.144	15.071	15.026	15.025
Sickle Cell Anemia (Hb-SS)	5.410	5.204	5.058	4.935	4.931
Beta Thalassemia Major	5.410	5.204	5.058	4.935	4.931
Combined and Other Severe					
Immunodeficiencies	5.839	5.714	5.636	5.578	5.576
Disorders of the Immune Mechanism	5.839	5.714	5.636	5.578	5.576
Coagulation Defects and Other Specified					
Hematological Disorders	4.605	4.499	4.413	4.331	4.329
Drug Use with Psychotic Complications	2.924	2.758	2.632	2.496	2.491
Drug Use Disorder, Moderate/Severe, or Drug					
Use with Non-Psychotic Complications	2.924	2.758	2.632	2.496	2.491
Alcohol Use with Psychotic Complications	1.113	0.972	0.844	0.716	0.712
Alcohol Use Disorder, Moderate/Severe, or					
Alcohol Use with Specified Non-Psychotic					
Complications	1.113	0.972	0.844	0.716	0.712
Schizophrenia	4.606	4.331	4.146	3.976	3.970
Delusional and Other Specified Psychotic					
Disorders, Unspecified Psychosis	3.008	2.800	2.630	2.454	2.448
Major Depressive Disorder, Severe, and					
Bipolar Disorders	2.668	2.474	2.307	2.135	2.128
Personality Disorders	0.452	0.356	0.244	0.126	0.121
Anorexia/Bulimia Nervosa	2.154	1.987	1.858	1.740	1.736
Prader-Willi, Patau, Edwards, and Autosomal					
Deletion Syndromes	1.637	1.531	1.457	1.379	1.376
Down Syndrome, Fragile X, Other					
Chromosomal Anomalies, and Congenital					
Malformation Syndromes	1.447	1.334	1.245	1.151	1.148
Autistic Disorder	2.668	2.474	2.307	2.135	2.128
Pervasive Developmental Disorders, Except					
Autistic Disorder	0.457	0.369	0.267	0.166	0.162
Traumatic Complete Lesion Cervical Spinal					
Cord	11.900	11.756	11.694	11.680	11.681
Quadriplegia	11.900	11.756	11.694	11.680	11.681
Traumatic Complete Lesion Dorsal Spinal	3 3				
Cord	8.823	8.627	8.523	8.442	8.440

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Paraplegia	8.823	8.627	8.523	8.442	8.440
Spinal Cord Disorders/Injuries	3.939	3.770	3.640	3.514	3.509
Amyotrophic Lateral Sclerosis and Other					
Anterior Horn Cell Disease	31.125	30.906	30.769	30.671	30.669
Quadriplegic Cerebral Palsy	3.767	3.620	3.568	3.551	3.553
Cerebral Palsy, Except Quadriplegic	0.599	0.481	0.379	0.257	0.252
Spina Bifida and Other Brain/Spinal/Nervous					
System Congenital Anomalies	2.207	2.103	2.029	1.960	1.957
Myasthenia Gravis/Myoneural Disorders and					
Guillain-Barre Syndrome/Inflammatory and					
Toxic Neuropathy	11.008	10.884	10.839	10.844	10.845
Muscular Dystrophy	4.534	4.387	4.277	4.164	4.161
Multiple Sclerosis	12.970	12.611	12.453	12.402	12.402
Parkinson's, Huntington's, and Spinocerebellar					
Disease, and Other Neurodegenerative	4.524	4.207	4.077	4.164	4.161
Disorders	4.534	4.387	4.277	4.164	4.161
Seizure Disorders and Convulsions	2.113	1.977	1.844	1.705	1.699
Hydrocephalus	4.439	4.348	4.290	4.251	4.250
Coma, Brain Compression/Anoxic Damage	4.611	4.505	4.439	4.386	4.385
Narcolepsy and Cataplexy	5.128	4.967	4.827	4.671	4.664
Respirator Dependence/Tracheostomy Status	31.476	31.422	31.478	31.622	31.628
Respiratory Arrest	10.252	10.067	9.988	9.945	9.946
Cardio-Respiratory Failure and Shock,	10.252	10.067	0.000	0.045	0.046
Including Respiratory Distress Syndromes	10.252	10.067	9.988	9.945	9.946
Heart Assistive Device/Artificial Heart	16.842	16.819	16.822	16.830	16.829
Heart Transplant Status/Complications	16.842	16.819	16.822	16.830	16.829
Heart Failure	6.072	5.984	5.925	5.881	5.879
Acute Myocardial Infarction	2.568	2.506	2.484	2.472	2.473
Unstable Angina and Other Acute Ischemic	2.569	2.506	2.494	2.472	2.472
Heart Disease Heart Infection/Inflammation, Except	2.568	2.506	2.484	2.472	2.473
Rheumatic Rheumatic	11.667	11.585	11.544	11.523	11.522
Hypoplastic Left Heart Syndrome and Other	11.007	11.363	11.544	11.525	11.322
Severe Congenital Heart Disorders	3.945	3.787	3.648	3.536	3.532
Major Congenital Heart/Circulatory Disorders	1.238	1.131	1.010	0.907	0.903
Atrial and Ventricular Septal Defects, Patent	1.236	1.131	1.010	0.907	0.903
Ductus Arteriosus, and Other Congenital					
Heart/Circulatory Disorders	0.750	0.653	0.558	0.481	0.479
Specified Heart Arrhythmias	3.495	3.352	3.245	3.157	3.154
Intracranial Hemorrhage	9.192	9.061	9.001	8.970	8.969
Ischemic or Unspecified Stroke	2.749	2.696	2.677	2.666	2.667
Cerebral Aneurysm and Arteriovenous	_,,,,,				
Malformation	3.235	3.082	2.980	2.885	2.881
Hemiplegia/Hemiparesis	6.650	6.551	6.492	6.441	6.439
Monoplegia, Other Paralytic Syndromes	4.100	3.979	3.898	3.817	3.813
Atherosclerosis of the Extremities with					
Ulceration or Gangrene	12.487	12.317	12.221	12.151	12.150
Vascular Disease with Complications	10.670	10.600	10.582	10.602	10.604
Pulmonary Embolism and Deep Vein					
Thrombosis	16.697	16.623	16.602	16.606	16.607
Lung Transplant Status/Complications	16.842	16.819	16.822	16.830	16.829
Cystic Fibrosis	48.890	48.432	48.224	48.173	48.173
Chronic Obstructive Pulmonary Disease,					
Including Bronchiectasis	2.923	2.793	2.682	2.564	2.561
Severe Asthma	0.807	0.642	0.473	0.284	0.277
Asthma, Except Severe	0.326	0.244	0.155	0.081	0.078
Fibrosis of Lung and Other Lung Disorders	1.481	1.388	1.299	1.221	1.218

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Aspiration and Specified Bacterial					
Pneumonias and Other Severe Lung Infections	6.551	6.508	6.495	6.508	6.509
Kidney Transplant Status/Complications	8.841	8.686	8.586	8.485	8.483
End Stage Renal Disease	41.577	41.472	41.473	41.558	41.561
Chronic Kidney Disease, Stage 5	4.600	4.492	4.394	4.283	4.279
Chronic Kidney Disease, Severe (Stage 4)	4.600	4.492	4.394	4.283	4.279
Ectopic and Molar Pregnancy	1.923	1.710	1.517	1.269	1.263
Miscarriage with Complications	0.748	0.621	0.449	0.237	0.227
Miscarriage with No or Minor Complications	0.748	0.621	0.449	0.237	0.227
Pregnancy with Delivery with Major					
Complications	3.475	3.173	2.908	2.463	2.447
Pregnancy with Delivery with Complications	3.475	3.173	2.908	2.463	2.447
Pregnancy with Delivery with No or Minor					
Complications	2.381	2.158	1.902	1.424	1.402
(Ongoing) Pregnancy without Delivery with					
Major Complications	0.695	0.548	0.358	0.177	0.172
(Ongoing) Pregnancy without Delivery with					
Complications	0.695	0.548	0.358	0.177	0.172
(Ongoing) Pregnancy without Delivery with					
No or Minor Complications	0.349	0.244	0.120	0.014	0.011
Chronic Ulcer of Skin, Except Pressure	2.815	2.721	2.638	2.567	2.565
Extensive Third Degree Burns	16.569	16.375	16.274	16.231	16.229
Major Skin Burn or Condition	2.060	1.921	1.808	1.694	1.690
Severe Head Injury	16.569	16.375	16.274	16.231	16.229
Hip and Pelvic Fractures	4.530	4.320	4.167	4.054	4.052
Vertebral Fractures without Spinal Cord					
Injury	3.934	3.751	3.603	3.446	3.440
Traumatic Amputations and Amputation					
Complications	4.758	4.565	4.430	4.284	4.279
Stem Cell, Including Bone Marrow,					
Transplant Status/Complications	16.842	16.819	16.822	16.830	16.829
Artificial Openings for Feeding or Elimination	10.291	10.196	10.202	10.268	10.272
Amputation Status, Upper Limb or Lower					
Limb	4.758	4.565	4.430	4.284	4.279

TABLE 4: Infant Risk Adjustment Model Factors for 2022 Benefit Year

TADLE 4. Illiant Kisk Auju	stillent wiot	ter i actors	TOT BUBB D	chem i	Jet 1
Group	Platinum	Gold	Silver	Bronze	Catastrophic
Extremely Immature * Severity Level 5	Ì				
(Highest)	219.854	218.550	217.927	217.743	217.744
Extremely Immature * Severity Level 4	142.713	141.194	140.396	140.023	140.018
Extremely Immature * Severity Level 3	32.417	31.185	30.495	30.117	30.109
Extremely Immature * Severity Level 2	32.417	31.185	30.495	30.117	30.109
Extremely Immature * Severity Level 1					
(Lowest)	32.417	31.185	30.495	30.117	30.109
Immature * Severity Level 5 (Highest)	130.150	128.727	128.031	127.783	127.781
Immature * Severity Level 4	68.882	67.469	66.748	66.449	66.443
Immature * Severity Level 3	32.417	31.185	30.495	30.117	30.109
Immature * Severity Level 2	25.400	24.244	23.568	23.149	23.138
Immature * Severity Level 1 (Lowest)	25.400	24.244	23.568	23.149	23.138
Premature/Multiples * Severity Level 5					
(Highest)	107.912	106.702	106.087	105.833	105.828
Premature/Multiples * Severity Level 4	28.422	27.186	26.499	26.110	26.103
Premature/Multiples * Severity Level 3	14.035	13.101	12.435	11.838	11.817
Premature/Multiples * Severity Level 2	7.977	7.290	6.663	5.951	5.922
Premature/Multiples * Severity Level 1					
(Lowest)	5.674	5.092	4.517	3.966	3.945
Term * Severity Level 5 (Highest)	81.816	80.759	80.174	79.859	79.852
Term * Severity Level 4	15.824	14.941	14.315	13.754	13.738
Term * Severity Level 3	5.991	5.423	4.855	4.253	4.230
Term * Severity Level 2	3.567	3.090	2.524	1.922	1.897
Term * Severity Level 1 (Lowest)	1.808	1.450	1.001	0.720	0.710
Age1 * Severity Level 5 (Highest)	62.403	61.770	61.417	61.239	61.234
Age1 * Severity Level 4	12.415	11.949	11.629	11.372	11.364
Age1 * Severity Level 3	3.129	2.858	2.629	2.433	2.426
Age1 * Severity Level 2	1.972	1.743	1.522	1.314	1.306
Age1 * Severity Level 1 (Lowest)	0.571	0.494	0.441	0.403	0.402
Age 0 Male	0.606	0.567	0.529	0.460	0.457
Age 1 Male	0.103	0.086	0.069	0.050	0.049

TABLE 5: HHS HCCs Included in Infant Model Maturity Categories

Maturity Category	HCC/Description
Extremely Immature	Extremely Immature Newborns, Birth weight < 500 Grams
Extremely Immature	Extremely Immature Newborns, Including Birth weight 500-749 Grams
Extremely Immature	Extremely Immature Newborns, Including Birth weight 750-999 Grams
Immature	Premature Newborns, Including Birth weight 1000-1499 Grams
Immature	Premature Newborns, Including Birth weight 1500-1999 Grams
Premature/Multiples	Premature Newborns, Including Birth weight 2000-2499 Grams
Premature/Multiples	Other Premature, Low Birth weight, Malnourished, or Multiple Birth Newborns
Term	Term or Post-Term Singleton Newborn, Normal or High Birth weight
Age 1	All age 1 infants

TABLE 6: HHS HCCs Included in Infant Model Severity Categories

Severity Category	HCC/Description
Severity Level 5 (Highest)	Metastatic Cancer
Severity Level 5	Pancreas Transplant Status
Severity Level 5	Liver Transplant Status/Complications
Severity Level 5	Intestine Transplant Status/Complications
Severity Level 5	Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis
Severity Level 5	Respirator Dependence/Tracheostomy Status
Severity Level 5	Heart Assistive Device/Artificial Heart
Severity Level 5	Heart Transplant Status/Complications
Severity Level 5	Heart Failure
Severity Level 5	Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders
Severity Level 5	Lung Transplant Status/Complications
Severity Level 5	Kidney Transplant Status/Complications
Severity Level 5	End Stage Renal Disease
Severity Level 5	Stem Cell, Including Bone Marrow, Transplant Status/Complications
Severity Level 4	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock
Severity Level 4	Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia
Severity Level 4	Mucopolysaccharidosis
Severity Level 4	Adrenal, Pituitary, and Other Significant Endocrine Disorders
Severity Level 4	Acute Liver Failure/Disease, Including Neonatal Hepatitis
Severity Level 4	Chronic Liver Failure/End-Stage Liver Disorders
Severity Level 4	Major Congenital Anomalies of Diaphragm, Abdominal Wall, and Esophagus, Age < 2
Severity Level 4	Myelodysplastic Syndromes and Myelofibrosis
Severity Level 4	Aplastic Anemia
Severity Level 4	Combined and Other Severe Immunodeficiencies
Severity Level 4	Traumatic Complete Lesion Cervical Spinal Cord
Severity Level 4	Quadriplegia
Severity Level 4	Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease
Severity Level 4	Quadriplegic Cerebral Palsy
Severity Level 4	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory
	and Toxic Neuropathy
Severity Level 4	Coma, Brain Compression/Anoxic Damage
Severity Level 4	Respiratory Arrest
Severity Level 4	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes
Severity Level 4	Acute Myocardial Infarction
Severity Level 4	Heart Infection/Inflammation, Except Rheumatic
Severity Level 4	Major Congenital Heart/Circulatory Disorders
Severity Level 4	Intracranial Hemorrhage
Severity Level 4	Ischemic or Unspecified Stroke
Severity Level 4	Vascular Disease with Complications
Severity Level 4	Pulmonary Embolism and Deep Vein Thrombosis
Severity Level 4	Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections
Severity Level 4	Chronic Kidney Disease, Stage 5
Severity Level 4	Artificial Openings for Feeding or Elimination
Severity Level 3	HIV/AIDS Control Nameous System Infactions Expant Vival Manipoitis
Severity Level 3	Central Nervous System Infections, Except Viral Meningitis
Severity Level 3 Severity Level 3	Opportunistic Infections Non-Hodgkin Lymphomas and Other Cancers and Tumors
Severity Level 3	Colorectal, Breast (Age < 50), Kidney and Other Cancers
Severity Level 3	Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other
<u> </u>	Cancers and Tumors
Severity Level 3	Lipidoses and Glycogenosis
Severity Level 3	Intestinal Obstruction
Severity Level 3	Necrotizing Fasciitis
Severity Level 3	Bone/Joint/Muscle Infections/Necrosis
Severity Level 3	Osteogenesis Imperfecta and Other Osteodystrophies
Severity Level 3	Cleft Lip/Cleft Palate

Severity Category	HCC/Description
Severity Category Severity Level 3	Hemophilia
Severity Level 3	Disorders of the Immune Mechanism
Severity Level 3	Coagulation Defects and Other Specified Hematological Disorders
Severity Level 3	Drug Use with Psychotic Complications
Severity Level 3	Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications
Severity Level 3	Alcohol Use with Psychotic Complications
•	Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic
Severity Level 3	Complications
Severity Level 3	Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes
Severity Level 3	Traumatic Complete Lesion Dorsal Spinal Cord
Severity Level 3	Paraplegia
Severity Level 3	Spinal Cord Disorders/Injuries
Severity Level 3	Cerebral Palsy, Except Quadriplegic
Severity Level 3	Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies
Severity Level 3	Muscular Dystrophy
Severity Level 3	Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative
•	Disorders
Severity Level 3	Hydrocephalus
Severity Level 3	Unstable Angina and Other Acute Ischemic Heart Disease
Severity Level 3	Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital
-	Heart/Circulatory Disorders
Severity Level 3	Specified Heart Arrhythmias
Severity Level 3	Cerebral Aneurysm and Arteriovenous Malformation
Severity Level 3	Hemiplegia/Hemiparesis
Severity Level 3	Cystic Fibrosis
Severity Level 3	Extensive Third Degree Burns
Severity Level 3	Severe Head Injury
Severity Level 3	Hip and Pelvic Fractures
Severity Level 3	Vertebral Fractures without Spinal Cord Injury
Severity Level 2	Viral or Unspecified Meningitis
Severity Level 2	Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors
Severity Level 2 Severity Level 2	Diabetes with Acute Complications Diabetes with Chronic Complications
Severity Level 2	Diabetes with Chronic Complications Diabetes without Complication
Severity Level 2	Protein-Calorie Malnutrition
Severity Level 2	Congenital Metabolic Disorders, Not Elsewhere Classified
Severity Level 2	Amyloidosis, Porphyria, and Other Metabolic Disorders
Severity Level 2	Cirrhosis of Liver
Severity Level 2	Chronic Pancreatitis
Severity Level 2	Acute Pancreatitis
Severity Level 2	Inflammatory Bowel Disease
Severity Level 2	Rheumatoid Arthritis and Specified Autoimmune Disorders
Severity Level 2	Systemic Lupus Erythematosus and Other Autoimmune Disorders
Severity Level 2	Congenital/Developmental Skeletal and Connective Tissue Disorders
Severity Level 2	Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn
Severity Level 2	Sickle Cell Anemia (Hb-SS)
•	Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital
Severity Level 2	Malformation Syndromes
Severity Level 2	Seizure Disorders and Convulsions
Severity Level 2	Monoplegia, Other Paralytic Syndromes
Severity Level 2	Atherosclerosis of the Extremities with Ulceration or Gangrene
Severity Level 2	Chronic Obstructive Pulmonary Disease, Including Bronchiectasis
Severity Level 2	Severe Asthma
Severity Level 2	Fibrosis of Lung and Other Lung Disorders
Severity Level 2	Chronic Kidney Disease, Severe (Stage 4)
Severity Level 2	Chronic Ulcer of Skin, Except Pressure
Severity Level 2	Major Skin Burn or Condition

Severity Category	HCC/Description
Severity Level 1 (Lowest)	Chronic Viral Hepatitis C
Severity Level 1	Chronic Hepatitis, Except Chronic Viral Hepatitis C
Severity Level 1	Beta Thalassemia Major
Severity Level 1	Autistic Disorder
Severity Level 1	Pervasive Developmental Disorders, Except Autistic Disorder
Severity Level 1	Multiple Sclerosis
Severity Level 1	Asthma, Except Severe
Severity Level 1	Traumatic Amputations and Amputation Complications
Severity Level 1	Amputation Status, Upper Limb or Lower Limb

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We received public comments on the proposed list of factors to be employed in the 2022 benefit year risk adjustment models (§ 153.320). The following is a summary of the comments on these proposals and our responses.

Comment: A few commenters expressed concerns that the HCC coefficients in the list of factors would adversely affect individuals with preexisting conditions or diagnosed disabilities. One of these commenters was also concerned with the gender differences in the list of factors.

Response: The list of factors for the adult, child, and infant risk adjustment models include the coefficients in the statistical models developed by HHS to predict the plan liability for an average enrollee based on demographics, diagnosed conditions (grouped into HCCs), enrollment duration (for the adult models), and prescription drugs (for the adult models). The list of factors represents the different levels of risk plans take on in providing health coverage to enrollees. These factors do not affect enrollee costs and therefore do not adversely affect any consumers, including individuals with preexisting conditions or diagnosed disabilities or based on gender. Rather, the purpose of the risk adjustment program is to transfer funds from risk adjustment covered plans with lower than average risk to risk adjustment covered plans with higher than average risk, with the goal of minimizing adverse selection and providing coverage to all consumers. Therefore, these factors actually help individuals with preexisting conditions or diagnosed disabilities through compensating plans more for more severe conditions, incentivizing plans to cover such individuals rather than avoid covering them. In addition, gender differences in the list of factors that will be used for the HHS risk adjustment models do not result in differences in premium paid by male and female enrollees.⁶⁸ Rather, the

 $^{68}\,\rm Section~2701$ of the PHS Act prohibits issuers of non-grandfathered coverage in the individual and

different age-sex factors represent differences in the level of risk plans take on in providing coverage to men and women; for example, adult women within childbearing years tend to cost more than men of the same age due to pregnancy and childbirth.

Comment: A few commenters made suggestions for additions to or deletions from the list of factors. These commenters asked that HHS not include acute, unpredictable HCCs in the list of factors, such as the severe head injury and extensive third degree burns HCCs, as these conditions do not differentiate adverse selection risk. One of these commenters asked that HHS bifurcate transplant status codes into a set of coefficients for transplant procedure codes and another set of coefficients for transplant history or status. Another commenter suggested that HHS simplify the risk adjustment models by combining coefficients for HCCs where similar risk selection patterns would result in minimal member-level prediction improvements when risk scores are averaged at the plan level to calculate the plan liability risk score.

Response: We continue to believe that the acute conditions identified by these commenters (severe head injury and extensive third degree burns) should be included in the risk adjustment models. We detailed our consideration of incorporating these HCCs in the risk adjustment models in the paper on the Potential Updates to HHS–HCCs for the HHS-operated Risk Adjustment Program. ⁶⁹ For example, we explained that severe head injury represents a condition with ongoing care costs, similar to other injury HCCs currently

included in the V05 models 70 (for example, hip fractures and vertebral fractures). Stakeholders also had an opportunity to comment on the addition of these HCCs as part of the 2021 Payment Notice rulemaking.⁷¹ Based on our analysis, these conditions indicate the presence of underlying chronic conditions and frailty, were underpredicted in the risk adjustment models, and have high costs in the year after the diagnosis.⁷² Therefore, we do not agree that the HCCs for severe head injury and extensive third degree burns do not differentiate adverse selection risk, and we believe they are appropriate to include in the risk adjustment models, as previously stated in the 2021 Payment Notice final rule.⁷³ There is evidence of ongoing chronic costs associated with these conditions, and issuers can potentially adversely select against enrollees with a higher risk of incurring costs related to these conditions in a given benefit year. Isolating and omitting the near-term ongoing costs for these conditions would reduce the predictive accuracy of the model without any benefit in reduced model complexity, as the costs for the excluded near-term codes would end up in the associated longer term HCCs. The ability to separate costs associated with the acute event and chronic conditions can be complex for certain HCCs, including severe head injury, extensive third degree burns, and transplants. We also believe that by including the acute costs for these conditions, we are also accounting for the ongoing costs of care during the first year. The continued inclusion of these HCCs in the risk adjustment models, as proposed, is consistent with our goals to improve model prediction and identify chronic or systematic conditions that represent insurance risk selection or risk

small group markets from varying rates with respect to any characteristic aside from whether the plan covers an individual or a family, rating area, age, and tobacco use. Therefore, those four factors held constant, female enrollees cannot be charged higher premiums than male enrollees, and vice versa, for the same plan.

⁶⁹ Potential Updates to HHS-HCCs for the HHS-operated Risk Adjustment Program. June 17, 2019. Available at https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Potential-Updates-to-HHS-HCCs-HHS-operated-Risk-Adjustment-Program.pdf.

⁷⁰ The shorthand "V05" refers to the HHS–HCC classification for the HHS risk adjustment models that applies through the 2020 benefit year.

 $^{^{71}\,85}$ FR 7088 at 7098 through 7101. Also see 85 FR 29164 at 29181.

^{72 85} FR 29164 at 29181.

^{73 85} FR 29164 at 29181.

segmentation. In addition, both of these HCCs—extensive third degree burns and severe head injury—are also payment HCCs in Medicare's CMS-HCC models. As for transplant procedure versus transplant status, we do not currently use procedure codes to define any HCCs, but we are interested in analyzing this topic for further consideration for potential model changes in future benefit years.

Consistent with the risk adjustment principles described previously,74 the HHS-operated risk adjustment models exclude HCCs containing diagnoses that are vague or nonspecific (for example, cough), discretionary in medical treatment or coding (for example, attention deficit disorder), or not medically significant (for example, heartburn). The payment models also exclude HCCs that do not add empirically to costs (for example, nonmelanoma forms of skin cancer). We did not propose to combine HCCs and are not finalizing combining HCCs in the 2022 risk adjustment models. At this time, we do not believe that combining HCCs for reasons stated by the commenter is necessary, as we have already analyzed and selected HCCs for inclusion in the models that capture the largest risk differences. However, in our efforts to continuously improve the risk adjustment models, we will continue to analyze the risk adjustment model factors for future benefit years and consider whether changes are needed.

For all these reasons, we believe the proposed and final list of factors applicable to the 2022 benefit year includes the appropriate HCCs.

Comment: One commenter suggested creating separate models for the individual and small group markets, using only individual market enrolleelevel EDGE data for the individual market models but supplementing small group market enrollee-level EDGE data with MarketScan® data for the small

group market models.

Response: We did not propose and are not finalizing separate individual and small group market models. At this time, we are concerned that creating two separate risk adjustment models for the individual and small group markets for each of the age groups (adult, child, and infant) would result in significantly increased complexity of the risk adjustment program. For example, this would double the number of risk

adjustment models, complicating rate setting for issuers and destabilizing the child and infant models due to small sample sizes. However, we intend to continue to analyze the differences in costs and utilization between the individual and small group markets to consider whether these types of changes would be necessary or appropriate in future benefit years. A more detailed discussion of our current analysis of these issues based on our review of the 2016, 2017 and 2018 enrollee-level EDGE data appears in the proposed rule as part of the discussion of the proposed changes to the adult model enrollment duration factors.75

After consideration of comments on the proposed factors, we are finalizing the above list of final coefficients for the

2022 benefit year.

As noted above in the Pricing Adjustment for the Hepatitis C Drugs preamble, we continuously assess the availability of drugs in the market and the associated mapping of those drugs to RXCs in the adult risk adjustment models. As a result of this ongoing assessment, we make quarterly updates to the RXC Crosswalk to ensure drugs are being mapped to RXCs where appropriate, including adding and removing new and old drugs based on approval status, prescribing patterns, and expenditure data. In a recent update, HHS removed hydroxychloroquine from RXC 09 effective March 24, 2021, due to concerns regarding unrepresentative expenditures and off-label prescribing during the COVID-19 public health emergency.⁷⁶ Additionally, based on pre-2020 data, HHS's analysis showed that the costs of hydroxychloroquine are much lower than the costs of other drugs that one with HCC 048, 056, or 057 may take. However, hydroxychloroquine still appears in the 2018 enrollee-level EDGE data we are otherwise finalizing for use for 2022 benefit year model recalibration. Therefore, we only used 2016 and 2017 enrollee-level EDGE data for the limited purpose of developing the RXC 09 coefficients, RXC 09 HCC related coefficients, and RXC 09 interaction term coefficients for the 2022 benefit year adult models.77 This approach best aligns the 2022 benefit year adult model

coefficients with the removal of hydroxychloroquine from RXC 09 and avoids the undesired impact of diluting the coefficient values for RXC 09 (including the associated interactions). As seen in Table 1, the coefficients for RXC 09 Immune Suppressants and Immunomodulators, the HCC factors relevant for RXC 09 (HCC41, HCC48, HCC56, HCC57), and the related RXC 09 interactions (RXC 09 × HCC056 or 057 and 048 or 041; RXC 09 × HCC056; RXC 09 × HCC057; RXC 09 × HCC048, 041) result from the equally weighted (averaged) blended factors from separately solved models using only the 2016 and 2017 enrollee-level EDGE data.

f. Cost-Sharing Reduction Adjustments

We proposed to continue including an adjustment for the receipt of CSRs in the risk adjustment models to account for increased plan liability due to increased utilization of health care services by enrollees receiving CSRs in all 50 states and the District of Columbia. For the 2022 benefit year, to maintain stability and certainty for issuers, we proposed to maintain the CSR factors finalized in the 2019, 2020, and 2021 Payment Notices.78

Consistent with the approach finalized in the 2017 Payment Notice,79 we also proposed to continue to use a CSR adjustment factor of 1.12 for all Massachusetts wrap-around plans in the risk adjustment plan liability risk score calculation, as all of Massachusetts' cost-sharing plan variations have AVs above 94 percent.

We are finalizing the CSR adjustment factors as proposed, including the CSR adjustment factor of 1.12 for all Massachusetts wrap-around plans.

We received public comments on the proposed cost-sharing reduction adjustments. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposed CSR adjustment factors for the 2022 benefit year and continuing the CSR adjustment factor of 1.12 for all Massachusetts wrap-around plans. Some of these commenters stated that the current CSR adjustment factors will ensure stability and that the CSR adjustment factor of 1.12 for all Massachusetts wrap-around plans appropriately accounts for the different market dynamics and the level of wrapped benefits in Massachusetts.

Response: We are finalizing the CSR adjustment factors as proposed.

 $^{^{74}\,\}mathrm{See},$ for example, the 2021 Payment Notice, and Section 2.1 of the "March 31, 2016 HHS-Operated Risk Adjustment Methodology Meeting Discussion Paper," March 24, 2016. Available at https:// www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/RA-March-31-White-Paper-032416.pdf.

⁷⁵ See 85 FR at 78585.

⁷⁶ See HHS-Developed Risk Adjustment Model Algorithm "Do It Yourself (DIY)" Software Instructions for the 2020 Benefit Year, April 15, 2021 Update, available at https://www.cms.gov/ files/document/cy2020-diy-instructions 04132021.pdf.

⁷⁷ The same concern was not present for the 2016 and 2017 enrollee-level EDGE data because hydroxychloroquine was not included in the crosswalk until 2018.

⁷⁸ See 83 FR 16930 at 16953; 84 FR 17454 at 17478 through 17479; and 85 FR 29164 at 29190.

⁷⁹ See 81 FR 12203 at 12228.

Consistent with the approach finalized in the 2017 Payment Notice,80 we will continue to use a CSR adjustment factor of 1.12 for all Massachusetts wraparound plans in the risk adjustment plan liability risk score calculation for the 2022 benefit year, as all of Massachusetts' cost-sharing plan variations have AVs above 94 percent. We agree that the CSR adjustment factor of 1.12 for all Massachusetts wraparound plans accounts for the state's unique market dynamics, and that the continuation of the current CSR adjustment factors for all states and the District of Columbia lend stability to the

Comment: Some commenters wanted HHS to analyze the CSR adjustment factors for future benefit years to consider whether changes are needed. These commenters specifically asked HHS to consider factors like whether or not the state expanded Medicaid or offers a Basic Health Program, as well as the impact of the discontinuation of CSR payments and implementation of

silver loading, in analyzing the CSR adjustment factors for future benefit years. One commenter opposed the CSR adjustment factors and stated that, as a result of these factors, the risk adjustment models overcompensate issuers for those enrolled in silver plans and undercompensate issuers for other metal level enrollees.

Response: We will continue to examine whether changes to the CSR adjustment factors are warranted in the future as more enrollee-level EDGE data becomes available. We appreciate the suggestions for analysis from commenters and may consider these and other elements in our future analysis. We note that the current CSR adjustment factors are set at a national level and do not vary by state, while the suggested analysis on the effect of expanded Medicaid or presence of a Basic Health Program would vary by state. Adopting an approach that would require further variation by state would introduce a level of complexity to the risk adjustment program, which is

another factor we would consider as part of any such analysis.

Furthermore, notwithstanding the cessation of federal CSR payments to issuers in October 2017, section 1402 of the ACA requires Exchange plans to provide CSRs for eligible enrollees, and plans face increased liability for silver plan enrollees receiving CSRs. As such, the CSR adjustment factors account for the higher plan liability of CSR plans, which is not experienced by other metal level plans. Therefore, we do not believe that the presence of CSR multipliers for CSR-eligible enrollees in silver plans automatically creates inaccurate risk differentials between CSR eligible and non-CSR eligible enrollees. Regardless, any refinements to the HHS-operated risk adjustment methodology, including any potential changes to the CSR adjustment factors for future benefit years, would be proposed through notice-and-comment rulemaking.

After consideration of the comments received, we are finalizing the CSR adjustment factors as proposed.

TABLE 7: Cost-Sharing Reduction Adjustment

TABLE 7. Cost-Sharing Keduction Adjustment					
Household Income	Plan AV	Induced Utilization Factor			
Silver Plan Variant Recipier	Silver Plan Variant Recipients				
100-150% of Federal Poverty Line (FPL)	Plan Variation 94%	1.12			
150-200% of FPL	Plan Variation 87%	1.12			
200-250% of FPL	Plan Variation 73%	1.00			
>250% of FPL	Standard Plan 70%	1.00			
Zero Cost Sharing Recipien	ts				
<300% of FPL	Platinum (90%)	1.00			
<300% of FPL	Gold (80%)	1.07			
<300% of FPL	Silver (70%)	1.12			
<300% of FPL	Bronze (60%)	1.15			
Limited Cost Sharing Recip	Limited Cost Sharing Recipients				
>300% of FPL	Platinum (90%)	1.00			
>300% of FPL	Gold (80%)	1.07			
>300% of FPL	Silver (70%)	1.12			
>300% of FPL	Bronze (60%)	1.15			

g. Model Performance Statistics

To evaluate risk adjustment model performance, we examined each model's R-squared statistic and predictive ratios. The R-squared statistic, which calculates the percentage of individual variation explained by a model, measures the predictive accuracy of the model overall. The predictive ratio for each of

the HHS risk adjustment models is the ratio of the weighted mean predicted plan liability for the model sample population to the weighted mean actual plan liability for the model sample population. The predictive ratio represents how well the model does on average at predicting plan liability for that subpopulation.

A subpopulation that is predicted perfectly would have a predictive ratio

of 1.0. For each of the HHS risk adjustment models, the R-squared statistic and the predictive ratios are in the range of published estimates for concurrent risk adjustment models.⁸¹ The final R-squared statistic for each model that is shown in Table 8 reflects the results from each dataset used. Because we are finalizing the 2022 benefit year coefficients from separately solved models based on blended data

⁸⁰ Ibid.

⁸¹ Hileman, Geof and Spenser Steele. "Accuracy of Claims-Based Risk Scoring Models." Society of Actuaries, October 2016.

from the 2016, 2017, and 2018 benefit years' enrollee-level EDGE data, we are publishing the R-squared statistic for each model separately to verify their statistical validity. The R-squared

statistic for each model is shown in Table 8.

TABLE 8: R-Squared Statistic for Proposed HHS Risk Adjustment Models

R-Squared Statistic				
Models	2016 Enrollee-	2017 Enrollee-	2018 Enrollee-	
	level EDGE Data	level EDGE Data	level EDGE Data	
Platinum Adult	0.4401	0.4371	0.4232	
Gold Adult	0.4349	0.4314	0.4174	
Silver Adult	0.4314	0.4276	0.4134	
Bronze Adult	0.4281	0.4241	0.4096	
Catastrophic Adult	0.4279	0.4239	0.4094	
Platinum Child	0.3147	0.3330	0.3366	
Gold Child	0.3108	0.3291	0.3327	
Silver Child	0.3076	0.3259	0.3295	
Bronze Child	0.3041	0.3225	0.3261	
Catastrophic Child	0.3040	0.3224	0.3259	
Platinum Infant	0.3276	0.3289	0.3095	
Gold Infant	0.3244	0.3255	0.3061	
Silver Infant	0.3224	0.3234	0.3039	
Bronze Infant	0.3206	0.3215	0.3020	
Catastrophic Infant	0.3205	0.3215	0.3020	

We received comments on the model performance statistics outlined in the proposed rule. The following is a summary of the comments we received and our responses.

Comment: One commenter requested more information on blending the coefficients from separately solved models based on the 2016, 2017, and 2018 benefit years' enrollee-level EDGE data and publishing the R-squared statistic for each model separately to verify their statistical validity.

Response: The final R-squared statistic for each model that is shown in Table 8 reflects the results from each dataset used in the separately solved models that are used to recalibrate the models for the 2022 benefit year, namely the 2016, 2017, and 2018 benefit years' enrollee-level EDGE data. 82 As stated in the proposed rule and the preamble section above, because we blended the coefficients from separately solved models based on these 3 years of enrollee-level EDGE data that were available at the time of the proposed rule, we publish the R-squared statistic

for each model separately to verify their statistical validity.

After consideration of the comments received on the model performance statistics and for the reasons stated in our responses, we are publishing the final R-squared statistic for each model above in Table 8.

h. Calculation of Plan Average Premium and State Average Premium Requirements for Extending Future Premium Credits (§ 153.320)

On August 4, 2020, HHS adopted temporary policies of relaxed enforcement for the premium rules set forth at 45 CFR 147.102, 155.200(f)(4), 155.400(e) and (g), 155.706(b)(6)(1)(A), 156.80(d), 156.210(a), and 156.286(a)(2) through (4) to allow issuers in the individual and small group markets the flexibility, when consistent with state law, to temporarily offer premium credits for 2020 coverage.83 HHS provided this flexibility with the intent of supporting continuity of coverage for individuals, families, and small employers who may struggle to pay premiums because of illness or loss of incomes or revenue resulting from the COVID-19 PHE.

In prior rulemaking,84 HHS finalized the calculation of plan average premium in the risk adjustment state payment transfer formula as equal to the actual premiums charged to plan enrollees, weighted by the number of months enrolled, and finalized the calculation of the state average premium as equal to the average of individual plan average premiums, weighted by each plan's share of statewide enrollment in the risk pool market, based on billable member months. In the interim final rule on COVID-19, HHS set forth risk adjustment reporting requirements for issuers offering temporary premium credits in the 2020 benefit year. In the proposed rule, we proposed how HHS would treat temporary premium credits provided for purposes of applying the state payment transfer formula for the 2021 benefit year and beyond should HHS adopt a similar relaxed enforcement stance and permit such temporary premium credits in future benefit years during a PHE declared by the Secretary of HHS (declared PHE).85 For states where issuers of risk adjustment covered plans provide temporary premium credits during a declared PHE when permitted by HHS,

⁸² Our approach to recalibration involves using blended, or averaged, coefficients from three years of separately solved models, which promotes stability for the risk adjustment coefficients year over year, particularly for conditions with small sample sizes. For more details, see "March 31, 2016, HHS-Operated Risk Adjustment Methodology Meeting Discussion Paper," March 24, 2016, available at https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/RA-March-31-White-Paper-032416.pdf.

^{**}B3 "Temporary Policy on 2020 Premium Credits Associated with the COVID-19 Public Health Emergency," August 4, 2020, https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Premium-Credit-Guidance.pdf.

⁸⁴ 2014 Payment Notice final rule, 78 FR 15409. Also see the 2020 Payment Notice final rule, 84 FR 17454.

⁸⁵ The Secretary of the Department of HHS may, under section 319 of the PHS Act determine that: (a) A disease or disorder presents a public health emergency; or (b) that a public health emergency, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists.

the plan average premium and statewide average premium used in the state payment transfer formula would be calculated using issuers' adjusted premium amounts. Thus, the actual premiums billed to plan enrollees would be the amounts used in the calculations under the state payment transfer formula. This is consistent with the general approach adopted in the interim final rule on COVID–19 for temporary premium credits in the 2020 benefit year.

We further proposed that HHS would use adjusted plan premiums for all enrollees to whom the issuer has actually provided premium credits as a reduction to the applicable benefit year premiums, when calculating transfers under the state payment transfer formula for the 2021 benefit year and beyond. This approach would also extend to the calculation of transfers under the state payment transfer formula in states that receive approval for a request to reduce transfers under § 153.320(d)—that is, the lower actual premiums for which plan enrollees would be responsible would be the amounts used in the calculations under the state payment transfer formula to reflect these temporary premium credits. As such, if an issuer in a state with an approved 50 percent small group market reduction request for a given benefit year chooses to provide temporary premium credits, the state average premium will decrease, and HHS would apply the 50 percent transfer reduction to the lower PMPM payment or charge transfer amount calculated under the state payment transfer formula for that state's small group market for that benefit year. As detailed further later in this preamble, we also proposed that issuers providing these temporary premium credits must report the lower, actual premium amounts billed to plan enrollees to their respective EDGE servers. We explained that we believe that the applicable definitions of plan average premium and state average premium retain the meaning previously finalized by reflecting the actual monthly premium billed to enrollees. The proposal would build on lessons learned from the COVID–19 PHE and would establish a framework to recognize premium credits as a reduction in premium for purposes of the HHS-operated risk adjustment program to align risk adjustment charges and payments under the state payment transfer formula with flexibilities HHS may provide to issuers and states in future benefit years during a declared PHE. The proposal would not change any other aspect of the state payment

transfer formula or the method for calculating payments and charges under the HHS risk adjustment methodology (inclusive of the state payment transfer formula and high-cost risk pool parameters). We are finalizing this policy as proposed.

We summarize and address all the comments received on this proposal in the Risk Adjustment Data Requirements for Future Premium Credits (§ 153.710) preamble section below.

2. Overview of the HHS Risk Adjustment Methodology (§ 153.320)

We proposed to continue to use the HHS state payment transfer formula that was finalized in the 2021 Payment Notice.86 Although the proposed HHS state payment transfer formula for the 2022 benefit year was unchanged from what was finalized for the previous benefit year, we republished it in the proposed rule. Additionally, we republished the description of the administrative cost reduction to the statewide average premium and highcost risk pool factors, although this reduction and the factors and terms also remain unchanged from what was finalized for the previous benefit year.87 We also proposed to apply this state payment transfer formula, including the administrative cost reduction, for the 2022 benefit year and beyond, unless changed through notice-and-comment rulemaking. Under this proposal, we would no longer republish these formulas in future annual HHS notice of benefit and payment parameter rules unless changes are being proposed. To align with this proposal, we proposed to update § 153.320(c) to replace the current language that refers to HHS specifying the applicable federallycertified risk adjustment methodology in the annual HHS notice of benefit and payment parameters for the applicable year, to instead require HHS to specify the applicable federally-certified risk adjustment methodology in notice-andcomment rulemaking that is published in advance of the applicable benefit year. We are finalizing these policies as proposed and will apply the proposed HHS risk adjustment methodology outlined in the proposed rule for the 2022 benefit year and beyond. The published methodology will remain in effect unless it is changed through future notice-and-comment rulemaking. We are also finalizing the update to § 153.320(c) as proposed.

We previously defined the calculation of plan average actuarial risk and the

calculation of payments and charges in the Premium Stabilization Rule.88 In the 2014 Payment Notice, we combined those concepts into a risk adjustment state payment transfer formula.89 This formula generally calculates the difference between the revenues required by a plan, based on the health risk of the plan's enrollees, and the revenues that the plan can generate for those enrollees. These differences are then compared across plans in the state market risk pool and converted to a dollar amount via a cost scaling factor. In the absence of additional funding, we established, through notice-andcomment rulemaking,90 the HHSoperated risk adjustment program as a budget-neutral program to provide certainty to issuers regarding risk adjustment payments and charges, which allows issuers to set rates based on those expectations. In light of the budget-neutral framework, HHS uses statewide average premium as the costscaling factor in the state payment transfer formula in the HHS-operated risk adjustment methodology, rather than a different parameter, such as each plan's own premium, which would not have automatically achieved equality between risk adjustment payments and charges in each benefit year.91

Risk adjustment transfers (total payments and charges, including high-cost risk pool payments and charges) are calculated after issuers have completed their risk adjustment EDGE data submissions for the applicable benefit year. Transfers (payments and charges) under the state payment transfer formula are calculated as the difference

 $^{^{86}\,84\;}FR$ 17454 at 17480 and 17485; and 85 FR 29164 at 29191.

⁸⁷ Ibid.

^{88 77} FR 17220 at 17246.

⁸⁹ The state payment transfer formula refers to the part of the HHS risk adjustment methodology that calculates payments and charges at the state market risk pool level prior to the calculation of the high-cost risk pool payment and charge terms that apply beginning with the 2018 benefit year.

⁹⁰ For example, see Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment, Proposed Rule, 76 FR 41938 (July 15, 2011); Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment, Final Rule, 77 FR 17232 (March 23, 2012); and the 2014 Payment Notice, Final Rule, 78 FR 15441 (March 11, 2013). Also see the 2018 Payment Notice, Final Rule, 81 FR 94058 (December 22, 2016); and the 2019 Payment Notice, Final Rule, 83 FR 16930 (April 17, 2018). Also see the Adoption of the Methodology for the HHS-Operated Permanent Risk Adjustment Program Under the Patient Protection and Affordable Care Act for the 2017 Benefit Year, Final Rule, 83 FR 36456 (July 30, 2018) and the Patient Protection and Affordable Care Act; and Adoption of the Methodology for the HHS-Operated Permanent Risk Adjustment Program for the 2018 Benefit Year Final Rule, 83 FR 63419 (December 10, 2018)

⁹¹ See the 2020 Payment Notice final rule for further details on why statewide average premium is the cost-scaling factor in the state payment transfer formula. See 84 FR 17454 at 17480 through 17484.

between the plan premium estimate reflecting risk selection and the plan premium estimate not reflecting risk selection. The state payment transfer calculation that is part of the HHS risk

adjustment methodology follows the formula:

$$T_{i} = \left[\frac{PLRS_{i} \cdot IDF_{i} \cdot GCF_{i}}{\sum_{i}(s_{i} \cdot PLRS_{i} \cdot IDF_{i} \cdot GCF_{i})} - \frac{AV_{i} \cdot ARF_{i} \cdot IDF_{i} \cdot GCF_{i}}{\sum_{i}(s_{i} \cdot AV_{i} \cdot ARF_{i} \cdot IDF_{i} \cdot GCF_{i})}\right] \overline{P}_{s}$$

Where:

 \bar{P}_S = statewide average premium;

 $PLRS_i = plan i$'s plan liability risk score;

 AV_i = plan *i*'s metal level AV;

 ARF_i = allowable rating factor;

 IDF_i = plan *i*'s induced demand factor;

 GCF_i = plan *i*'s geographic cost factor;

 s_i = plan i's share of state enrollment.

The denominators are summed across all risk adjustment covered plans in the risk pool in the market in the state.

The difference between the two premium estimates in the state payment transfer formula determines whether a plan pays a risk adjustment charge or receives a risk adjustment payment. The value of the plan average risk score by itself does not determine whether a plan would be assessed a charge or receive a payment-even if the risk score is greater than 1.0, it is possible that the plan would be assessed a charge if the premium compensation that the plan may receive through its rating (as measured through the combination of metal level AV, allowable rating factor, induced demand factor, and geographic cost factor) exceeds the plan's predicted liability associated with risk selection. Risk adjustment transfers under the state payment transfer formula are calculated at the risk pool level, and catastrophic plans are treated as a separate risk pool for purposes of the risk adjustment state payment transfer calculations.92 This resulting PMPM plan payment or charge is multiplied by the number of billable member months to determine the plan payment or charge based on plan liability risk scores for a

plan's geographic rating area for the risk pool market within the state. The payment or charge under the state payment transfer formula is thus calculated to balance the state market risk pool in question.

We previously defined the cost scaling factor, or the statewide average premium term, as the sum of the average premium per member month of each plan $i(P_i)$ multiplied by plan i's share of statewide enrollment in the market risk pool (s_i). We also previously adopted a 14 percent administrative cost reduction to the statewide average premium 93 and proposed maintaining it for the 2022 benefit year and beyond, unless amended through notice-andcomment rulemaking. The following formula shows the calculation of the statewide average premium and the adjustment to remove a portion of the administrative costs that do not vary with claims (14 percent):

=
$$(\Sigma_i (s_i \cdot P_i)) * (1 - 0.14) = (\Sigma_i (s_i \cdot P_i)) * 0.86$$

Where:

 s_i = plan *i*'s share of statewide enrollment in the market in the risk pool;

 P_i = average premium per member month of plan i.

To account for costs associated with exceptionally high-risk enrollees, we previously added a high-cost risk pool adjustment to the HHS risk adjustment methodology. As finalized in the 2020 Payment Notice, 94 we intend to maintain the high-cost risk pool parameters with a threshold of \$1 million and a coinsurance rate of 60 percent for benefit years 2020 and onward, unless amended through notice-and-comment rulemaking. We did not propose any changes to the high-cost risk pool parameters as part of the proposed rule; therefore, we would maintain the threshold of \$1 million and coinsurance rate of 60 percent for the 2022 benefit year.

The high-cost risk pool adjustment amount is added to the state payment transfer formula to account for: (1) The payment term, representing the portion of costs above the threshold reimbursed to the issuer for high-cost risk pool payments (HRP_i), if applicable; and (2) the charge term, representing a percentage of premium adjustment, which is the product of the high-cost risk pool adjustment factor (HRPC_m) for the respective national high-cost risk pool m (one for the individual market, including catastrophic, non-catastrophic and merged market plans, and another for the small group market), and the plan's total premiums (TP_i). For this calculation, we use a percent of premium adjustment factor that is applied to each plan's total premium amount. The total plan transfers for a

⁹² As detailed elsewhere in this final rule, catastrophic plans are considered part of the individual market for purposes of the national highcost risk pool payment and charge calculations.

⁹³ See 84 FR 17454 at 17486.

^{94 84} FR 17466 through 17468.

given benefit year are calculated as the product of the plan's PMPM transfer amount (T_i) multiplied by the plan's billable member months (M_i) , plus the high-cost risk pool adjustments. The total plan transfer (payment or charge) amounts under the HHS risk adjustment methodology formula are calculated as follows:

Total transfer_i = $(T_i \cdot M_i) + HRP_i - (HRPC_m \cdot TP_i)$

Where:

 $Total\ Transfer_i = Plan\ i$'s total HHS risk

adjustment program transfer amount; $T_i = \text{Plan } i$'s PMPM transfer amount based on the state transfer calculation;

 M_i = Plan i's billable member months; HRP_i = Plan i's total high-cost risk pool payment;

 $HRPC_{\rm m}$ = High-cost risk pool percent of premium adjustment factor for the respective national high-cost risk pool m; and

 TP_i = Plan *i*'s total premium amounts.

We sought comment on the proposed HHS risk adjustment methodology for the 2022 benefit year and beyond and the proposed updates to § 153.320(c). We are finalizing these policies as proposed and will apply the proposed HHS risk adjustment methodology outlined in the proposed rule for the 2022 benefit year and beyond. We are also finalizing the update to § 153.320(c) as proposed.

We received public comments on the proposed 2022 benefit year HHS risk adjustment methodology, the proposal to apply the same methodology to future benefit years unless changed through notice-and-comment rulemaking, and the proposed updates to § 153.320(c). The following is a summary of the comments we received and our

responses.

Comment: Several commenters supported the proposed HHS risk adjustment methodology. One commenter asked HHS to continue to publish the methodology in the annual Payment Notice to prevent issuers from having to reference previous rulemakings.

Response: We appreciate the support for the state payment transfer formula and believe that maintaining the HHS risk adjustment methodology for the 2022 benefit year and beyond, unless changed through notice-and-comment rulemaking, will result in stability in the markets by making it easier for issuers to set rates because of the predictability and consistency of the methodology. We do not believe it is necessary to continue to publish the methodology in the annual Payment Notice, as we will cite to the version of the Payment Notice where the current methodology appears in subsequent Payment Notices. We are

therefore finalizing the HHS risk adjustment methodology and this policy as proposed. As a result, for the 2023 benefit year and beyond, we will not republish the HHS risk adjustment methodology in the annual Payment Notice, unless we are proposing to make changes to the methodology. We are also finalizing the proposed update to § 153.320(c) to reflect this approach.

Comment: A few commenters opposed certain aspects of the state payment transfer formula, such as the use of the statewide average premium and the 14 percent administrative cost reduction. One commenter suggested that HHS use statewide average claims rather than statewide average premium as the scaling factor in the state payment transfer formula, and further suggested that if HHS continues to use statewide average premium, HHS should increase the administrative cost reduction to 20 percent. A few commenters wanted HHS to reevaluate the state payment transfer formula, suggesting a focus on the level of the administrative cost reduction and an inquiry into whether the administrative cost reduction and the induced utilization factors should differ between the individual and small group markets. One commenter asked for more information on the administrative cost reduction, specifically what information HHS would find helpful in evaluating the sufficiency of the existing administrative cost reduction.

Response: We did not propose and are not finalizing changes to the use of the statewide average premium in the state payment transfer formula. As detailed in prior rulemakings,95 in light of the program's budget neutral framework, HHS chose to use statewide average premium to convert required revenue and allowable premium state average factors in the state payment transfer formula from relative factors to dollar amounts so that the total calculated payment amounts equal total calculated charges in each state market risk pool. Thus, each plan in the state market risk pool receives a risk adjustment state transfer payment or charge that is scaled based on the determination of plan average risk within a state market risk pool, resulting in balanced, budgetneutral transfers. This approach supports the overall goal of the risk adjustment program to encourage

issuers to rate for average risk and mitigates incentives for issuers to operate less efficiently, or to develop benefit designs or create marketing strategies to avoid high-risk enrollees. In addition, our analysis shows that statewide average claims is a volatile measure, both across states within a year and across years within a state, and would be sensitive to unexpected claims experience. Furthermore, unexpected claims experience could particularly cause instability for smaller issuers, thereby reducing the predictability of risk adjustment transfers. For these reasons, we are not proposing or otherwise considering the use of statewide average claims in the state payment transfer formula.

We also did not propose and are not finalizing changes to the 14 percent administrative cost reduction in the risk adjustment state payment transfer formula. As we noted in the 2018 Payment Notice,⁹⁶ we analyzed administrative and other non-claims expenses, including quality improvement expenses, in the MLR Annual Reporting Form, and estimated, by category, the extent to which administrative expenses varied with claims.97 We compared those expenses to the total costs that issuers finance through premiums, including claims, administrative expenses, and taxes, to ensure that the estimated administrative cost percentage was not distorted by under- or over-pricing during the years for which MLR data were available. Using this methodology, we determined the mean administrative expense in both the individual and small group markets was 14 percent. For the 2022 benefit year, we engaged in the same analysis and arrived at the same conclusion. We set the administrative cost adjustment based on our estimate of the percentage of total costs that did not vary by risk, so that issuers with higher risk enrollees would still receive credit through risk adjustment for the cost of administrative activities that varied based on the risk of the population (for examples, discharge planning or preventing facility-acquired infections and reducing clinical errors). At this time, we have not found evidence that

⁹⁵ See, for example, the Adoption of the Methodology for the HHS-operated Risk Adjustment Program under the Patient Protection and Affordable Care Act for the 2017 Benefit Year; Final Rule, 83 FR 36456 (July 31, 2018); and the Adoption of the Methodology for the HHS-operated Risk Adjustment Program for the 2018 Benefit Year; Final Rule, 83 FR 63419 (December 10, 2018).

⁹⁶81 FR 94099 through 94100.

⁹⁷ In 2016 and 2017, we removed the impact of the reconciled amount of CSRs on claims costs as part of this calculation. Payments through the CSR program were discontinued in October 2017 due to lack of a Congressional appropriation. As such, although this line item still exists in the MLR Annual Reporting Form, the amount entered by issuers for the CSR line item should be zero dollars, and it therefore should no longer impact the administrative cost reduction calculation.

demonstrates that a higher percentage is necessary.

In response to comments, we further clarify that the MLR Annual Reporting Form provides all the information we use to analyze the sufficiency of the 14 percent administrative cost reduction, including administrative and other nonclaims expenses like quality improvement activity expenses, and taxes and fees that do not vary based on enrollee health risk. We believe that this is a sufficient and reasonable source for data to calculate and analyze the administrative cost reduction to the statewide average premium in the risk adjustment state payment transfer formula.

Furthermore, we did not propose and are not finalizing induced utilization factors that vary by market. We are concerned that adding different utilization factors based on market to the state payment transfer formula would make the formula much more complex, as this would double the number of induced utilization factors in the formula and make it more difficult for issuers to price for. We note that we intend to further consider the differences between markets and implications for risk adjustment, and that any related changes to the risk adjustment program would be proposed in notice-and-comment rulemaking.

Comment: One commenter asked HHS to study the correlation between risk adjustment transfers and MLR rebates, stating that it appears that transfers are too high because a number of issuers receiving risk adjustment payments must pay MLR rebates to their enrollees.

Response: While risk adjustment payments reduce the numerator of the MLR calculation,98 whether an issuer will owe MLR rebates is influenced by a number of factors that are unrelated to risk adjustment transfers. For example, an issuer's MLR and rebate position is heavily influenced by the degree to which its pricing assumptions accurately accounted for realized claims costs for the applicable benefit year. As such, issuers may owe MLR rebates to consumers while either receiving risk adjustment payments or owing risk adjustment charges for the applicable benefit year. Additionally, our examination of the HHS risk adjustment methodology and risk adjustment data for recent benefit years has shown the program mitigates the influence of risk selection on premiums and the incentive for plans to avoid sicker enrollees.99

Comment: One commenter asked that HHS reevaluate the state payment transfer formula and stated that it favors larger issuers over smaller issuers because larger issuers have the ability to dedicate resources to enable more robust coding practices

 $\begin{array}{c} {\rm robust\ coding\ practices.} \\ {\it Response:}\ {\rm We\ disagree\ that\ the\ state} \end{array}$ payment transfer formula favors larger issuers over small issuers. The risk adjustment program transfers funds from plans with lower-than-average risk enrollees to plans with higher-thanaverage risk enrollees in accordance with section 1343 of the ACA, and our internal analysis has found that smaller plans that enroll sicker than average enrollees have also received high payments as a percent of their premiums. Further, HHS conducts HHS-RADV in any state where HHS operates the risk adjustment program to validate the accuracy of the data submitted by issuers to their EDGE servers. 100 EDGE server data are used to calculate issuers' plan liability risk scores for use in the state payment transfer formula as a part of the risk adjustment program. HHS-RADV establishes uniform audit standards to ensure that actuarial risk is accurately and consistently measured, thereby strengthening the integrity of the risk adjustment program.¹⁰¹ Therefore, any potential coding differences between plans of any size should not inappropriately impact risk adjustment, and to the extent there is any impact, it should be significantly mitigated through HHS-RADV.

Comment: One commenter requested that HHS adjust the state payment transfer formula applicable in states where HHS operates the program to ensure that charges for enrollees with no HCCs do not exceed premium.

Response: We do not believe that adjusting the state payment transfer formula to cap or otherwise limit charges to the level of premiums for enrollees is appropriate. We are concerned that, given the budget-neutral nature of the HHS program, a cap on charges would result in lower payments to issuers with plans with higher-thanaverage actuarial risk. 102 The cap may also incentivize small issuers with plans that attract healthier-than-average enrollees to underprice premiums because they would know their charges would be capped to a percentage of premium. Furthermore, consistent with the framework set forth in section 1343 of the ACA, the HHS-operated risk adjustment program focuses on risk differentials at the plan level, not the enrollee level.¹⁰³ Risk adjustment transfers under the state payment transfer formula are therefore calculated based on the plan liability risk score and the statewide average premium, not based on individual enrollees' premiums. As described in a previous section of this rulemaking, we continue to consider future policy options to improve the predictive power of the risk adjustment models for certain subpopulations (including enrollees with no HCCs).

After consideration of the comments received on these proposals, we are finalizing the proposed HHS risk adjustment methodology for the 2022 benefit year and beyond, unless changed through notice-and-comment rulemaking. We are also finalizing the accompanying proposed update to § 153.320(c).

3. State Flexibility Requests (§ 153.320(d))

In the 2019 Payment Notice, we provided states the flexibility to request a reduction to the otherwise applicable risk adjustment state transfers calculated by HHS under the state payment transfer formula, which is calibrated on a national dataset, for the

⁹⁸ See 45 CFR 158.130(b)(5).

⁹⁹ See, for example, the Summary Report on Permanent Risk Adjustment Transfers for the 2019

Benefit Year (July 17, 2020), available at https://www.cms.gov/CCIIO/Programs-and-Initiatives/
Premium-Stabilization-Programs/Downloads/RA-Report-BY2019.pdf; the Summary Report on
Permanent Risk Adjustment Transfers for the 2018
Benefit Year (June 28, 2019), available at https://www.cms.gov/CCIIO/Programs-and-Initiatives/
Premium-Stabilization-Programs/Downloads/
Summary-Report-Risk-Adjustment-2018.pdf; and
the Summary Report on Permanent Risk
Adjustment Transfers for the 2017 Benefit Year
(July 9, 2018), available at https://
downloads.cms.gov/cciio/Summary-Report-Risk-Adjustment-2017.pdf.

¹⁰⁰ See 45 CFR 153.350 and 153.630.

¹⁰¹ See, for example, the 2014 Payment Notice final rule, 78 FR 15409 at 15436–15438; and the 2018 Benefit Year Protocols ACA HHS Risk Adjustment Data Validation, released June 24, 2019, available at https://www.regtap.info/uploads/library/HRADV_2018Protocols_070319_5CR_070519.pdf.

¹⁰² Congress did not authorize or appropriate additional funding for risk adjustment beyond the amount of charges paid in, and did not authorize HHS to obligate itself for risk adjustment payments in excess of charges collected. In the absence of additional, independent funding or the creation of budget authority in advance of an appropriation, the introduction of a cap on charges would mean that payments would have to be reduced by a similar amount because HHS cannot make payments in excess of charges collected consistent with binding appropriations law. See New Mexico Health Connections v. United States Department of Health and Human Services, 946 F.3d 1138 (10th Cir. 2019).

¹⁰³ Compare 42 U.S.C. 18063 (establishing the permanent risk adjustment program, which involves an assessment and comparison of the actuarial risk in each issuer's plans in a state market risk pool with the average actuarial risk of all plans in the applicable state market risk pool) with 42 U.S.C. 18061 (establishing the transitional reinsurance program, which involves an assessment of actuarial risk of individual enrollees to identify those that qualify as "high risk.")

state's individual (catastrophic or non-catastrophic risk pools), small group, or merged markets by up to 50 percent to more precisely account for differences in actuarial risk in the applicable state's markets. ¹⁰⁴ We proposed that any requests received would be published in the applicable benefit year's proposed HHS notice of benefit and payment parameters, and the supporting evidence provided by the state in support of its request would be made available for public comment. ¹⁰⁵

If the state requests that HHS not make publicly available certain supporting evidence and analysis because it contains trade secrets or confidential commercial or financial information within the meaning of the HHS Freedom of Information Act (FOIA) regulations at 45 CFR 5.31(d), HHS will only make available on the CMS website the supporting evidence submitted by the state that is not a trade secret or confidential commercial or financial information by posting a redacted version of the state's supporting evidence. 106 In accordance with § 153.320(d)(2), beginning with the 2020 benefit year, states must submit such requests with the supporting evidence and analysis outlined under § 153.320(d)(1) by August 1st of the calendar year that is 2 calendar years prior to the beginning of the applicable benefit year. If approved by HHS, state reduction requests will be applied to the plan PMPM payment or charge state payment transfer amount (T_i in the state payment transfer formula above). For the 2020 and 2021 benefit years, the state of Alabama submitted a 50 percent risk adjustment transfer reduction request for its small group market and HHS approved both requests. 107

We received several general comments on the state flexibility request framework outlined in § 153.320(d). However, we did not propose any changes to that framework other than the proposal to allow multi-year state flexibility requests as explained below. As such, these general comments on the state flexibility request framework are out of scope of this rulemaking and will not be addressed in this rule.

a. Requests To Reduce Risk Adjustment Transfers for the 2022 Benefit Year

For the 2022 benefit year, HHS received a request to reduce risk adjustment transfers calculated under the state payment transfer formula for

the Alabama individual 108 and small group markets by 50 percent. 109 Alabama's request states that the presence of a dominant carrier in the individual and small group markets precludes the HHS-operated risk adjustment program from working as precisely as it would with a more balanced distribution of market share. The state regulators stated that their review of the risk adjustment payment issuers' financial data suggested that any premium increase resulting from a reduction to risk adjustment payments of 50 percent in the individual and small group markets for the 2022 benefit year would not exceed 1 percent, the de minimis premium increase threshold set forth in § 153.320(d)(1)(iii) and (d)(4)(i)(B). We sought comment on this request to reduce risk adjustment state transfers in the Alabama individual and small group markets by 50 percent for the 2022 benefit year. The request and additional documentation submitted by Alabama was posted under the "State Flexibility Requests" heading at https:// www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/index.html. We are approving Alabama's requested reductions to 2022 benefit year transfers calculated under the state payment transfer formula for its individual and small group markets.

We received public comments on Alabama's requests to reduce risk adjustment transfers for the 2022 benefit year. The following is a summary of the comments we received and our responses.

Comment: Multiple commenters supported Alabama's request to reduce risk adjustment transfers in its individual and small group markets for the 2022 benefit year, stating that the HHS-operated risk adjustment program has not worked properly in Alabama's markets and that states are best suited to decide whether an adjustment is necessary in their market risk pools. Several other commenters opposed Alabama's request, stating that the state did not meet its burden to substantiate such request, that state flexibility should not be permitted, and that states seeking a reduction in risk adjustment state transfers should operate their own risk adjustment program. Many commenters opposed to Alabama's request expressed more concern with

the transfer reduction request for the individual market compared to the small group market. One commenter stated that there was no mathematical reason why the presence of one large issuer would preclude HHS-operated risk adjustment from functioning appropriately in Alabama.

Response: In the 2019 Payment Notice, HHS provided the flexibility for states to request a reduction in risk adjustment state transfers calculated by HHS under the state payment transfer formula when a state elects not to operate the risk adjustment program. We reviewed Alabama's requests and supporting documentation regarding the state's individual and small group market dynamics that it believes warrant an adjustment to the HHScalculated risk adjustment individual (including catastrophic and noncatastrophic) and small group market transfers under the state payment transfer formula for the 2022 benefit year. Alabama state regulators noted they do not assert that the HHS risk adjustment formula is flawed, only that it results in imprecise results in Alabama's markets that could further reduce competition and increase costs for consumers. The state regulators provided information demonstrating that the request would have a de minimis impact on necessary premium increases in both the individual and small group markets for payment issuers, consistent with § 153.320(d)(1)(iii) and (d)(4)(i)(B). HHS analyzed the information provided by the state in support of its request, along with additional data and information available to HHS and the public comments submitted during the comment period on the proposed rule, separately by market and found that the request meets de minimis regulatory standard in both markets. While we recognize the comments expressing more concern with the reduction request for the individual market and questioning how the presence of one large issuer would impact how the HHSoperated risk adjustment program functions in Alabama, we did not propose and are not finalizing any changes to the general framework or review standards under § 153.320(d). As such, a state is permitted to pursue these reduction requests for the individual, small group, or merged market risk pools if the applicable regulatory requirements are met. In this instance, Alabama's individual and small group market requests both met the applicable regulatory requirements; therefore, HHS is approving Alabama's requested reductions to 2022 benefit

¹⁰⁴ 83 FR 16955 through 16960.

¹⁰⁵ 45 CFR 153.320(d)(3).

¹⁰⁶ See 45 CFR 153.320(d)(3).

 $^{^{107}\,\}mathrm{See}$ 84 FR 17484 through 17485 and 85 FR 29193 through 29194.

¹⁰⁸ Alabama's individual market request is for a 50 percent reduction to risk adjustment transfers for its individual market non-catastrophic and catastrophic risk pools.

¹⁰⁹ Due to the COVID–19 PHE, we permitted states seeking to request a reduction in risk adjustment transfers for the 2022 benefit year an extension until September 1, 2020 to submit such request.

year transfers calculated under the state payment transfer formula.

Comment: Some commenters asserted that the evidence provided by Alabama does not substantiate the individual market request. One commenter requested that HHS conduct its own comprehensive actuarial analysis of the evidence provided by Alabama and further noted that the 2018 and 2019 risk adjustment results provided by Alabama in support of the request may not be indicative of 2022 transfers, as the past results do not take into account the changes to the HHS risk adjustment models applicable beginning with the 2020 and 2021 benefit years or the proposed changes outlined in the 2022 Payment Notice proposed rule. Another commenter stated that Alabama's suggestion that transfers were difficult to predict is inaccurate.

Response: The evidence provided by Alabama in support of its requests to reduce risk adjustment state transfers by 50 percent in its individual and small group markets was sufficient to justify its request under the de minimis requirement for HHS approval under 45 CFR 153.320(d)(4)(i)(B). We further note that Alabama requested that, consistent with 45 CFR 153.320(d), HHS not publish certain information in support of its request because it contained trade secrets or confidential commercial or financial information. If the state requests that HHS not make publicly available certain supporting evidence and analysis because it contains trade secrets or confidential commercial or financial information within the meaning of the HHS Freedom of Information Act (FOIA) regulations at 45 CFR 5.31(d), HHS will only make available on the CMS website the supporting evidence submitted by the state that is not a trade secret or confidential commercial or financial information by posting a redacted version of the state's supporting evidence. 110 Consistent with the state's request, we therefore posted a redacted version of the supporting evidence for Alabama's request. However, we note that HHS reviewed the state's unredacted supporting analysis in evaluating Alabama's request, along with other plan-level data available to HHS and the relevant public comments submitted within the applicable comment period for the proposed rule. We conducted a comprehensive analysis of the available information and found the supporting evidence submitted by Alabama to be sufficient for us to determine the validity of Alabama's 2022 benefit year requests. We also

evaluated the comments timely submitted, and determined whether the state's requests met the applicable criteria for approval.

We recognize there is some level of uncertainty regarding future market dynamics, including their potential impact on future benefit year transfers. However, to align with the annual pricing cycle for health insurance coverage, the applicable risk adjustment parameters (including approval or denial of state flexibility reduction requests) must generally be finalized sufficiently in advance of the applicable benefit year to allow issuers to consider such information when setting rates. As such, there will always be an opportunity for some uncertainty regarding the precise impact of future methodological changes (such as the risk adjustment model changes applicable beginning with the 2020 and 2021 benefit years) or unforeseen events (such as the COVID-19 PHE and its impact on enrollment and utilization). With respect to Alabama's 2022 benefit year requests, HHS believes that the evidence submitted by Alabama in support of its transfer reduction requests was sufficient, along with other information available to HHS and timely submitted comments, for HHS to review and confirm that the requests meet the criteria for approval set forth in § 153.320(d)(4)(i)(B).

Comment: Some commenters stated that the reduction requests would diminish the effectiveness of the HHS-operated risk adjustment program and suggested that Alabama set up its own risk adjustment program if it does not believe the HHS-operated risk adjustment program is appropriate for its markets.

Response: We agree that states that do not believe the HHS program is appropriate for its markets can and should consider operating their own state risk adjustment program with a federally-certified alternate risk adjustment methodology tailored to their market risk pools. However, as detailed in the proposed rule and the 2019 Payment Notice, we adopted the state flexibility reduction request regulations in response to specific feedback from certain states, and under our current regulations, it is appropriate to extend this flexibility for the 2022 benefit year. In addition, the approval criteria codified in 45 CFR 153.320(d)(4) are intended to ensure that approved adjustments do not diminish the effectiveness of the HHS-operated risk adjustment program. As part of our assessment of state flexibility requests, we consider the potential impact on the effectiveness of the HHS-operated risk

adjustment program for the applicable state market risk pools. We also intend to continue to analyze the impact of state flexibility requests and may propose changes or solicit comments on potential changes for future benefit years.

Comment: A few commenters stated that the approval of the requests would result in increased adverse selection, especially in the individual market. One of these commenters asserted that the reduction request in the individual market would result in a premium increase of more than 1 percent. This commenter also asserted that approval of the reduction request in the individual market would make it difficult for issuers to offer individual market plans with broad networks.

Response: We appreciate commenters' concerns and generally agree that adverse selection concerns are heightened in the individual market, as enrollees typically have higher actuarial risk, risk selection, and risk segmentation in plan selection than those enrolled in the small group market. However, in this case, Alabama has met the criteria for approval at 45 CFR 153.320(d)(4)(i)(B) for both its individual and small group market requests.

In addition, these commenters did not provide any data or supporting evidence during the public comment period to support their assertions. Our analysis of the information submitted as part of the state's request, along with other relevant factors, including the premium impact of the transfer reduction for the state market risk pool, showed that the transfer reduction requested by Alabama would have de minimis impact on the premiums to cover the difference in transfers for issuers that would receive reduced transfer payments. That is, approval of the request would not result in an increase in premiums of more than 1 percent. HHS does not believe that a change in transfers small enough to have a de minimis impact on premiums should affect issuers' operations, such as changes to its provider networks. Therefore, after consideration of the information submitted in support of the state's request and other data and information available to HHS, we find that the evidence provided substantiates the reduction request in both the individual and small group markets and meets the regulatory requirements for HHS approval under 45 CFR 153.320(d)(4)(i)(B).

Based on our review of the comments received on the proposed state flexibility reduction requests within the comment period and HHS's analysis of the requests submitted by Alabama,

¹¹⁰ See 45 CFR 153.320(d)(3).

HHS is granting Alabama's requests to reduce risk adjustment transfers in the individual (including catastrophic and non-catastrophic risk pools) and small group markets by 50 percent for the 2022 benefit year. Therefore, the 50 percent reduction will be applied to the 2022 benefit year plan PMPM payment or charge transfer amount (T_i in the state payment transfer calculation above) for the Alabama individual and small group markets.

b. Multi-Year State Flexibility Requests

We proposed several amendments to § 153.320(d) to allow states to request a reduction to otherwise applicable risk adjustment calculations under the state payment transfer formula for up to 3 years, beginning with the 2023 benefit year. Under current policy, states seeking to reduce risk adjustment state transfers in one or more of their market risk pools must submit a request to HHS each year describing the nature of their request and providing supporting documentation. HHS then reviews the request, sets forth the request in the applicable benefit year's HHS notice of benefit and payment parameters, and approves or denies it based on the evidence and analysis provided by the state in the request and the comments received to the applicable benefit year's proposed HHS notice of benefit and payment parameters.

Under § 153.320(d)(1), states must submit this request annually, and HHS publishes state requests in the applicable benefit year's proposed and final annual HHS notice of benefit and payment parameters. Stakeholders have requested that HHS allow states to request multi-year risk adjustment flexibility reductions. In recognition of these comments, we proposed to provide the flexibility for states to request a reduction to otherwise applicable risk adjustment state transfers under the HHS-operated risk adjustment methodology's state payment transfer formula for up to 3 years beginning with the 2023 benefit year.111

We are not finalizing the proposed policies or accompanying proposed updates to § 153.320(d) to permit states to pursue multi-year state flexibility reduction requests. We are maintaining the existing language and framework, which permits states to submit annual requests to reduce the otherwise applicable risk adjustment calculations under the state payment transfer

formula for its individual and small group (or merged) markets for a given benefit year to more precisely account for state-specific factors or other unique market characteristics.

We received public comments on the proposed policies and updates to § 153.320(d) to permit states to seek multi-year state flexibility requests for up to 3 years. The following is a summary of the comments we received and our responses.

Comment: Some commenters supported our proposal to permit states to request reductions in otherwise applicable risk adjustment state transfers for up to three benefit years, stating that multi-year state flexibility requests would promote stability and competition in the affected state market risk pool(s) and would reduce burden on states and HHS. However, several other commenters opposed this proposal, asserting that states would not be able to accurately or reliably anticipate state market risk pool conditions or market dynamics that far into the future in order for HHS to provide sufficient support for multi-year reduction requests. These commenters also raised the same concerns raised to the Alabama request above, including that the proposal would undermine the effectiveness of the HHS-operated risk adjustment program and result in risk selection, market destabilization, higher premiums, and narrow or restricted provider networks. These commenters noted that states can run their own risk adjustment program if they believe the HHS-operated program does not function properly in their market risk pool(s). One commenter also noted that inadequate advance notice of HHS's decision to terminate or modify the request based on new available information could disrupt rate setting.

Response: We are not finalizing these proposed policies or the updates to § 153.320(d), as we agree with commenters that there are concerns and barriers to multi-year state flexibility reduction requests. We agree that state market conditions, including enrollment and new entrants and exits to the market, can change significantly over 3 years, and three-year reduction requests could destabilize the market if conditions significantly change during the request's approval period. While our proposed framework included mechanisms to address such situations (for example, the proposed process and authority for HHS to terminate or modify a previously approved multiyear request during any one of the subsequent years during the approval period if additional data or new information did not support the

continuation of the state's reduction request and the state did not provide sufficient supplemental evidence to rebut such data or information), we agree that further consideration of these types of issues is warranted before pursuing these proposals to permit multi-year state flexibility reduction requests. We are maintaining the existing language and framework in § 153.320(d), which currently permits states to submit annual requests to reduce the otherwise applicable risk adjustment calculations under the state payment transfer formula for its individual and small group (including merged) markets for a given benefit year to more precisely account for statespecific factors or other unique market characteristics.

After consideration of the comments on the policies and changes related to the multi-year state flexibility reduction requests, we are not finalizing the proposals or changes to § 153.320(d) related to such requests.

- 4. Audits and Compliance Reviews of Issuers of Reinsurance-Eligible Plans (§ 153.410(d)) and Audits and Compliance Reviews of Issuers of Risk Adjustment Covered Plans (§ 153.620(c))
- a. Audits and Compliance Reviews of Issuers of Reinsurance-Eligible Plans (§ 153.410(d))

HHS recently completed the 2014 benefit year audits of a sample of issuers of ACA transitional reinsurance-eligible plans. During this process, HHS encountered significant challenges that impeded its ability to efficiently administer and complete the audits. More specifically, HHS experienced difficulties receiving requested audit data and materials in a timely fashion from some issuers, and had difficulty obtaining data from these issuers in a format that was usable by HHS. HHS is of the view that codifying additional audit requirements and parameters is an appropriate and necessary measure to ensure that 2015 and 2016 benefit year audits of ACA transitional reinsuranceeligible plans appropriately function to protect the integrity of our programs.

We proposed several amendments to § 153.410(d) to provide more clarity around the audit requirements for issuers of reinsurance-eligible plans. As proposed, the amendments explain the audit process, including what it means to properly comply with an audit and the consequences for failing to comply with audit requirements. We also proposed to expand the oversight tools available to HHS to also provide authority for HHS to conduct compliance reviews of issuers of

¹¹¹ See 85 FR at 78599–78601 for details on the proposed updates to §153.320(d) to permit states to seek multi-year state flexibility requests for up to 3 years.

reinsurance-eligible plans to assess compliance with the applicable requirements of subparts E and H of part 153. We explained that the proposed HHS compliance reviews would follow the standards set forth for compliance review of QHP issuers participating in FFEs established in 45 CFR 156.715. However, compliance reviews under this section would only be conducted in connection with confirming reinsurance-eligible plans' compliance with the standards related to reinsurance payments in subparts E and H of part 153. A compliance review may be targeted at a specific potential error and conducted on an ad hoc basis.112 For example, HHS may require an issuer to submit data pertaining to a specific data submission (for example, capitated claims). Unlike the compliance review authority established in § 156.715, which is limited to QHP issuers participating in FFEs, the compliance review authority we proposed to codify in the amendments to § 153.410(d) would apply to all issuers of reinsurance-eligible plans. We believe this flexibility is necessary and appropriate to provide a mechanism for HHS to address situations in which a systematic error or issue is identified during the random and targeted auditing of issuers of reinsurance-eligible plans, and HHS suspects similarly situated issuers may have experienced the same systematic error or issue, but were not selected for audit in the year in

Specifically, we proposed to rename § 153.410(d) to "Audits and Compliance Reviews" in order to clarify that the authority described in this section would apply to audits and the proposed HHS compliance reviews to evaluate issuers of reinsurance-eligible plans' compliance with the applicable requirements in subparts E and H of part 153. We similarly proposed to update the introductory language in § 153.410(d) to incorporate a reference to HHS compliance reviews and to note that we would conduct these compliance reviews consistent with the standards set forth in § 156.715.

We also proposed to amend the existing introductory language in § 153.410(d) to remove the last sentence that discusses audit results and the accompanying requirements that an issuer must follow if an audit results in a finding of material weakness or significant deficiency. Additionally, as detailed further below, we proposed to replace this with a new proposed framework that captures more details on the audit process and requirements for

reinsurance-eligible plans. As amended, the introductory language at § 153.410(d) would reflect the authority for HHS, or its designee, to audit or conduct a compliance review of an issuer of a reinsurance-eligible plan to assess its compliance with the applicable requirements of subparts E and H of part 153. We also proposed to move the existing introductory language in paragraph (d) requiring an issuer to ensure its relevant contractors, subcontractors, and agents cooperate with audits to a new proposed section, as detailed further below.

Also at § 153.410, we proposed to add new paragraph (d)(1) to establish notice and conference requirements for these audits. The introductory language in proposed paragraph (d)(1) reflects that HHS would provide at least 15 calendar days advance notice of its intent to conduct an audit of an issuer of a reinsurance-eligible plan. In proposed paragraph (d)(1)(i), we proposed to codify that all audits under this section would include an entrance conference at which the scope of the audit would be presented and an exit conference at which the initial audit findings would be discussed.

Further, we proposed to amend § 153.410(d) to add a new paragraph (d)(2) to capture the requirements issuers must meet to comply with an audit under this section. In proposed paragraph (d)(2)(i), we proposed to capture the requirement that currently appears in the introductory text of paragraph (d) for the issuer to ensure that its relevant contractors, subcontractors, and agents cooperate with any audit or compliance review under this section and also proposed to expand it to similarly require the issuer to ensure its relevant employees, downstream entities and delegated entities also cooperate with any audit or compliance review under this section. In new proposed paragraph (d)(2)(ii), we proposed to require issuers to submit complete and accurate data to HHS or its designees that is necessary to complete the audit. We explained that such data would need to support the appropriateness and accuracy of the reinsurance payments under review as part of the audit. For example, HHS may request that issuers of reinsuranceeligible plans provide enrollment and claims files, plan reference data, and associated enrollee data sufficient to show that reinsurance payments received were appropriate.

HHS encountered significant challenges in the 2014 benefit year audits when some issuers submitted data in a format that was not readable by HHS. To address this issue, we

proposed in new paragraph (d)(2)(ii) that issuers must submit audit data in the format and manner specified by HHS no later than 30 calendar days after the initial deadline communicated and established by HHS at the entrance conference described in proposed paragraph (d)(1)(i). For example, HHS may require issuers to submit the requested audit data via Electronic File Transfer. Additionally, under proposed paragraph (d)(2)(iii), HHS proposed to require that issuers respond to any audit notices, letters, request, and inquiries, including requests for supplemental or supporting information, no later than 15 calendar days after the date of the notice, letter, request, or inquiry. We noted that we believe that the proposed requirements in paragraph (d)(2) are necessary and appropriate to ensure the timely completion of audits and to prevent waste that results from repeated, fruitless attempts by HHS to obtain data.

Recognizing that there may be situations that warrant an extension of the timeframes under § 153.410(d)(2)(ii) or (iii), as applicable, we proposed to also add a new paragraph (d)(2)(iv) to establish a process for issuers to request an extension for good cause. To request an extension, we proposed to require the issuer to submit a written request to HHS within the applicable timeframe established in paragraphs (d)(2)(ii) or (iii). The written request would have to detail the reasons for the extension request and good cause in support of the request. For example, good cause may include an inability to produce information in light of unforeseen emergencies, natural disasters, or a lack of resources due to a PHE. If the extension is granted, the issuer must respond within the timeframe specified in HHS's notice granting the extension of time.

Under § 153.410(d)(3), HHS proposed it would share its preliminary audit findings with the issuer, and further proposed that the issuer would then have 30 calendar days to respond to such findings in the format and manner specified by HHS. HHS would describe the process, format, and manner by which an issuer can dispute the preliminary findings in the preliminary audit report sent to the issuer. For example, if the issuer disagrees with the findings set forth in the preliminary audit report, HHS would require the issuer to respond to such findings by submitting written explanations that detail its dispute(s) or additional rebuttal information via Electronic File Transfer. Additionally, we proposed at paragraph (d)(3)(i) that if the issuer does not dispute or otherwise respond to the

 $^{^{112}}$ For further details, please see 78 FR 65100.

preliminary findings within 30 calendar days, the audit findings would become final. We proposed in paragraph (d)(3)(ii) that if the issuer timely responds and disputes any audit finding within 30 calendar days, HHS would review and consider such response and finalize the audit findings after such review. HHS would provide contact and other information necessary for an issuer to respond to the preliminary audit findings in the preliminary audit report sent to the issuer.

We proposed to add a new paragraph $\S 153.410(d)(4)$ to capture the process and requirements related to final audit findings and reports. If an audit results in the inclusion of a finding in the final audit report, the issuer must comply with the actions set forth in the final audit report in the manner and timeframe established by HHS. We noted that the actions set forth in the final audit report could require an issuer to return reinsurance payments. We maintained the regulatory requirements related to corrective action plans for reinsurance audits that currently appear in paragraph (d) in proposed paragraph (d)(4), which stated that (1) the issuer must provide a written corrective action plan to HHS for approval within 30 calendar days of the issuance of the final audit report; (2) the issuer must implement the corrective action plan; and (3) the issuer must provide HHS with written documentation demonstrating the adoption and completion of the required corrective actions.

Lastly, if an issuer fails to comply with the audit requirements set forth in proposed § 153.410(d), HHS proposed in paragraph (d)(5)(i) that HHS would notify the issuer of reinsurance payments received that the issuer has not adequately substantiated, and under proposed paragraph (d)(5)(ii), HHS would notify the issuer that HHS may recoup any payments identified as not adequately substantiated. We explained that under this framework, the continued failure to comply with the audit requirements and provide the necessary information to substantiate the payments made could result in HHS recouping up to 100 percent of the reinsurance payments made to an issuer for the applicable benefit year(s) that are the subject of the audit.

We also clarified that reinsurance payment amounts recovered by HHS as a result of an audit under § 153.410(d) would be allocated, on a pro rata basis, as further payments to the U.S. Treasury under section 1341(b)(3)(B)(iv) of the ACA and further reimbursement of administrative expenses related to operating the reinsurance program

under section 1341(b)(3)(B)(ii) of the ACA.¹¹³

We sought comment on these proposals, including HHS's clarification of its compliance review authority, the proposed timeframes for issuers to respond to audit notices, reports, inquiries, and requests for supplemental information, and the process for issuers to request an extension to respond to such requests. We are finalizing the proposed updates to the audit and compliance reviews of issuers of reinsurance eligible plans in § 153.410(d), with modifications to certain audit timelines in response to comments stating that issuers would need more time to provide complete and accurate data for an audit and respond to HHS requests.

We received public comments on the proposed updates to audits and compliance reviews of issuers of reinsurance-eligible plans (§ 153.410(d)). The majority of the comments we received to this section were general comments that were also applicable to the similar amendments proposed in the below sections regarding audits and compliance reviews of issuers of risk adjustment covered plans (§ 153.620(c)) and audits and compliance reviews of APTC, CSRs, and user fees (§ 156.480(c)). We responded to these generally applicable comments in the below section on audits and compliance reviews of APTC, CSRs, and user fees (§ 156.480(c)). What follows is a summary and our responses to the comments we received that were specific to audits and compliance reviews of issuers of reinsuranceeligible plans.

Comment: A few commenters were concerned that HHS is still conducting audits of issuers of reinsurance-eligible plans for monies received more than 5 years ago for a program that ended after the 2016 benefit year. These commenters asked that HHS reconsider the overall approach and need for conducting audits of issuers of reinsurance-eligible plans.

Response: HHS has the authority ¹¹⁴ and the responsibility to audit issuers of reinsurance-eligible plans to protect the integrity of the reinsurance program and ensure issuers received the appropriate reinsurance payments during the 2014 through 2016 benefit years. We recognize that the program ended with the 2016 benefit year, but activities

related to the operation of the program continued for several years. For example, the final deadline for remittance of 2016 benefit year reinsurance contributions was not until November 2017 115 and the last payments to issuers of reinsurance eligible plans were made in Spring 2018. Activities, such as these audits, continue as HHS closes out the program. We are planning to combine reinsurance program audits for the 2015 and 2016 benefit years, which will help facilitate a more efficient audit process and allow HHS to end the audits of reinsuranceeligible plans more quickly. We will similarly look for ways to combine efforts for compliance reviews of reinsurance-eligible plans, should we determine it is necessary or appropriate to pursue those additional oversight measures.

After consideration of the comments related to the proposals regarding audits and compliance review of reinsuranceeligible plans, we are finalizing these provisions as proposed, with slight modifications to certain audit timelines in response to comments 116 stating that issuers need more time during audits to provide complete and accurate data and respond to HHS requests. As finalized at § 153.410(d)(1), HHS will provide at least 30 calendar days advance notice of its intent to conduct an audit of an issuer of a reinsurance-eligible plan, rather than the proposed 15 calendar days. Additionally, as finalized at § 153.410(d)(4)(i), if HHS determines the need for a corrective action plan as the result of an audit, issuers must provide a written corrective action plan to HHS for approval within 45 calendar days of the issuance of the final audit report, rather than the proposed 30 calendar

We also clarify that we will recoup monies owed due to a finding as the result of an audit of a reinsurance-eligible plan using the same method with which we collect all debts. That is, to recoup the amount identified in § 153.410(d)(5)(i), we will first net using the process set forth in 45 CFR 156.1215, and we will then invoice issuers for the remaining debt (if any was owed).

¹¹³ See the Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond, Final Rule, 79 FR 30240 at 30257 through 30259 (May 27, 2014).

^{114 45} CFR 153.410(d).

¹¹⁵ https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/The-Transitional-Reinsurance-Program/2016-Benefit-Year-Page.

¹¹⁶ These comments, along with the other general comments submitted on the parallel amendments to the sections on audits and compliance reviews of reinsurance-eligible plans, risk adjustment covered plans, and QHP issuer compliance with federal standards for APTC, CSRs, and user fees, are summarized and responded to in the below preamble section on audits and compliance reviews of APTC, CSRs, and user fees (§ 156.480(c)).

b. Audits and Compliance Reviews of Issuers of Risk Adjustment Covered Plans (§ 153.620(c))

Although currently HHS primarily uses the HHS-RADV process to audit issuers of risk adjustment covered plans, § 153.620(c) provides HHS with the authority to conduct audits of issuers of risk adjustment-covered plans outside of the HHS-RADV process. HHS intends to begin audits of issuers of risk adjustment covered plans to ensure the proper payment of high-cost risk pool payments and confirm compliance with applicable requirements. As such, similar to the proposals related to audits and compliance reviews of issuers of reinsurance-eligible plans and learning from our experience with those 2014 benefit year audits, we proposed to provide more clarity around the audit requirements for issuers of risk adjustment covered plans. These proposals sought to explain the audit process, including what it means to properly comply with an audit and the consequences for failing to comply with such requirements.

We also proposed to expand the oversight tools available to HHS beyond traditional audits to also provide authority for HHS to conduct compliance reviews of risk adjustment covered plans to assess compliance with the applicable requirements of subparts G and H of part 153. We explained that the proposed HHS compliance reviews would follow the standards set forth for compliance review of QHP issuers participating in FFEs established in 45 CFR 156.715. However, compliance reviews under this section would only be conducted in connection with confirming risk adjustment covered plans' compliance with the applicable requirements related to the risk adjustment program in subparts G and H of part 153. A compliance review may be targeted at a specific potential error and conducted on an ad hoc basis.117 For example, HHS may require an issuer to submit data pertaining to a specific data submission (for example, capitated claims). Unlike the compliance review authority established in § 156.715, which is limited to QHP issuers participating in FFEs, the compliance review authority we proposed to codify in the amendments to § 153.620(c) would apply to all issuers of risk adjustment covered plans. We explained that we believe this flexibility is necessary and appropriate to provide a mechanism for HHS to address situations in which a systematic error or issue is identified during the random

Specifically, we proposed to rename § 153.620(c) to "Audits and Compliance Reviews" to clarify that the authority described in this section would apply to audits and the proposed HHS compliance reviews to evaluate risk adjustment covered plans' compliance with the applicable requirements in subparts G and H of part 153. We similarly proposed to update the introductory language in paragraph (c) to incorporate a reference to HHS compliance reviews and to note that we would conduct these compliance reviews consistent with the standards

set forth in 45 CFR 156.715.

We also proposed to amend the existing introductory language in § 153.620(c) to remove the last sentence that discusses audit results and the accompanying requirements that an issuer must follow if an audit results in a finding of material weakness or significant deficiency. As detailed further below, we proposed to replace this with a new proposed framework that captures more details on the audit process and requirements for risk adjustment covered plans. As amended, the introductory language at paragraph (c) would reflect the authority for HHS or its designee to audit or conduct a compliance review of an issuer of a risk adjustment covered plan to assess its compliance with the applicable requirements of subparts G and H of part 153. We also proposed to move the existing introductory language in paragraph (c) requiring an issuer to ensure its relevant contractors, subcontractors, and agents cooperate with audits to a new proposed section, as described further below.

We proposed to add new paragraph (c)(1) to establish notice and conference requirements for these audits. The introductory language in proposed paragraph (c)(1) reflects that HHS would provide at least 15 calendar days advance notice of its intent to conduct an audit of an issuer of a risk adjustment covered plan. In proposed paragraph (c)(1)(i), we proposed to codify that all audits under this section would include an entrance conference at which the scope of the audit would be presented

and an exit conference at which the initial audit findings would be discussed.

Further, we proposed to amend § 153.620(c) to add paragraph (c)(2) to capture the requirements issuers must meet to comply with an audit under this section. In proposed paragraph (c)(2)(i), we would capture the requirement that currently appears in the introductory text of paragraph (c) for the issuer to ensure that its relevant agents, contractors, and subcontractors cooperate with any audit or compliance review under this section and also proposed to expand it to similarly require the issuer to ensure its relevant employees, downstream entities and delegated entities also cooperate with any audit or compliance review under this section. In proposed paragraph (c)(2)(ii), we proposed to require issuers to submit complete and accurate data to HHS or its designees that is necessary to complete the audit. We explained that such data would need to support the appropriateness and accuracy of the risk adjustment transfers (including highcost risk pool payments and charges) under review as part of the audit. For example, HHS may request that issuers of risk adjustment covered plans provide enrollment and claims files and plan reference data and associated enrollee data.

In new paragraph (c)(2)(ii), we proposed that issuers must submit audit data, in the format and manner specified by HHS, no later than 30 calendar days after the initial deadline communicated and established by HHS at the entrance conference described in proposed paragraph (c)(1)(i). For example, HHS may require issuers to submit the requested audit data via Electronic File Transfer. Additionally, under proposed paragraph (c)(2)(iii), HHS proposed to require that issuers respond to any audit notices, letters, and inquires, including requests for supplemental or supporting information, no later than 15 calendar days after the date of the notice, letter, request, or inquiry. We noted that we believe that the proposed requirements in paragraph (c)(2) are necessary and appropriate to ensure the timely completion of audits and to prevent waste that results from repeated, fruitless attempts by HHS to obtain necessary data.

Recognizing that there may be situations that warrant an extension of the timeframes under § 153.620(c)(2)(ii) or (iii), as applicable, we proposed to also add a new paragraph (c)(2)(iv) to establish a process for issuers to request an extension for good cause. To request an extension, we proposed to require the issuer to submit a written request to

and targeted auditing of a sample of issuers of risk adjustment covered plans, and HHS suspects similarly situated issuers may have experienced the same systematic error or issue but were not selected for audit in the year in question. As noted in the proposed rule, we anticipate focusing our audit and compliance review activities under § 153.620(c) on ensuring compliance with requirements applicable to the high-cost risk pool payments under the HHS risk adjustment methodology.

¹¹⁷ For further details, please see 78 FR 65100.

HHS within the applicable timeframe established in paragraph (c)(2)(ii) or (iii). The written request would be required to detail the reasons for the extension request and the good cause in support of the request. For example, good cause may include an inability to produce information in light of unforeseen emergencies, natural disasters, or a lack of resources due to a PHE. If the extension is granted, the issuer must respond within the timeframe specified in HHS's notice granting the extension of time.

Under § 153.620(c)(3), HHS proposed that it would share its preliminary audit findings with the issuer, and further proposed that the issuer would then have 30 calendar days to respond to such findings in the format and manner specified by HHS. HHS would describe the process, format, and manner by which an issuer can dispute the preliminary findings in the preliminary audit report sent to the issuer. For example, if the issuer disagrees with the findings set forth in the preliminary audit report, HHS would require the issuer to respond to such findings by submitting written explanations that detail its dispute(s) or additional rebuttal information via Electronic File Transfer. Additionally, we proposed under paragraph (c)(3)(i) that if the issuer does not dispute or otherwise respond to the preliminary findings within 30 calendar days, the audit findings would become final. We proposed under paragraph (c)(3)(ii) that if the issuer timely responds and disputes any audit finding within 30 calendar days, HHS would review and consider such response and finalize the audit findings after such review. HHS would provide contact and other information necessary for an issuer to respond to the preliminary audit findings in the preliminary audit report sent to the issuer.

HHS proposed to add a new $\S 153.620(c)(4)$ to capture the process and requirements related to final audit findings and reports. If an audit results in the inclusion of a finding in the final audit report, the issuer must comply with the actions set forth in the final audit report in the manner and timeframe established by HHS. We noted that the actions set forth in the final audit reports could require an issuer to return risk adjustment (including high-cost risk pool) payments, or pay increased risk adjustment (including high-cost risk pool) charges. We maintained the regulatory requirements for corrective action plans for risk adjustment (including high-cost risk pool) audits that currently appear in § 153.620(c) in

proposed paragraph (c)(4), which stated that (1) the issuer must provide a written corrective action plan to HHS for approval within 30 calendar days of the issuance of the final audit report; (2) the issuer must implement the corrective action plan; and (3) the issuer must provide HHS with written documentation demonstrating the adoption and completion of the required corrective actions.

Lastly, if an issuer fails to comply with the audit requirements set forth in proposed § 153.620(c)(2), HHS proposed in paragraph (c)(5)(i) that HHS would notify the issuer of payments received that the issuer has not adequately substantiated, and in proposed paragraph (c)(5)(ii), HHS would notify the issuer that HHS may recoup any payments identified as not adequately substantiated. We explained that under this framework, the continued failure to comply with the audit requirements and provide the necessary information to substantiate the transfer amounts under review could result in HHS recouping up to 100 percent of the risk adjustment (including high-cost risk pool) payments, or increased risk adjustment (including high-cost risk pool) charges, made to an issuer for the applicable benefit year(s) that are the subject of the audit.

We noted that any risk adjustment payments or charges recovered by HHS during an audit of a risk adjustment covered plan would be paid on a pro rata basis similar to the process for risk adjustment default charge allocations to the other issuers participating in the applicable state market risk pool in the applicable benefit year. 118 We noted that any high-cost risk pool payments or charges recovered by HHS during an audit of a risk adjustment covered plan would be paid on a pro rata basis to other issuers in the relevant national market in the form of a reduced highcost risk pool charge in the applicable benefit year. HHS would not, however, re-run or otherwise recalculate transfers for the applicable benefit year if monies are recouped as a result of an audit under § 153.620(c).

We sought comment on these proposals, including HHS's clarification of its compliance review authority, the proposed timeframes for issuers to respond to audit notices, reports, and requests for supplemental information, and the process for issuers to request an extension to respond to such requests. We are finalizing the proposed updates to the audit and compliance reviews of issuers of risk adjustment covered plans

in § 153.620(c), with modifications to certain audit timelines in response to comments stating that issuers would need more time to provide complete and accurate data for an audit and respond to HHS requests. We will also adopt the approach outlined for distribution of risk adjustment payments or charges under the state payment transfer formula recovered by HHS during an audit of a risk adjustment covered plan would be paid on a pro rata basis similar to the process for risk adjustment default charge allocations to the other issuers participating in the applicable state market risk pool in the applicable benefit year. 119 We also reaffirm that HHS would not re-run or otherwise recalculate transfers for the applicable benefit year if monies are recouped as a result of an audit under § 153.620(c). However, after consideration of comments and further evaluation, we are not finalizing our proposal to disburse high-cost risk pool payments or charges recovered by HHS during an audit of a risk adjustment covered plan on a pro rata basis to other issuers in the relevant national market in the form of a reduced high-cost risk pool charge for the same applicable benefit year. We are continuing to consider options and the best possible process to disburse such amounts and will set forth any proposed process in future notice-and-comment rulemaking.

We received public comments on the proposed updates to audits and compliance reviews of issuers of risk adjustment covered plans (§ 153.620(c)). The majority of the comments we received to this section were general comments that were also applicable to the similar amendments proposed in the sections regarding audits and compliance reviews of issuers of reinsurance-eligible plans (§ 153.410(d)) and audits and compliance reviews of APTC, CSRs, and user fees (§ 156.480(c)). We responded to these generally applicable comments in the below section regarding audits and compliance reviews of APTC, CSRs, and user fees (§ 156.480(c)). We received one comment specific to audits and compliance reviews of issuers of risk adjustment covered plans, and the following is a summary of this comment and our response.

Comment: One commenter asked for clarification on the distribution of risk adjustment amounts that are recovered as the result of an audit and may be due to an issuer that is no longer in business.

Response: As noted above, we will disburse risk adjustment payments or

¹¹⁸ See the 2016 Payment Notice final rule, 80 FR 10780–10781.

¹¹⁹ Ibid.

charges under the state payment transfer formula recovered by HHS during a risk adjustment audit on a pro rata basis similar to the process for risk adjustment default charge allocations to the other issuers participating in the applicable state market risk pool benefit year. As such, we will allocate state payment transfer amounts (payments or charges) recovered by HHS during an audit under § 153.620(c) among the other plans in the impacted state market risk pool(s) proportional to each plan's relative revenue requirement as calculated under the state payment transfer formula relative to the market average of these products.120 HHS will pursue options to make payments to all of the appropriate issuers, including those that may no longer be operating in the relevant market. As for disbursing high-cost risk pool payments or charges recovered by HHS during an audit of a risk adjustment covered plan, we are continuing to consider options and the best possible process to disburse highcost risk pool payments or charges and will set forth any proposed process in future notice-and-comment rulemaking. For example, we may propose in future notice-and-comment rulemaking a recoupment disbursement methodology that provides eligible issuers participating in the current benefit year with a reduction in high-cost risk pool charges.

After consideration of comments on these proposals, we are finalizing the majority of the audit and compliance review provisions as proposed, with slight modifications to certain audits timelines in response to comments 121 stating that issuers need more time during audits to provide complete and accurate data and respond to HHS requests. As finalized at $\S 153.620(c)(1)$, HHS will provide at least 30 calendar days advance notice of its intent to conduct an audit of an issuer of a risk adjustment covered plan, rather than the proposed 15 calendar days. Additionally, HHS is finalizing at § 153.620(c)(4)(i) that if HHS determines the need for a corrective action plan as the result of an audit, issuers must provide a written corrective action plan to HHS for approval within 45 calendar

report, rather than the 30 calendar days

days of the issuance of the final audit

that currently appears at § 153.620(c)(1) and was proposed at § 153.620(c)(4)(i). We adopt the proposed approach for distribution of risk adjustment payments or charges under the state payment transfer formula recovered by HHS during an audit of a risk adjustment covered plan and will pay those amounts on a pro rata basis similar to the process for risk adjustment default charge allocations to the other issuers participating in the applicable state market risk pool in the applicable benefit year. 122 We reaffirm that HHS will not re-run or otherwise recalculate transfers for the applicable benefit year if monies are recouped as a result of an audit under § 153.620(c). As stated above, based on comments received and after further evaluation, we are not finalizing our disbursement proposal for high-cost risk pool payments or charges recovered by HHS during an audit of a risk adjustment covered plan and intend to address this issue in future rulemaking.

Finally, we clarify that we will recoup monies owed due to a finding as the result of an audit of a risk adjustment covered plan using the same method with which we collect all debts. That is, to recoup the amount identified in § 153.620(d)(5)(i), we will first net using the process set forth in 45 CFR 156.1215, and we will then invoice issuers for the remaining debt (if any is owed).

5. EDGE Discrepancy Materiality Threshold

As stated in § 153.710(a) through (c), an issuer of a risk adjustment covered plan must provide to HHS, through their EDGE server,¹²³ access to enrollee-level plan enrollment data, enrollee claims data, and enrollee encounter data as specified by HHS for a benefit year. Consistent with § 153.730, to be considered for risk adjustment payments and charges, issuers of risk adjustment covered plans must submit their respective EDGE data by April 30 of the year following the applicable benefit year. At the end of the EDGE data submission process, HHS issues final EDGE server reports 124 which

reflect an issuer's data that was successfully submitted by the data submission deadline. Within 15 calendar days of the date of these final EDGE server reports, the issuer must confirm to HHS that the information in the final EDGE server reports accurately reflect the data to which the issuer has provided access to HHS through its EDGE server for the applicable benefit year by submitting an attestation; or the issuer must describe to HHS any discrepancies it identifies in the final EDGE server reports.

HHS reviews all reported EDGE discrepancies to evaluate the implications of each incorrect data submission for risk adjustment transfers and risk adjustment data validation. For risk adjustment transfers calculated under the state payment transfer formula, HHS evaluates whether the reported EDGE discrepancy is material and has a process to address incorrect EDGE data submissions that have a material impact on risk adjustment transfers for a state market risk pool.125 126 Currently, HHS uses the same materiality threshold for reconsideration requests set forth in § 156.1220(a)(2) for determining whether the EDGE discrepancy has a material impact on the risk adjustment transfers calculated under the state payment transfer formula. Consequently, the reported EDGE discrepancy is considered material if the amount in dispute is equal to or exceeds the lower of either \$10,000 or one percent of the total estimated transfers in the applicable state market risk pool. After analyzing reported EDGE discrepancies in prior benefit years, we proposed to codify a materiality threshold for EDGE discrepancies and also proposed to establish a higher materiality threshold for EDGE

discrepancies. More specifically, we

threshold for EDGE discrepancies: The

proposed the following materiality

 $^{^{120}\,\}mathrm{See}$ the 2016 Payment Notice final rule, 80 FR 10780–10781.

¹²¹These comments, along with the other general comments submitted on the parallel amendments to the sections on audits and compliance reviews of reinsurance-eligible plans, risk adjustment covered plans, and QHP issuer compliance with federal standards for APTC, CSRs, and user fees, are summarized and responded to in the below preamble section on audits and compliance reviews of APTC, CSRs, and user fees (§ 156.480(c)).

 $^{^{122}\,\}mathrm{See}$ the 2016 Payment Notice final rule, 80 FR 10780–10781.

¹²³ This is also known as the dedicated distributed data collection environment.

¹²⁴ These reports are: Enrollee (Without) Claims Summary (ECS), Enrollee (Without) Claims Detail (ECD), Frequency Report by Data Element for Medical Accepted Files (FDEMAF), Frequency Report by Data Element for Pharmacy Accepted Files (FDEPAF), Frequency Report by Data Element for Supplemental Accepted Files (FDESAF), Frequency Report by Data Element for Enrollment Accepted Files (FDEEAF), Claim and Enrollee Frequency Report (CEFR), High Cost Risk Pool

Summary (HCRPS), High Cost Risk Pool Detail Enrollee (HCRPDE), Risk Adjustment Claims Selection Summary (RACSS), Risk Adjustment Claims Selection Detail (RACSD), Risk Adjustment Transfer Elements Extract (RATEE), Risk Adjustment Risk Score Summary (RARSS), Risk Adjustment Risk Score Detail (RARSD), Risk Adjustment Data Validation Population Summary Statistics (RADVPS), Risk Adjustment Payment Hierarchical Condition Category Enrollee (RAPHCCER), Risk Adjustment User Fee (RAUF).

¹²⁵ See, for example, https://www.cms.gov/CCIIO/ Resources/Regulations-and-Guidance/Downloads/ EDGE-2019-QQ-Guidance.pdf. Also see 83 FR 16970 through 16971.

¹²⁶HHS may also take action on reported material EDGE discrepancy if the discrepancy involved a processing error by HHS, HHS's incorrect application of the relevant methodology, or a HHS mathematical error, consistent with the bases upon which an issuer may request reconsideration under § 156.1220.

amount in dispute must equal or exceed \$100,000 or one percent of the total estimated transfer amount in the applicable state market risk pool, whichever is less. 127 Where an identified material EDGE discrepancy negatively affects the issuer without having a negative effect on other issuers within the state market risk pool, issuers would be required to adhere to the initial data submission and accept the consequences of the data submission, even when the monetary impact of the inaccuracy on the issuer submitting incorrect data is potentially substantial. Therefore, HHS would generally only take action on material discrepancies that harm other issuers in the same state market risk pool.128 In general we expect about half of discrepancies that are material under previous criteria would no longer be material under the new criteria.

We proposed to amend § 153.710, by creating new paragraph (e) and redesignating paragraphs (e), (f) and (g), as (f), (g) and (h) respectively, to capture the proposed EDGE discrepancy materiality threshold and proposed to apply it beginning with the 2020 benefit year.129 We explained that we believe this increased materiality threshold will reduce burden on issuers having to submit additional data to HHS when a discrepancy is determined to be potentially material and allow more certainty and stability for risk adjustment transfers. If a reported EDGE discrepancy is determined to not meet the materiality threshold, HHS would take no action on the discrepancy and the issuer's data submission would remain as submitted by the data submission deadline for the applicable

We also explained that while HHS generally only takes action on reported material EDGE discrepancies that are determined to harm other issuers, issuers must continue to report and describe any identified EDGE discrepancy to HHS in a format specified by HHS for each benefit year. Issuers must report all data discrepancies in order to permit HHS to

determine whether such an error is material and actionable and to evaluate the impact on other issuers in the state market risk pool. We sought comment on the proposed EDGE discrepancy materiality threshold and the accompanying amendments to § 153.710. We are finalizing the EDGE discrepancy materiality threshold and the amendments to § 153.710 as proposed.

We received public comments on the proposed updates to the EDGE discrepancy materiality threshold. The following is a summary of the comments we received and our responses.

Comment: Most commenters supported the proposed increase to the EDGE discrepancy materiality threshold. These commenters noted the increased threshold amount would enhance program integrity by focusing efforts on discrepancies that negatively impact other issuers in the applicable market risk pool, reduce the administrative burden associated with these data requests, and allow more certainty and stability for risk adjustment transfers. A few commenters expressed the belief that the previous threshold had been too low. One commenter agreed with increasing the threshold but noted they lacked the data to confirm the proposed threshold was appropriate.

Response: We appreciate the support for increasing the EDGE discrepancy materiality threshold. We agree with commenters that the increased discrepancy materiality threshold will reduce issuer burden and allow for more certainty and stability for risk adjustment transfers. We also agree that the current threshold, which was established to be consistent with the materiality threshold for reconsideration requests set forth in 45 CFR 156.1220(a)(2), is too low for discrepancies and most of the time required HHS to reallocate minimal amounts of risk adjustment monies. As such, we are finalizing the EDGE materiality threshold as proposed.

In assessing different EDGE discrepancy materiality thresholds, HHS analyzed the 2017 benefit year EDGE discrepancies. Specifically, we reviewed the discrepancy amounts and impacts on affected issuers in the impacted state market risk pools and considered a variety of threshold amounts. We found that \$100,000 or one percent of the total estimated transfer amount in the applicable state market risk pool balanced reducing the number of reallocations involving small amounts with maintaining data integrity and confidence in the risk adjustment program.

After consideration of the comments on these proposals, for the 2020 benefit year and beyond, we are finalizing the EDGE discrepancy materiality threshold as proposed, including the accompanying proposed amendments to § 153.710, to reflect the amount in dispute must equal or exceed \$100,000 or one percent of the total estimated transfer amount in the applicable state market risk pool, whichever is less. Where an identified material EDGE discrepancy negatively affects the issuer without having a negative effect on other issuers within the state market risk pool, issuers will be required to adhere to the initial data submission and accept the consequences of their data submission, even when the negative financial impact of the inaccuracy on the issuer submitting incorrect data is above this materiality threshold. Therefore, HHS will only take action on material discrepancies that harm other issuers in the same state market risk pool.¹³⁰

6. Risk Adjustment User Fee for 2022 Benefit Year (§ 153.610(f))

If a state is not approved to operate, or chooses to forgo operating, its own risk adjustment program, HHS will operate risk adjustment on its behalf. As noted previously in this final rule, for the 2022 benefit year, HHS will be operating the risk adjustment program in every state and the District of Columbia. As described in the 2014 Payment Notice, HHS's operation of risk adjustment on behalf of states is funded through a risk adjustment user fee. 131 Section 153.610(f)(2) provides that, where HHS operates a risk adjustment program on behalf of a state, an issuer of a risk adjustment covered plan must remit a user fee to HHS equal to the product of its monthly billable member enrollment in the plan and the PMPM risk adjustment user fee specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year.

OMB Circular No. A–25 established federal policy regarding user fees, and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from federal activities beyond those received by the general public. The risk adjustment program will provide special

 $^{^{127}}$ We are not proposing any changes to the materiality threshold for reconsideration requests in \S 156.1220(a)(2).

¹²⁸ Consistent with the current process, HHS may also take action on reported material EDGE discrepancies if the discrepancy involved a processing error by HHS, HHS's incorrect application of the relevant methodology, or a HHS mathematical error, consistent with the bases upon which an issuer may request reconsideration under § 156.1220.

¹²⁹The deadline for submission of 2020 benefit year risk adjustment data is April 30, 2021. See 45 CFR 153.730. As such, the EDGE discrepancy reporting process for the 2020 benefit year will not begin until May 2021.

¹³⁰Consistent with the current process, HHS may also take action on reported material EDGE discrepancies if the discrepancy involved a processing error by HHS, HHS's incorrect application of the relevant methodology, or a HHS mathematical error, consistent with the bases upon which an issuer may request reconsideration under § 156.1220.

^{131 78} FR 15416 through 15417.

benefits as defined in section 6(a)(1)(B) of Circular No. A–25 to issuers of risk adjustment covered plans because it mitigates the financial instability associated with potential adverse risk selection. The risk adjustment program also contributes to consumer confidence in the health insurance industry by helping to stabilize premiums across the individual, merged, and small group markets.

In the 2021 Payment Notice, HHS calculated the federal administrative expenses of operating the risk adjustment program for the 2021 benefit vear to result in a risk adjustment user fee rate of \$0.25 PMPM based on our estimated costs for risk adjustment operations and estimated billable member months for individuals enrolled in risk adjustment covered plans. For the 2022 benefit year, we proposed to use the same methodology to estimate our administrative expenses to operate the program. These costs cover development of the model and methodology, collections, payments, account management, data collection, data validation, program integrity and audit functions, operational and fraud analytics, stakeholder training, operational support, and administrative and personnel costs dedicated to risk adjustment program activities. To calculate the user fee, we divided HHS's projected total costs for administering the risk adjustment programs on behalf of states by the expected number of billable member months in risk adjustment covered plans in states where the HHS-operated risk adjustment program will apply in the 2022 benefit year.

We estimate that the total cost for HHS to operate the risk adjustment program on behalf of states for the 2022 benefit year will be approximately \$60 million, and the risk adjustment user fee would be \$0.25 PMPM. The risk adjustment user fee costs for the 2022 benefit year are expected to remain steady from the prior 2021 benefit year estimates. However, we project a small decline in billable member months in the individual and small group markets overall in the 2022 benefit year based on the declines observed in the 2019 benefit year. We sought comment on the proposed risk adjustment user fee for the 2022 benefit year. We also explained that we would continue to examine the costs and enrollment projections for the 2022 benefit year, particularly as we receive more information on the impact of the coronavirus disease 2019 (COVID-19) PHE, and proposed to incorporate any such newly available data to update the final 2022 benefit year risk adjustment user fee rate that

we would announce in the final rule. We sought comment on these estimates and the use of any newly available data to update the estimates to reflect any emerging cost or enrollment trends for the final 2022 benefit year user fee. We are finalizing the 2022 benefit year risk adjustment user fee as proposed.

We received public comments on the proposed risk adjustment user fee for 2022 benefit year (§ 153.610(f)) and accompanying solicitation of comments. The following is a summary of the comments we received on the proposed 2022 benefit year user fee and our responses.

Comment: One commenter expressed concern regarding HHS's assumption that overall enrollment would decline in the 2022 benefit year, which would result in an increased risk adjustment user fee amount. This commenter requested additional detail on the projected decrease in billable member months.

Response: Our methodology for calculating the 2022 benefit year risk adjustment user fee was the same as the one used for 2021 benefit year. But as the commenter noted, when we proposed the rule, we anticipated a small decline in billable member months in the individual and small group markets overall based on the declines observed in 2019 benefit year. We continue to believe that the finalized rate will ensure adequate funding for HHS to operate the risk adjustment program in all 50 states and the District of Columbia for 2022. Importantly, we also note that our assumption of a small decline in billable member months did not actually result in any increase in the risk adjustment user fee from the previous 2021 benefit year amount. 132

After consideration of the comments on this proposal, we are finalizing the risk adjustment user fee for the 2022 benefit year as \$0.25 PMPM as proposed.

7. Risk Adjustment Data Validation Requirements When HHS Operates Risk Adjustment (HHS–RADV) (§ 153.630)

To ensure the integrity of the HHS-operated risk adjustment program, HHS conducts risk adjustment data validation (HHS–RADV) under §§ 153.350 and 153.630 in any state where HHS is operating risk adjustment on a state's behalf. The purpose of HHS–RADV is to ensure issuers are providing accurate and complete risk adjustment data to HHS, which is crucial to the purpose and proper functioning of the

HHS-operated risk adjustment program. HHS-RADV also ensures that risk adjustment transfers reflect verifiable actuarial risk differences among issuers, rather than risk score calculations that are based on poor data quality, thereby helping to ensure that the HHS-operated risk adjustment program assess charges to issuers with plans with lower-thanaverage actuarial risk while making payments to issuer with plans with higher-than-average actuarial risk. HHS-RADV consists of an initial validation audit and a second validation audit.133 Under § 153.630, each issuer of a risk adjustment covered plan must engage an independent initial validation audit entity. The issuer provides demographic, enrollment, and medical record documentation for a sample of enrollees selected by HHS to the issuer's initial validation auditor for data validation. Each issuer's initial validation audit is followed by a second validation audit, which is conducted by an entity HHS retains to verify the accuracy of the findings of the initial validation audit.

a. Exemptions From HHS–RADV (§ 153.630(g))

In 2020 Payment Notice, we codified several exemptions from the HHS-RADV requirements. In this rule, we proposed to codify the previously established exemption 134 for issuers who only offer small-group carryover coverage in the state during the benefit year being audited at new proposed $\S 153.630(g)(4)$. As we discussed in the 2020 Payment Notice, under this policy, a small group market issuer with offcalendar vear coverage who exits the market but has only carry-over coverage that ends in the next benefit year (that is, carry-over of run out claims for individuals enrolled in the previous benefit year, with no new coverage being offered or sold in the state) would be considered an exiting issuer and would be exempt from HHS-RADV for the benefit year with the carry-over coverage. 135

We also proposed to codify the previously established exemption ¹³⁶ for issuers who are the sole issuer in a state market risk pool during the benefit year that is being audited at new proposed § 153.630(g)(5). As we discussed in the 2020 Payment Notice, for single issuer market risk pool(s), there are no risk adjustment transfers calculated under the state payment transfer formula and thus, no payment or financial

¹³²The 2021 benefit year risk adjustment user fee amount is also \$0.25 PMPM. See 85 FR at 29194–29195

¹³³ 45 CFR 153.630(a) through (c).

¹³⁴ 84 FR 17503 through 17504.

¹³⁵ Ibid.

^{136 84} FR 17504

accountability to other issuers for that risk pool. ¹³⁷ As such, a sole issuer in a state market risk pool is not required to participate in the HHS-operated risk adjustment program (except for purposes of high-cost risk pool payments and charges) for that state market risk pool. However, if the sole issuer was participating in multiple risk pools in the state during the year that is being audited, that issuer will be subject to HHS–RADV for those risk pools with other issuers that had risk adjustment transfers calculated under the state payment transfer formula.

We noted that these exemptions do not introduce new policies; instead, the proposed amendments to § 153.630(g) were simply to codify these previously established exemptions in regulation. We also clarified that any issuer that qualifies for the small group carryover coverage exemption in new proposed paragraph (g)(4) would not have its risk score and its associated risk adjustment transfers adjusted due to its own risk score error rate, as the issuer would not have participated in HHS-RADV for the benefit year in which it only offered the small group carryover coverage. However, that issuer's risk score and resulting risk adjustment transfers could be subject to HHS-RADV adjustments if other issuers in that state market risk pool were outliers and received HHS-RADV risk score error rates for that benefit vear.

We solicited comments on these proposals.

We only received comments in support of codifying the HHS-RADV exemption for issuers who are the sole issuer in a state market risk pool during the benefit year being audited and are finalizing the amendment to § 153.630(g)(5) to codify that exemption as proposed. We received several public comments on the codification of the HHS-RADV exemption for issuers providing only small group carryover coverage in the benefit year being audited at § 153.630(g)(4), some of these comments restated the proposal without providing an opinion while others expressed opposition to the proposal. After consideration of the comments received, we are also finalizing the amendment to § 153.630(g)(4) to codify this exemption as proposed.

The following is a summary of the comments we received on the codification of the exemption for issuers providing only small group carryover coverage and our responses.

Comment: Some commenters asked HHS to reconsider the HHS–RADV exemption for issuers providing only small group carryover coverage in the benefit year being audited. These commenters expressed concern that an exiting issuer with only small group carryover coverage may potentially make up a large portion of the market for that calendar year. The commenters also stated that issuers providing only small group carryover coverage, who have not undergone HHS–RADV in the previous 2 years, should still be subject to HHS–RADV requirements for that year.

Response: After reviewing the comments on the proposed amendments to § 153.630(g)(4), we are finalizing, as proposed, the codification of the exemption from HHS–RADV for issuers providing only small group carryover coverage in the benefit year being audited. As discussed above and in the proposed rule, neither of these exemptions are new ¹³⁸ and the proposals were to codify the previously established exemptions in regulation. We continue to believe that both exemptions are appropriate.

With respect to the exemption for sole issuers, we believe it is appropriate because we do not calculate risk adjustment transfers for a benefit year in a state market risk pool in which there is only one issuer and thus, there is no payment or financial accountability to other issuers for that risk pool. With respect to the small group carryover coverage exemption, we believe that this exemption ensures that such small group carryover only issuers (who are considered exiting issuers) are treated the same as other exiting issuers with regards to HHS–RADV requirements.

With respect to concerns that issuers seeking to use the small group carryover coverage exemption might make up a large portion of the market, based on our past experience operating HHS-RADV for the 2017 and 2018 benefit years, we found that issuers that would qualify for this exemption criteria are typically very small issuers, with the majority having fewer than 500 billable member months statewide or below \$15 million in total premium. As a result, we do not believe issuers that would qualify for this exemption would make up a large portion of a state's market risk pool and these issuers have generally had a reasonable chance of being exempted under other exemption categories. 139

With respect to the comment on issuers being subject to HHS–RADV requirements if they have not participated in HHS–RADV in the previous 2 years, we note that generally all issuers of risk adjustment covered

plans in a state market risk pool must participate in HHS-RADV unless they qualify for an exemption specified in 153.630(g). As established at 153.630(g)(2), it is only issuers at or below the materiality threshold that are subject to random and targeted sampling for HHS-RADV participation approximately every 3 years (barring any risk-based triggers based on experience that will warrant more frequent audits). This exemption for issuers at or below materiality threshold was created in response to stakeholder requests to ease the burden of annual audit requirements for smaller issuers of risk adjustment covered plans. We maintain that this exemption for issuers at or below materiality threshold is important given the fixed costs associated with hiring an initial validation auditor and submitting results to HHS on an annual basis; therefore, we do not intend to make changes to it at this time.

After consideration of the comments received on these proposals, we are finalizing the codification of the sole issuer and small group carryover coverage issuer exemptions from HHS–RADV and the amendments to § 153.630(g) as proposed.

b. IVA Requirements (§ 153.630(b)(3))

In accordance with § 153.630(b)(3), an issuer must ensure that its IVA Entity is reasonably free of conflicts of interest, such that it is able to conduct the IVA in an impartial manner and its impartiality is not reasonably open to question. In prior rulemaking, we explained that to meet this standard, the IVA Entity, among other things, may not have had a role in establishing any relevant internal controls of the issuer related to the risk adjustment data validation process when HHS is operating risk adjustment on behalf of a state, or serve in any capacity as an advisor to the issuer regarding the IVA.¹⁴⁰ In the proposed rule, we proposed to amend this standard and clarify that to demonstrate that the IVA Entity is reasonably free of conflicts, the IVA Entity must also not have or previously have had a role in establishing any relevant internal controls of the issuer related to risk adjustment or the EDGE server data submission process for the applicable benefit year for which the IVA Entity is performing the IVA on behalf of the issuer. Additionally, the IVA Entity must also not have served in any capacity as an advisor to the issuer regarding the risk adjustment or EDGE server data submission for the

¹³⁸ See 84 FR 17503 through 17504.

¹³⁹ See 45 CFR 153.630(g)(1) and (g)(2).

¹⁴⁰ See 79 FR 13758.

applicable benefit year. For example, the IVA Entity cannot serve as the issuer's third party administrator (TPA) for purposes of the EDGE data submission for HHS-operated risk adjustment in the 2020 benefit year and serve as the IVA Entity for that issuer for the 2020 benefit year. We proposed these changes because we are concerned about conflicts of interest that could arise if the same entity assists or completes the EDGE data submissions for an issuer for an applicable benefit year, and then also serves as the IVA Entity auditing the submission of that data in HHS-RADV. This proposal was in addition to the requirements set forth in 2014 and 2015 Payment Notices. 141 We sought comment on this proposal.

The only comments we received on the proposed updates to IVA requirements (§ 153.630(b)(3)) supported the proposal noting that there is a potential conflict of interest if an IVA Entity for a company also served as the company's TPA for purposes of EDGE data submission or risk adjustment. These commenters were in support of the regulatory change. After consideration of comments on these proposals, we are finalizing this policy and the accompanying amendment to § 153.630(b)(3) as proposed.

c. HHS-RADV Administrative Appeals

In the 2015 Payment Notice, we established a three-level administrative appeals process for issuers to seek reconsideration of amounts under certain ACA programs, including the calculation of risk adjustment charges, payments and user fees.¹⁴² In the 2018 Payment Notice final rule, we extended this three-level administrative appeal process to permit issuers to dispute the findings of a second validation audit with respect to the 2016 benefit year HHS–RADV and beyond. 143 As previously explained, issuers are not permitted to use the discrepancy reporting or administrative appeal processes under §§ 153.630(d)(2) and 156.1220, respectively, to contest the IVA findings, because HHS does not conduct the IVA or produce those

results. 144 Instead, issuers should review their IVA findings and discuss any concerns with its IVA Entity prior to attesting to and submitting those results to HHS.¹⁴⁵ As explained in the 2020 Payment Notice, only those issuers who have insufficient pairwise agreement between the IVA and second validation audit will receive a Second Validation Audit Findings Report, and therefore, have the right to appeal the second validation audit findings. 146 The existing regulation at § 153.630(d)(2) captures this policy. In the proposed rule, we proposed conforming amendments to paragraph (d)(3) to similarly add "if applicable" to the reference to an issuer's ability to appeal the findings of the second validation audit to ensure these regulatory provisions also appropriately capture this limitation. 147 We sought comment on these proposed amendments.

The only comment we received on the proposal to codify the previously established limits on the ability to appeal SVA findings as part of the HHS–RADV administrative appeals process was in support of the proposed clarifications. After consideration of the comments on this proposal, we are finalizing the conforming amendments to § 153.630(d)(3) as proposed.

d. Timeline for Collection of HHS– RADV Payments and Charges

In the 2020 Payment Notice,148 we finalized an updated timeline for the publication, collection, and distribution of HHS–RADV adjustments to transfers. This timeline was adopted to allow issuers to report HHS-RADV adjustments in a later MLR reporting year and to consider, in accordance with any guidance from the state DOIs, these adjustments in rate setting during a later benefit year (specifically, the year in which the HHS-RADV adjustments are collected and paid). We proposed, beginning with 2019 benefit year HHS-RADV, to revert to the previous schedule 149 for the collection of HHS-

RADV charges and disbursement of payments in the calendar year in which HHS–RADV results are released (for example, collection and disbursement of 2021 benefit year HHS–RADV adjustments would begin in summer or fall of 2023). We are finalizing the change in the HHS–RADV adjustment timeline as proposed.

HHS publishes the final summary report of risk adjustment transfers (without HHS-RADV adjustments) and information on risk adjustment default charges for the applicable benefit year in the summer of the year after the applicable benefit year (typically June 30th of the year after the applicable benefit year), and issuers report those risk adjustment amounts in their MLR reports by July 31st of the year after the applicable benefit year. 150 Payment and collection of these risk adjustment transfer and default charge amounts generally occurs in August and September of the year after the applicable benefit year. We separately report the HHS-RADV adjustments and information on default data validation charges for the applicable benefit year approximately one year after the final summary report of risk adjustment transfers for that benefit year is published (typically 2 years after the applicable benefit year in August 151).

Under the HHS–RADV timeline effective prior to the publication of this rule, HHS begins collection and disbursement of HHS–RADV adjustments and default data validation charges and allocations 2 years after announcing the HHS–RADV adjustments (for example, collection and disbursement of 2017 benefit year HHS–RADV adjustments will begin in 2021 ¹⁵²). For MLR reporting purposes, under the 2020 Payment Notice approach applicable through 2018 benefit year HHS–RADV, issuers will

¹⁴¹ The 2014 Payment Notice final rule required that that issuers ensure that IVA Entities are reasonably capable of performing the audit, the audit is completed, the auditor is free from conflicts of interest, and the auditor submits information regarding the IVA to HHS in the manner and timeframe specified by HHS. 78 FR 15410 at 15437. The 2015 Payment Notice final rule established standards and guidelines regarding the qualifications of the IVA Entity, including further details on the conflict of interest standards. 79 FR 13744 at 13758–13759.

^{142 78} FR 13818 through 13820.

¹⁴³ 81 FR 94106.

¹⁴⁴ Ibid.

¹⁴⁵ See, for example, Sections 9.1, 9.5 and 9.7 of the "2017 Benefit Year Protocols ACA HHS Risk Adjustment Data Validation, Version 2.0," August 10, 2018

¹⁴⁶ 84 FR 17495. If the pairwise means test results conclude there is sufficient agreement between the IVA and SVA findings, the IVA findings are used to adjust risk scores. Issuers with sufficient pairwise agreement do not receive a Second Validation Audit Findings Report and there are no SVA findings to appeal. See 84 FR at 17495.

¹⁴⁷ As detailed further below, we propose similar conforming amendments to the references to an issuer's ability to appeal the findings of the second validation audit in 45 CFR 156.1220(a)(1) and (a)(3).

¹⁴⁸ 84 FR 17506 through 17507.

 $^{^{149}\,\}mathrm{See}$ 79 FR 13768 and 13769. Also see, for example, Table 3 in the document entitled

[&]quot;Proposed Key Dates for Calendar Year 2019: Qualified Health Plan (QHP) Certification in the Federally-facilitated Exchanges (FFEs); Rate Review; and Risk Adjustment." Available at https:// www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Key-Dates-Table-for-CY2019.pdf.

¹⁵⁰The one exception is for the rare circumstances that HHS is unable to collect full risk adjustment charges in a state market risk pool or high-cost risk pool charges in a national market risk pool. In such situations, issuers receiving lesser payments can reflect the reductions in their MLR reports.

¹⁵¹HHS–RADV adjustments for the 2019 benefit year will be published under a different timeline due to the COVID–19-related delay in HHS–RADV activities for the 2019 benefit year. See https:// www.cms.gov/files/document/2019-HHS-RADV-Postponement-Memo.pdf.

¹⁵² https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/ Downloads/BY2017-HHSRADV-Adjustments-to-RA-Transfers-Summary-Report.pdf.

reflect the HHS-RADV adjustment amounts and default data validation charges and allocations in the MLR reporting year in which collections and payments of those amounts occur. Subject to approval by state DOIs, issuers are also permitted to reflect these amounts in rate setting for the same benefit year in which those amounts are paid or collected. For example, 2017 benefit year HHS-RADV adjustments and default data validation charges and allocations were announced in August 2019 and issuers will report these amounts in the 2021 MLR reporting year (MLR reports filed in 2022), the same year that the adjustments and default data validation charges will be collected and paid. Additionally, subject to permission by state DOIs, issuers were permitted to account for the impacts of those 2017 benefit year HHS-RADV adjustments in rate setting for the 2021 benefit year.

The 2020 Payment Notice timeline was intended to address stakeholder concerns regarding the predictability of HHS-RADV adjustments, especially for the initial payment year. However, since the publication of the 2020 Payment Notice, we have received feedback stating that the extended timeline has not provided the increased flexibility intended by the policy and instead has introduced undue complexity. Specifically, stakeholders have expressed concern that this policy conflicts with state requirements for financial accounting, and can negatively impact their MLR rebate position, particularly if the issuer experiences substantial changes in enrollment over the 3-year MLR calculation period. 153 Additionally, in the 2020 HHS-RADV Amendments Rule, we finalized a transition from the prospective application of HHS-RADV adjustments 154 to a concurrent application beginning with 2020 benefit year HHS-RADV. 155 More specifically, we finalized a policy to transition to applying HHS-RADV adjustments to the risk scores and transfers of the same benefit year being audited for all issuers (for example, 2021 benefit year HHS-RADV adjustments will apply to 2021 benefit year risk scores and risk adjustment transfers, rather than to 2022 benefit year risk scores and risk

adjustment transfers, as would have taken place prior to the finalization of the 2020 HHS–RADV Amendments Rule).156 To transition to this policy, HHS will average the 2019 and 2020 benefit year HHS-RADV results of nonexiting issuers who participated in risk adjustment for both benefit years 157 to calculate the HHS-RADV adjustment to 2020 benefit year risk scores and transfers, and will publish the HHS-RADV adjustments to transfers along with information on any default data validation charges imposed for both benefit years. 158 Beginning with the 2021 benefit year of HHS-RADV, risk scores and transfers will only be adjusted once based on the same benefit year's HHS-RADV results (that is, 2021 benefit year HHS–RADV results would adjust 2021 benefit year plan liability risk scores).

Although the operational timelines of the risk adjustment program and the nature of HHS-RADV causes HHS-RADV results to always be at least a year behind the associated risk adjustment transfers report, we have continued to consider these issues. The above referenced changes to the benefit year to which HHS-RADV adjustments are applied also lead us to revisit these issues. We adopted the 2020 Payment Notice timeline to provide issuers (and states) with more options on how and when to account for the financial impacts from HHS-RADV. However, as noted above, stakeholder feedback has indicated that the approach did not achieve its policy goal and instead introduced unnecessary complexity. Therefore, we proposed to revert to the previous schedule for collection and

disbursement of HHS-RADV adjustments and default data validation charges and begin such activities in the summer or fall of the calendar year in which HHS-RADV results are released. For example, collection of 2021 benefit vear HHS-RADV adjustments and default data validation charges and disbursement of such amounts would begin in summer or fall of 2023. In support of the new proposed timeline for collection and disbursement of HHS–RADV adjustments and default data validation charges, we explained that HHS would need to release the applicable benefit year's report on HHS-RADV adjustments and default data validation charges earlier in the year so the amounts are available for issuers to use for MLR reporting purposes. We therefore also proposed to release the applicable benefit year's HHS-RADV summary report no later than early summer, and require issuers to report those amounts in the MLR reports submitted by July 31st of the same calendar year in which the results are released. For example, as proposed, the summary report on 2021 benefit year HHS-RADV adjustments and default data validation charges and allocations would be released no later than early summer 2023, and issuers would be instructed to report these amounts in the 2022 MLR reporting year (MLR reports that include 2022 benefit year data that are submitted by July 31, 2023; See Table 9). We would then collect and disburse HHS-RADV adjustments and default data validation charges and allocations in summer or fall of the calendar year in which HHS-RADV results are released (for example, collection and disbursement of 2021 benefit year HHS-RADV adjustments and default data validation charges would begin in summer or fall of 2023). We noted that the Unified Rate Review Template (URRT) instructions currently permit issuers and states to consider HHS-RADV impacts in rates for the year when these amounts will be collected and disbursed and specified, as an example, that as 2017 RADV adjustments will be collected in the 2021 calendar year, a state may allow issuers to consider these adjustments in their 2021 rate setting. Therefore, in the proposed rule, we proposed to remove this flexibility from the URRT instructions.

We further explained that the proposed timeline would help mitigate concerns regarding the incongruity with state financial accounting requirements, as well as potential undue impacts of HHS–RADV adjustments on MLR rebate liability, which could result from the

¹⁵³ Issuer MLRs are calculated using a 3-year average. See section 2718(b)(1)(B)(ii) of the Act and 45 CFR 158.220(b).

¹⁵⁴ The exception to the prospective application of HHS–RADV adjustments is for exiting issuers, whose HHS–RADV results are currently used to adjust risk scores and transfers for the benefit year being audited (rather than the following benefit year's transfers). See 83 FR 16965 through 16966 and 84 FR 17503 through 17504.

^{155 85} FR 77002-77005.

¹⁵⁶ Ibid.

 $^{^{\}rm 157}\,\rm Exiting$ and new issuers who participate in only one of the two benefit years will not have their results for 2019 and 2020 averaged before being applied to the relevant benefit year's transfers. For exiting issuers, positive error rate outlier issuers 2019 and 2020 HHS-RADV results will be applied to the risk scores and risk adjustment transfers for the benefit year being audited. If a new issuer entered a state market risk pool in 2020, its plan liability risk score(s) and risk adjustment transfer for the 2020 benefit year could be impacted by the new issuer's own 2020 HHS-RADV results, the combined 2019 and 2020 HHS-RADV results of other non-exiting issuers in the same state market risk pool, as well as the 2020 HHS-RADV results of exiting positive error rate outlier issuers in the same state market risk pool.

¹⁵⁸We note that we intend to publish a separate 2019 benefit year HHS–RADV results memo that will provide an overview of the 2019 benefit year error rate results. We also plan to release a separate 2019 benefit year HHS–RADV Summary Report that details adjustments to 2019 benefit year risk scores and transfers if there are any exiting positive error rate outlier issuers in the 2019 benefit year of HHS–RADV. The average error rate approach is not applicable for these issuers because exiting issuers who participated in 2019 HHS–RADV will not have 2020 benefit year risk scores or transfers to adjust.

HHS-RADV adjustments being reported outside the 3-year MLR aggregation window and thus potentially distorting the MLR experience of the benefit year to which HHS-RADV adjustments apply. Additionally, we noted this proposed change may also help mitigate the impact of any substantial changes in enrollment between benefit years.

We proposed to begin this policy with the collection and disbursement of HHS-RADV adjustments and default data validation charges for the 2019 benefit year and noted that due to the delay in the 2019 benefit year HHS-RADV,159 the timing of collections and disbursements is different for the 2019 benefit year. We sought comment on this proposal and whether any consideration should be made in the transition to this policy to account for 2017 and 2018 benefit year HHS-RADV collection and disbursement of payments and charges (under the 2020 Payment Notice timeline) also occurring in 2021 and 2022.

We are finalizing the updates to the timeline for collection of HHS–RADV payments and charges, as proposed. As such, HHS will publish the 2019 and 2020 benefit year HHS–RADV Summary Report for non-exiting issuers in early summer of 2022. ¹⁶⁰ ¹⁶¹ Issuers will also be required to include any payments and charges reflected on this report, along with risk adjustment transfers for the 2021 benefit year, in their 2021 MLR

¹⁵⁹ HHS–RADV adjustments for the 2019 benefit year will be published under a different timeline due to the COVID–19-related delay in HHS–RADV activities for the 2019 benefit year. See https:// www.cms.gov/files/document/2019-HHS-RADV-Postponement-Memo.pdf.

¹⁶⁰ In the proposed rule, we proposed to publish separate 2019 and 2020 summary reports in early summer of 2022. However, as noted earlier in this preamble, in the 2020 HHS–RADV Amendments Rule (85 FR 77002–77005), we finalized a transition from the prospective application of HHS–RADV adjustments to a concurrent application beginning with 2020 benefit year HHS–RADV. To effectuate this transition, HHS–RADV adjustments for issuers who participated in both the 2019 and 2020 benefit years will be averaged together and applied to 2020 risk adjustment risk scores. As a result, we will be publishing a single HHS–RADV summary report in calendar year 2022 that details transfer information from both the 2019 and 2020 benefit years of HHS–RADV.

¹⁶¹Consistent with the current application of HHS-RADV results for exiting issuers identified as positive error rate outliers, issuers who fit this description for 2019 HHS-RADV will have their results applied to the risk scores and transfer amounts for the benefit year being audited, that is, the 2019 benefit year. See the 2020 Payment Notice, 84 FR at 17503-17504. We will publish the 2019 HHS-RADV Summary Report for these issuers (if any) in the 2022 calendar year. Additionally, as finalized in the 2020 Payment Notice, for HHS-RADV benefit years beginning with 2018, HHS only adjusts exiting issuers if they are positive error rate outliers. This policy remains unchanged for the 2019 benefit year and beyond. See the 2020 HHS-RADV Amendments Rule (85 FR at 77003).

reports, which must be filed by July 31, 2022. Issuers will be required to report the 2019 and 2020 benefit year HHS-RADV adjustments to transfers (including default data validation charge and allocation amounts) in their MLR reports for the 2021 MLR reporting year (MLR reports that include 2021 benefit year data that are submitted by July 31, 2022). Finally, HHS will begin collecting both 2019 162 and 2020 HHS-RADV adjustments to transfers for nonexiting issuers along with any default data validation charges imposed for these 2 benefit years and disbursing related payments in late summer or early fall of 2022.

We received public comments on the proposed updates to the timeline for collection of HHS–RADV payments and charges. The following is a summary of the comments we received on the proposed updated timeline and our responses.

Comment: Many commenters expressed general support for reverting to the original schedule for the collection and disbursement of HHS-RADV payments and charges. Commenters largely concurred with HHS that these changes would help resolve incongruities with state financial accounting requirements and potential undue impacts of HHS-RADV adjustments on MLR rebate liability for issuers whose enrollment experiences substantially change over a 3-year period. However, other commenters were concerned about the overlap that would occur during the transition period as issuers would be required to report 2017 benefit year HHS-RADV impacts alongside 2019 and 2020 benefit years HHS-RADV impacts 163 during 2021 MLR reports (filed in summer 2022) and would be required to report 2018 and 2021 HHS-RADV impacts in their 2022 MLR reports (filed in summer 2023). Some of these commenters requested clarification about how the proposed policy affects reporting of 2017 and 2018 HHS-RADV adjustments, while one commenter suggested that 2017 HHS-RADV be reported in 2020 MLR filings and 2018

HHS–RADV adjustments be reported in 2021 filings. Another commenter noted the overlap in timelines, but did not see the need to account for 2017 and 2018 HHS–RADV adjustments differently than was proposed.

Finally, we received a few comments requesting that we retain the allowance in the URRT for states to determine whether an adjustment for HHS–RADV in the URRT would be reasonable and justifiable in any particular benefit year.

Response: After considering all comments on the proposed updated timeline, we are finalizing the changes to the timeline for collection and disbursement of HHS-RADV results as proposed, beginning with the 2019 benefit year of HHS-RADV.164 In response to comments concerning the transition period between the current HHS-RADV timeline (applicable for the 2017 and 2018 benefit years) and the timeline finalized in this rule (applicable beginning with the 2019 benefit year), we considered whether accommodations would be needed during the transition period as we recognize that the transition years will result in 2 years of HHS-RADV being reported during one MLR reporting period.

This included consideration of the options from the commenter suggesting that 2017 HHS-RADV be reported in 2020 MLR filings and 2018 HHS-RADV adjustments be reported in 2021 filings. However, we did not propose and are not making any changes with respect to the timeline for collection and disbursement of HHS-RADV results for the 2017 or 2018 benefit year of HHS-RADV. We also do not believe these alternative options would appropriately address 2017 and 2018 HHS-RADV for MLR reporting purposes. First, the current timeline for 2017 and 2018 HHS-RADV were established in noticeand-comment rulemaking,165 and as such, issuers have expected and are preparing to report these amounts on their 2021 and 2022 MLR reports, respectively, since the finalization of the 2020 Payment Notice. Second, we note that the suggested option would require that 2018 HHS-RADV be reported alongside the combined results for 2019 and 2020 RADV, which would createrather than eliminate or mitigate—the same concerns the commenter was trying to address through their alternative suggestions. The alternative would just shift the overlap to a different MLR reporting year. We further note this type of overlap during a transition period is a natural result of

 $^{^{162}}$ See https://www.cms.gov/files/document/2019-HHS-RADV-Postponement-Memo.

^{163 2019} HHS–RADV is delayed due to COVID–19 and, as such, results are scheduled to be released in late spring/early summer 2022 (See https://www.cms.gov/files/document/2019-HHS-RADV-Postponement-Memo.pdf). Furthermore, we finalized in the 2020 RADV Amendments Rule (85 FR 77002–77005) that 2019 and 2020 error rates for non-exiting issuers will be averaged together at the issuer level and will be applied to 2020 risk adjustment transfers. Positive error rate exiting issuer HHS–RADV adjustments for the 2019 and 2020 benefit years will continue to be applied separately to the risk scores and transfers for the respective benefit year being audited.

¹⁶⁴ Ibid.

^{165 84} FR 17454 at 17506-17507.

implementing this type of policy change.

As outlined elsewhere in this rule and in the proposed rule, after further consideration of stakeholder concerns regarding the timeline established in the 2020 Payment Notice, we proposed and are finalizing the proposed update to revert to the prior schedule for collection and disbursement of HHS—RADV results beginning with the 2019 benefit year. This update responds to stakeholder concerns about the potential

conflicts with certain state accounting requirements and the potential negative impact on certain issuers' MLR rebate position. It also aligns with other recently finalized changes to HHS—RADV program requirements. We intend to monitor implementation of the collection and disbursement of HHS—RADV payments and charges, including feedback on lessons learned from stakeholders, and will consider whether further guidance or consideration of these issues is warranted.

To assist stakeholders in understanding the MLR reporting period associated with each benefit year of risk adjustment and HHS–RADV, incorporating the updated timeline that is finalized in this rule, we have created the following table that explains which benefit years of risk adjustment and HHS–RADV adjustments should be reported in which MLR reporting years for the 2020–2025 MLR Reporting Years:

TABLE 9: Risk Adjustment and HHS-RADV Benefit Years to Include in MLR Reports for MLR Reporting Years 2020-2025

MLR Reporting Year	RA Benefit Year to Include	RADV Benefit Year(s) to Include
2020 (Filed in 2021)	2020	NA
2021 (Filed in 2022)	2021	2017
		2019 & 2020 *, **
2022 (Filed in 2023)	2022	2018
		2021*
2023 (Filed in 2024)	2023	2022
2024 (Filed in 2025)	2024	2023
2025 (Filed in 2026)	2025	2024

^{*} Including multiple years of HHS-RADV due to transition to the policy finalized in this rule to revert to the prior schedule for collection and disbursement of HHS-RADV results beginning with the 2019 benefit year.

Finally, we disagree with commenters who suggest retaining portions of the URRT instructions pertaining to reporting HHS-RADV adjustments that allowed states the option to allow issuers to take into consideration the impact of HHS-RADV from another benefit year in rating for the upcoming benefit year. Without the 2-year delay between the release of HHS-RADV results and the collections of HHS-RADV adjustments, we are concerned that the continued inclusion of these instructions would be confusing. Further, there is no longer a connection between the collection and disbursement of HHS-RADV adjustments and the applicable upcoming benefit year to support continuing to provide the flexibility in the URRT instructions. We intend to monitor implementation of the collection and disbursement of HHS-RADV payments and charges and will consider whether further guidance is needed.

e. Second Validation Audit and Error Rate Discrepancy Reporting Windows

Under § 153.630(d)(2), issuers have 30 calendar days to confirm the findings of the SVA (if applicable) or the calculation of the risk score error rate, or file a discrepancy report, in the manner set forth by HHS, to dispute the foregoing. As explained in the 2020 Payment Notice, only those issuers who have insufficient pairwise agreement between the IVA and SVA receive SVA findings. 166 We proposed to amend paragraph (d)(2) to shorten the window to confirm the findings of the SVA (if applicable) or the calculation of the risk score error rate, or file a discrepancy, to within 15 calendar days of the notification by HHS, beginning with the 2020 benefit year HHS-RADV. The proposed shorter discrepancy reporting timeframes were intended to ensure that we can resolve as many issues as possible in advance of publication of the Summary Report of Risk Adjustment Data Validation Adjustments to Risk Adjustment Transfers for the applicable

benefit year. Based on the first 2 payment years of HHS-RADV, we explained that HHS believes that this shortened window would not be overly burdensome to issuers, and that any disadvantages of this shortened window would be outweighed by the benefits of timely resolution of as many discrepancies as possible prior to the release of the Summary Report of Risk Adjustment Data Validation Adjustments to Risk Adjustment Transfers for the applicable benefit year. We further noted that a 15 calendar day discrepancy reporting window is consistent with the IVA sample and EDGE discrepancy reporting windows at §§ 153.630(d)(1) and 153.710(d), respectively. We proposed shortening the discrepancy window in the 2020 Payment Notice, but did not finalize the proposal in response to comments suggesting that we revisit this proposal once we had completed a payment year of HHS-RADV.

We are not finalizing the proposal to shorten the discrepancy reporting windows under § 153.630(d)(2) for issuers to confirm the findings of the

^{**} See 2020 HHS-RADV Amendments Rule, where we finalized a transition from the prospective application of HHS-RADV adjustments. [The exception to the prospective application of HHS-RADV adjustments is for exiting issuers, whose HHS-RADV results are currently used to adjust risk scores and transfers for the benefit year being audited (rather than the following benefit year's transfers). See 83 FR 16965 - 66 and 84 FR 17503 - 04.]

SVA (if applicable) or the calculation of the risk score error rate, or file a discrepancy report to dispute the foregoing from 30 to 15 calendar days and will instead maintain the existing 30 calendar day discrepancy reporting windows.

We received public comments on the proposed updates to the SVA and error rate discrepancy reporting windows. The following is a summary of the comments we received and our responses.

Comment: Commenters were opposed to the proposal to shorten the SVA and risk score error rate attestation and discrepancy reporting timeframe from 30 to 15 days and instead recommended maintaining the existing 30 calendar day reporting window. Several commenters stated that they believed that the proposed 15-day timeline would not provide adequate time for issuers to complete a thorough review of the SVA findings or the calculation of the risk score error rate. Another commenter suggested that the timeframes could be shortened elsewhere in the HHS-RADV process in order to keep the 30-day reporting timeframes, noting that it would be helpful for issuers to receive their HHS-RADV error rates sooner for use in pricing.

Response: After consideration of the comments received, we are not finalizing the proposal to shorten the attestation and discrepancy reporting window under § 153.630(d)(2) from 30 to 15 calendar days and will instead maintain the existing 30 day attestation and discrepancy reporting window. Issuers will continue to have 30 calendar days to confirm the findings of the SVA (if applicable) or the calculation of the risk score error rate, or file a discrepancy report.

As a result of these comments, we are not finalizing the proposal to shorten the SVA and risk score error rate attestation and discrepancy reporting timeframes from 30 calendar days to 15 calendar days.

8. Risk Adjustment Data Reporting Requirements for Future Premium Credits (§ 153.710)

As detailed earlier in this preamble, on September 2, 2020, we issued an interim final rule (IFR) on COVID–19 wherein we set forth risk adjustment reporting requirements for issuers offering temporary premium credits in the 2020 benefit year to align with the relaxed enforcement policy announced in guidance. ¹⁶⁷ For the 2021 benefit year

and beyond, we proposed to permanently adopt these risk adjustment reporting requirements for all health insurance issuers in the individual and small group markets who elect to offer premium credits during a public health emergency declared by the Secretary of HHS (declared PHE) 168 if the premium credits are permitted by HHS in future benefit years. Specifically, we proposed that issuers of risk adjustment covered plans that provide temporary premium credits during a declared PHE when permitted by HHS in future benefit years must report to their EDGE servers adjusted plan premiums that reflect actual premiums billed to enrollees, taking the premium credits into account as a reduction in premiums. In the proposed rule, we also proposed to clarify that HHS's calculation of risk adjustment payment and charges for the 2021 benefit year and beyond under the state payment transfer formula would be calculated using the statewide average premium reflecting actual premiums billed, which takes into account any temporary premium credits provided as a reduction in premium for the applicable months of coverage during a declared PHE when permitted by HHS in future benefit years. 169

As noted in the September 2020 IFR on COVID-19, we believe that these requirements are necessary and appropriate because if HHS permitted issuers that provided premium credits to submit unadjusted premiums for the purposes of calculating risk adjustment, distortions could occur that financially impact individual issuers. For example, absent the requirement that issuers offering premium credits report the adjusted, lower premium amount for risk adjustment purposes, an issuer with a large market share with higher-thanaverage risk enrollees that provides temporary premium credits would inflate the statewide average premium by submitting the higher, unadjusted premium amount, thereby increasing its risk adjustment payment. In such a scenario, a smaller issuer in the same

Public Health Emergency," August 4, 2020. Available at https://www.cms.gov/CCIIO/Programsand-Initiatives/Health-Insurance-Marketplaces/ Downloads/Premium-Credit-Guidance.pdf. state market risk pool that owes a risk adjustment charge, and also provides premium credits to enrollees, would pay a risk adjustment charge that is relatively higher than it would have been if it were calculated based on a statewide average that reflected the actual, reduced premium charged to enrollees by issuers in the state market risk pool.

Therefore, we believe that requiring issuers that offer temporary premium credits during a declared PHE, when permitted by HHS, to accurately report to the EDGE server the adjusted, lower premium amounts actually billed to enrollees is most consistent with existing risk adjustment program requirements and mitigates the distortions that would occur if issuers that offer these temporary premium credits did not report the actual amounts billed to enrollees, while not imposing additional financial burdens on issuers, as compared to an approach that would permit issuers to report unadjusted premium amounts. We requested comment on this proposal. We are finalizing this policy as proposed. Issuers of risk adjustment covered plans that provide temporary premium credits when permitted by HHS in the 2021 benefit year and beyond during a declared PHE must report to their EDGE servers adjusted plan premiums that reflect actual premiums billed to enrollees, taking the premium credits into account as a reduction in premiums for the applicable months of coverage.

We received public comments on the proposals related to risk adjustment data reporting requirements for future premium credits (§ 153.710) and the accompanying proposed policies related to the calculation of plan average premium and state average premium requirements for extending future premium credits (§ 153.320). The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that they supported the policies related to the adoption of the flexibility to allow issuers to grant temporary premium credits to beneficiaries should a future PHE be declared as this supports beneficiary access to care. One commenter expressed concern that allowing plans to change their premiums with knowledge of their competitors' premiums in the state market risk pool gives them an unfair advantage in risk adjustment. This commenter was concerned that a plan that initially offered too high a premium relative to its risk could offer a premium reduction to lower its risk adjustment

¹⁶⁷ See, for example, "Temporary Policy on 2020 Premium Credits Associated with the COVID–19

¹⁶⁸ The Secretary of the Department of HHS may, under section 319 of the PHS Act determine that: (a) A disease or disorder presents a public health emergency; or (b) that a public health emergency, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists.

¹⁶⁹ As noted above, we are finalizing this clarification and will calculate transfers under the state payment transfer for the 2021 benefit year and beyond using the statewide average premium, reflecting actual premiums billed, taking into account any temporary premium credits provided during a declared PHE when permitted by HHS.

payout after knowing its competitors pricing structure.

Response: We believe that it is important to require issuers that choose to offer temporary premium credits during a declared PHE to report the actual reduced amount of premium billed to enrollees in the state market risk pool. If HHS permitted issuers that provided premium credits to submit unadjusted premiums for the purposes of calculating risk adjustment, distortions could occur that financially impact other issuers. For example, absent the requirement that issuers that offer premium credits report the adjusted, lower premium amount for risk adjustment purposes, an issuer with a large market share with higher-thanaverage risk enrollees that provides temporary premium credits would inflate the statewide average premium by submitting the higher, unadjusted premium amount, thereby increasing its risk adjustment payment. In such a scenario, a smaller issuer in the same state market risk pool that owes a risk adjustment charge, would pay a risk adjustment charge that is relatively higher than it would have been if it were calculated based on a statewide average that reflected the actual, reduced premium billed to enrollees by the issuer in the state market risk pool. Therefore, the finalized approach is most consistent with existing risk adjustment program requirements and mitigates the distortions that would occur if issuers that offer these temporary premium credits did not report the actual amounts billed to enrollees, while not imposing additional financial burdens on issuers, as compared to an approach that would permit issuers to report unadjusted premium amounts.

We also note that this proposal does not seek to extend or expand issuer ability to offer temporary premium credits. Rather, we proposed to permanently adopt policies to guide risk adjustment calculations and reporting if issuers of risk adjustment covered plans elect to offer premium credits during a declared PHE when permitted by HHS in future benefit years. By limiting this policy to future declared PHEs, the potential creation of incentives for issuers to adjust premiums with knowledge of their competitors' premiums in an attempt to achieve a more favorable risk adjustment transfer (that is, a higher payment or lower charge) is limited. Further, we believe the benefits associated with encouraging issuers to provide temporary premium credits to help consumers maintain continuous health coverage during a declared PHE outweigh these potential

risks and is an appropriate approach to balancing the different equities involved during declared PHEs.

Comment: A few commenters expressed concern as to how small group market plans will be able submit the actual premium amount billed to plan enrollees through EDGE data, as small group market premium reporting is completed at a subscriber level. These commenters requested that HHS clarify the intended approach for issuers facing this operational challenge.

Response: We understand the importance of clarifying this process for all issuers in the individual and small group markets (including merged markets) who offer temporary premium credits during a declared PHE, when permitted by HHS for future benefit years, may fulfill the data reporting requirements to offer premium credits during a declared PHE if the premium credits are permitted by HHS in future benefit years. Issuers of small group plans should apply the premium credit or discount provided in the small group market uniformly to all enrollees in the policy eligible for the credit for the applicable month, ensuring that the aggregate premium reflected in their internal system and EDGE is the lower, reduced amount for that month, including any premium changes that result from retro-active enrollment changes. If these premium credits are permitted in the 2021 benefit year or beyond, we intend to continue to work closely with issuers to implement this policy and will consider whether further guidance is warranted.

Comment: Several commenters supported the proposed approach to use the actual premium amount billed to enrollees, reflective of permitted temporary premium credits, when calculating the plan average premium and statewide average premium for their application in the risk adjustment program. A few of these commenters also mentioned that they supported our proposal to follow this approach when calculating the plan average premium and state average premium calculation in states with approved state flexibility requests under § 153.320(d).

Response: We appreciate these comments and agree with commenters. We are finalizing this policy as proposed. This policy ensures that the plan average premium and statewide average premium used in the state payment transfer formula is calculated using the actual premiums billed to plan enrollees, and also applies this methodology to the calculation of transfers under the state payment transfer formula in states that receive

approval for a request to reduce transfers under § 153.320(d).

After consideration of comments on these proposals, we are finalizing as proposed the policy to permanently adopt these risk adjustment reporting requirements for the 2021 benefit year and beyond, for all issuers of risk adjustment covered plans who elect to offer premium credits during a PHE declared by the Secretary of HHS (declared PHE) if the premium credits are permitted by HHS in future benefit years. We are also finalizing, as proposed, the permanent adoption of the accompanying policy for HHS to calculate the plan average premium and statewide average premium under the state payment transfer formula using issuers' adjusted premium amounts, reflective of temporary premium credits provided by issuers during a declared PHE when such credits are permitted by HHS. That is, the lower actual premiums for which plan enrollees would be responsible would be the amounts used in the calculations under the state payment transfer formula to reflect these temporary premium credits. This approach will also extend to calculations under the state payment transfer formula in states that receive approval for a request to reduce transfers under § 153.320(d).

- D. Part 155—Exchange Establishment Standards and Other Related Standards Under the Affordable Care Act
- 1. Definitions (§ 155.20)
- a. Definitions of QHP Issuer Direct Enrollment Technology Provider and Agent or Broker Direct Enrollment Technology Provider

We proposed to amend § 155.20 to add a definition of QHP issuer direct enrollment technology provider, which we proposed to mean a business entity that provides technology services or provides access to an information technology platform to QHP issuers to facilitate participation in direct enrollment under §§ 155.221 and 156.1230. We also proposed that this definition of QHP issuer direct enrollment technology provider explicitly acknowledge that a webbroker may also provide services to QHP issuers as a QHP issuer direct enrollment technology provider to clarify that being a web-broker does not preclude that entity from providing technology services or an information technology platform to QHP issuers to facilitate QHP issuers' participation in direct enrollment. In addition, we proposed to modify the current definition of direct enrollment technology provider in § 155.20 to

distinguish it from the new proposed definition of QHP issuer direct enrollment technology provider by renaming the term agent or broker direct enrollment technology provider. We proposed these new and modified definitions to capture the full array of potential arrangements between technology companies and entities seeking to use the direct enrollment pathways to facilitate enrollments in QHPs offered in an FFE or SBE–FP in a manner that constitutes enrollment in the Exchange. To align with these proposed new and modified definitions, we further proposed to modify the definition of web-broker to replace the last sentence, which stated that the term includes a direct enrollment technology provider, to instead indicate that the term web-broker includes an agent or broker direct enrollment technology provider.

In the 2020 Payment Notice final rule, we amended § 155.20 to define "direct enrollment technology provider" to mean "a type of web-broker business entity that is not a licensed agent, broker, or producer under [s]tate law and has been engaged or created by, or is owned by an agent or broker, to provide technology services to facilitate participation in direct enrollment under §§ 155.220(c)(3) and 155.221." 170 This definition captures instances in which an individual agent or broker, a group of agents or brokers, or an agent or broker business entity, engages the services of or creates a technology company that is not licensed as an agent, broker, or producer to assist with the development and maintenance of a non-Exchange website that interfaces with an Exchange to assist consumers with direct enrollment in QHPs offered through the Exchanges as described in §§ 155.220(c)(3) and 155.221. When the technology company is not itself licensed as an insurance agency or brokerage, the current framework establishes that these technology companies are a type of web-broker that must comply with applicable webbroker requirements under §§ 155.220 and 155.221, unless indicated otherwise.171

As the FFE direct enrollment program has evolved, particularly with the introduction and increased utilization of the enhanced direct enrollment (EDE) pathway, the technical requirements

and expertise needed to participate in direct enrollment have become substantially more complex. As a result, technology companies are increasingly relied upon to develop, host, manage, and customize the technical platforms that underpin direct enrollment entity non-Exchange websites. Technology companies have emerged to support the participation of QHP issuers in direct enrollment, as well as agents, brokers, and web-brokers. In the context of EDE, some of these technology companies build technical platforms prior to finalizing contractual relationships with agents, brokers, web-brokers, or QHP issuers and some of these technology companies provide platforms that are used to host direct enrollment websites for both QHP issuers and agents, brokers, or web-brokers. Under the current framework, the technology company is itself a web-broker and often provides direct enrollment services under its own branding while also wanting to offer its technology platform and accompanying services to other agents, brokers, web-brokers, or QHP issuers to facilitate their respective participation in direct enrollment. As part of the services it provides as a technology company, it may offer customized direct enrollment websites that leverage its technical platform to other entities that allows for additional systems or functionality or the use of the other entity's branding. Because the current regulatory definition does not include a reference to QHP issuers, questions have arisen regarding the ability and accompanying requirements for QHP issuers to engage such entities to assist with the development and hosting of a non-Exchange website to facilitate the QHP issuer's participation in direct enrollment. For these reasons we proposed to create a new definition of OHP issuer direct enrollment technology provider and update the definitions of direct enrollment technology provider and web-broker as described above, to clarify that QHP issuers can also engage the services of these technology companies and better align with the evolving business models of entities involved in the FFE direct enrollment program. We also proposed to include language in the new definition of QHP issuer direct enrollment technology provider to clarify that when such entities partner with QHP issuers, they are downstream or delegated entities of the QHP issuer. This is similar to the approach adopted in § 155.221(e) for third-party auditors hired by QHP issuers or web-brokers to perform operational readiness audits. By including this language, we intended to

clarify and ensure that these OHP issuer direct enrollment technology providers would be subject to HHS oversight as the delegated or downstream entity of the QHP issuer, and the QHP issuer would be responsible for compliance with all applicable requirements. This approach was also intended to clarify that when providing its technology services and support, or providing access to an information technology platform, to a QHP issuer, QHP issuer direct enrollment technology providers would be subject to the rules applicable to the QHP issuer with whom they are partnering to the extent they are performing activities on behalf of the QHP issuer implicating those rules. For example, if a QHP issuer direct enrollment technology provider is assisting with the development of a non-Exchange website for a QHP issuer, the QHP issuer display requirements captured at § 156.1230(a)(1)(ii) would apply.

We sought comment on this proposal. We did not receive public comments on the proposal to update the definition of web-broker, and are finalizing that proposal as proposed. We received public comments on the proposed addition of a definition of QHP issuer direct enrollment technology provider and updates to the definition of direct enrollment technology provider. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal to define QHP issuer direct enrollment technology provider and agent or broker direct enrollment technology provider. One commenter noted that technology providers play an important role in shaping the experience of consumers and supported making regulations more clearly applicable to them. Another commenter supported the proposed definitions, but requested clarification that a single entity could serve as both types of technology provider and as a web-broker.

Response: We appreciate the comments in support of this proposal and are finalizing the proposal as proposed. To clarify, a single entity may serve as a QHP issuer direct enrollment technology provider, an agent or broker direct enrollment technology provider, and as a web-broker. However, we note that an entity that functions in multiple capacities must comply with the applicable rules for the context in which they are operating. For example, if a web-broker is hosting a direct enrollment website for a QHP issuer and therefore is operating as a QHP issuer direct enrollment technology provider, the QHP issuer display requirements

¹⁷⁰ See Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters; Final rule, 84 FR 17454 at 17562 (April 25, 2019).

¹⁷¹ For example, § 155.220(d)(2) exempts direct enrollment technology providers from the training requirement that is part of the annual FFE registration process for agents and brokers.

captured at § 156.1230(a)(1)(ii) would apply to the website the web-broker is hosting on behalf of the QHP issuer while the web-broker display requirements in § 155.220 would remain applicable to the website the web-broker is hosting with its own branding.

2. Consumer Assistance Tools and Programs of an Exchange (§ 155.205)

To continue our efforts to standardize regulatory references to web-brokers, we proposed to replace all references in § 155.205(c) to "an agent or broker subject to § 155.220(c)(3)(i)" with the term "web-broker." In the 2020 Payment Notice final rule, we amended § 155.20 to define the term "web-broker" 172 to mean an individual agent or broker, a group of agents or brokers, or an agent or broker business entity, that is registered with an Exchange under § 155.220(d)(1) and develops and hosts a non-Exchange website that interfaces with an Exchange to assist consumers with the selection of and enrollment in QHPs offered through the Exchange (a process referred to as direct enrollment). We also amended §§ 155.220 and 155.221 to incorporate the term webbroker as newly defined, where applicable. However, at the time, we overlooked the fact that § 155.205(c) also contains several of these general references to agents and brokers subject to § 155.220(c)(3)(i) that should have been updated as part of this earlier effort to use the term web-broker as newly defined. Such references appear in § 155.205 paragraphs (c)(2)(i)(B), (c)(2)(iii)(B), (c)(2)(iv) introductory text, and (c)(2)(iv)(C). To avoid confusion and correct this oversight, we proposed to standardize regulatory references to web-brokers by replacing all references in § 155.205(c) to "an agent or broker subject to § 155.220(c)(3)(i)" with the term "web-broker." We sought comment on this proposal.

In addition, we proposed to revise a requirement related to website content translations for QHP issuers and webbrokers participating in the FFE EDE program that are subject to §§ 155.205(c)(2)(iv)(B) and 155.205(c)(2)(iv)(C) respectively. Currently under §§ 155.205(c)(2)(iv)(B) and (C), QHP issuers and web-brokers are required to translate website content into any non-English language that is spoken by a limited English proficient (LEP) population that makes up 10 percent or more of the total population of the relevant state. Web-brokers are currently required to translate website content within 1 year of registering with the Exchange, while QHP issuers are

In the proposed rule, we proposed to allow QHP issuers and web-brokers participating in the FFE EDE program additional time to come into compliance with the website content translation requirements. Specifically, we proposed that a OHP issuer or web-broker participating in the FFE EDE program would have 12 months from the date the QHP issuer or web-broker begins operating its FFE-approved EDE website in the relevant state to comply with website content translation requirements under §§ 155.205(c)(2)(iv)(B) and (C) for website content added to their websites as a condition of participation in the FFE EDE program. We noted this proposed flexibility would not absolve QHP issuers and web-brokers from complying with website content translation requirements under paragraphs (c)(2)(iv)(B) and (C) that are unrelated to their participation in the FFE EDE program within the applicable timeframes. 173

We sought comment on whether this proposed flexibility for QHP issuers and web-brokers participating in the FFE EDE program in relevant states would have impacted accessibility to Exchange coverage for LEP communities, or otherwise would have negatively impacted the operation of and consumer access to Exchanges. In addition, we sought comment from QHP issuers and web-brokers as to whether this proposed change would have fostered investment in states where there is a significant LEP community and provide additional incentives for such entities to expand into relevant states. Lastly, we sought comment from assisters about any impacts this proposed change would have had on their proposed ability to work with web-brokers and use EDE websites as described in the proposed rule (and below) when assisting members of the LEP community with Exchange enrollment.

We did not receive public comments on the proposal to replace all references in § 155.205(c) to "an agent or broker subject to § 155.220(c)(3)(i)" with the term "web-broker." We are finalizing that proposal as proposed. We did receive public comments on the proposal to provide additional time to entities participating in EDE to translate website content added to their websites as a condition of participation in the FFE EDE program. The following is a summary of the comments we received and our responses.

Comment: The vast majority of comments received opposed finalizing the proposal to provide EDE entities up to 12 months to translate EDE-specific website content. Generally, commenters expressed concerns about possible conflicts between the proposal and statutory non-discrimination requirements or asserted that the proposal would create or exacerbate racial or ethnic disparities. Some commenters stated that allowing EDE entities to delay the translation of their website content could deprive LEP populations of meaningful access in violation of the non-discrimination provisions in Section 1557 of the ACA. One commenter pointed out this could allow an EDE entity to go through an entire open enrollment period without translating its website content, potentially leaving significant numbers of LEP consumers without information in their languages. The same commenter acknowledged the significant resources involved in developing an EDE website, but did not believe it should take 12 more months to have it translated. Another commenter stated this proposal would limit coverage received by LEP populations, creating racial and ethnic disparities that raise serious concerns under both the ACA and broader federal civil rights laws. Another commenter stated the existing translation requirements are already inadequate and should not be weakened at the expense of LEP consumers. Two commenters supported the proposal. One stated the proposed rule struck an appropriate balance between affording EDE entities additional implementation flexibility and maintaining the language accessibility standards.

Response: While we appreciate the comments in support of this proposal, we are not finalizing this proposal given the concerns expressed by the majority of commenters, and the fact that no QHP issuers or web-brokers (small or otherwise) commented to specifically indicate this proposal would incentivize their participation in states where there is a significant LEP population and where translation of their websites would have eventually been required. Almost all commenters stated that this proposal could reduce access to coverage for LEP populations, create further health inequities among this population, or possibly violate statutory

currently required to translate website content beginning no later than the first day of the individual market open enrollment period for the 2017 benefit year.

¹⁷³ See also "Guidance and Population Data for Exchange, Qualified Health Plan Issuers, and Web-Brokers to Ensure Meaningful Access by Limited-English Proficient Speakers Under 45 CFR 155.205(c) and § 156.250," March 30, 2016. Available at https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Language-access-guidance.pdf.

¹⁷² See 84 FR 17563.

non-discrimination requirements. We acknowledge these concerns are worth careful consideration and outweigh any argument to finalize this proposal at this time.

3. Navigator Program Standards (§ 155.210)

Sections 1311(d)(4)(K) and 1311(i) of the ACA require the Secretary to establish a Navigator program under which HHS awards grants to entities to conduct public education activities to raise awareness of the availability of OHPs, distribute fair and impartial information concerning enrollment in QHPs and the availability of APTC and CSRs, and facilitate enrollment in QHPs; provide referrals to any applicable office of health insurance consumer assistance or health insurance ombudsman established under section 2793 of the PHS Act, or any other appropriate state agency or agencies for any enrollee with a grievance, complaint, or question regarding their health plan, coverage, or a determination under such plan or coverage; and provide information in a manner that is culturally and linguistically appropriate to the needs of the population being served by the Exchange. The statute also requires the Secretary, in collaboration with states, to develop standards to ensure that information made available by Navigators is fair, accurate, and impartial. We have implemented the statutorily required Navigator duties through regulations at §§ 155.210 (for all Exchanges) and 155.215 (for Navigators in FFEs). Certified Application Counselors (CACs) duties have been implemented through regulations at § 155.225.

We proposed allowing, but not requiring, Navigators and CACs in FFEs and SBE-FPs to use web-broker non-Exchange websites to assist consumers with applying for insurance affordability programs and QHP enrollment under certain circumstances and to the extent permitted by state law. For a discussion of the proposal to allow Navigators and CACs to use web-broker non-Exchange websites to assist consumers with applying for insurance affordability programs and QHP enrollment, along with a summary of comments received and our responses to these comments, please see the preamble to § 155.220.

- 4. Ability of States To Permit Agents and Brokers To Assist Qualified Individuals, Qualified Employers, or Qualified Employees Enrolling in QHPs (§ 155.220)
- a. Navigator and Certified Application Counselor Use of Web-Broker Websites

In the 2020 Payment Notice, we proposed, but did not finalize, a modification of our policy that prohibits Navigators and CACs (together referred to here as "assisters") from using webbroker websites to assist with QHP selection and enrollment.174 At the time, adoption of EDE functionality by web-brokers was still limited, and we decided to focus on the implementation and oversight of the EDE pathway before revisiting the current policy regarding assister use of web-broker websites. Since then, EDE functionality has become more user-friendly and increasingly more consumers are using the EDE pathway to enroll in Exchange coverage.

In the proposed rule, we proposed permitting but not requiring, assisters in FFEs and SBE–FPs to use web-broker non-Exchange websites to assist consumers with QHP selection and enrollment, provided the non-Exchange website met certain conditions. We proposed to provide states with a State Exchange that does not rely on HealthCare.gov the discretion to permit their assisters to use web-broker non-Exchange websites.

We proposed several amendments to § 155.220 to capture this flexibility for assisters in FFE and SBE–FP states to use web-broker non-Exchange websites to assist consumers and sought comment on all of these proposals.

We received public comments on the proposal to allow, but not require, Navigators and CACs in FFEs and SBE–FPs to use web-broker non-Exchange websites to assist consumers with applying for insurance affordability programs and QHP enrollment under certain circumstances and to the extent permitted by state law. The following is a summary of the comments we received and our responses.

Comment: The majority of commenters opposed the proposal to allow assisters to use web-broker non-Exchange websites to assist consumers with applying for insurance affordability programs and QHP enrollment. Commenters were concerned about whether assisters could remain fair and impartial if they were assisting consumers using web-broker non-Exchange websites that did not offer enrollment into all QHPs offered

through the Exchange, or that included OHP recommendations. Some commenters highlighted the confusion assisters and consumers may encounter when using web-broker non-Exchange websites that include marketing for non-QHP products. Several commenters also expressed concerns regarding the cost of providing adequate training to assisters to understand multiple platforms for enrollment. They noted that this may take critical time away from assisters serving consumers. Many commenters expressed concern that assister use of web-broker non-Exchange websites to assist with QHP selection and enrollment would reduce or not facilitate enrollment in Medicaid and CHIP. Also, many commenters suggested that CMS invest resources to improve and expand the functionality of HealthCare.gov and expand assister programs instead of dedicating resources to implement this proposal.

Response: After consideration of the comments received in response to this proposal, we agree with the commenters that there are concerns related to assister use of web-broker non-Exchange websites to assist with QHP selection and enrollment that warrant further consideration. Therefore, we are not finalizing the proposed modification to the current policy that prohibits assisters from using web-broker non-Exchange websites to assist with OHP selection and enrollment or the accompanying proposals to amend and replace § 155.220(c)(3)(i)(D). The current policy, which prohibits the use of web-broker non-Exchange websites by assisters to assist with QHP selection and enrollment, remains in effect.

b. QHP Information Display on Web-Broker Websites

We proposed to provide flexibility to web-brokers regarding the information they are required to display on their non-Exchange websites for OHPs in certain circumstances. Currently, § 155.220(c)(3)(i)(A) requires that a webbroker non-Exchange website must disclose and display all QHP information provided by the Exchange or directly by QHP issuers consistent with the requirements of § 155.205(b)(1) and (c). To the extent that not all information required under § 155.205(b)(1) is displayed on the webbroker's website for a QHP, the webbroker's website must prominently display a standardized disclaimer provided by HHS stating that information required under § 155.205(b)(1) for the QHP is available on the Exchange website, and provide a link to the Exchange website. The preamble in the proposed and final

¹⁷⁴ See 84 FR 17515 through 17521.

rules that established the current text in § 155.220(c)(3)(i)(A) explained the intent of this requirement was that a web-broker website must display all information required under § 155.205(b)(1) unless the information was not available to the web-broker, in which case the web-broker website must display the standardized disclaimer. 175 Section 155.220(c)(3)(i)(D) similarly currently requires web-brokers to display all QHP data provided by an Exchange on its non-Exchange website used to participate in the FFE direct enrollment program (whether Classic DE or EDE). In the early years of Exchange operations, we released a data file with limited QHP details (the QHP limited file) that provided web-brokers with a basic set of QHP data that could be used to satisfy the display requirements. Display of the data elements from the QHP limited file data, in combination with a standardized disclaimer (the plan detail disclaimer), became the de facto minimum required to satisfy the webbroker's obligation to display QHP information on its non-Exchange website. In adopting this approach, we recognized that the Exchange may not have been able to provide web-brokers with certain data elements necessary to meet the § 155.205(b)(1) requirements, such as premium information, due to confidentiality requirements, webbroker appointments with QHP issuers, and state law. We also recognized some of the data elements, such as quality rating information, were not going to be available in the initial years of the Exchanges' operation. 176

In new proposed § 155.220(n), we proposed to establish an exception to the web-broker display requirements captured at paragraphs (c)(3)(i)(A) and (D). We proposed to revise paragraph (c)(3)(i)(A) to require a web-broker non-Exchange website to disclose and display all QHP information provided by the Exchange or directly by QHP issuers consistent with the requirements of § 155.205(b)(1) and (c), except as permitted under § 155.220(n). We proposed a similar revision to § 155.220(c)(3)(i)(D). At new proposed paragraph (n), we proposed certain flexibilities regarding display of QHP information if a web-broker's non-Exchange website does not support enrollment in a QHP, except in cases where the web-broker's website is intended to be available for use by assisters consistent with proposed

paragraph (c)(3)(iii)(A). In that case, the flexibility at new proposed paragraph (n) would not be available. A webbroker's non-Exchange website may not support enrollment in a QHP if the webbroker does not have an appointment with a QHP issuer and therefore is not permitted under state law to enroll consumers in the coverage offered by that QHP issuer. In such circumstances, we proposed that the web-broker's non-Exchange website would not be required to provide all the information identified under § 155.205(b)(1). Instead, webbrokers would be required to display the following limited, minimum information for such QHPs: Issuer marketing name, plan marketing name, plan type, metal level, and premium and cost-sharing information. To take advantage of this new proposed flexibility, we also proposed that the web-broker's non-Exchange website would be required to identify to consumers the QHPs, if any, for which the web-broker's website does not facilitate enrollment by prominently displaying the plan detail disclaimer provided by the Exchange. The plan detail disclaimer explains that the consumer can get more information about such QHPs on the Exchange website, and includes a link to the Exchange website. We noted that we believed this proposal struck an appropriate balance by recognizing that web-brokers may not be permitted to assist with enrollments in QHPs for which they do not have an appointment while still providing key information about all QHPs on web-broker non-Exchange websites to allow consumers to window shop and identify whether they may want to explore other QHP options. It also would minimize burdens for web-brokers by not requiring them to build functionality and processes to display all of the required comparative information listed in § 155.205(b)(1) for those QHPs for which they do not have an appointment to sell.

To more closely align the plan detail disclaimer text ¹⁷⁷ with the intent of this proposal, we noted that we planned to issue further guidance revising the text of the disclaimer so that it can be clearly associated with any QHPs for which the

web-broker website does not facilitate enrollment. For example, the current disclaimer text states, in relevant part, the web-broker "isn't able to display all required plan information about this Qualified Health Plan at this time." We noted that we were considering modifying this text so that it states, in relevant part, the web-broker "doesn't display all plan information about, and doesn't facilitate enrollment in, this Qualified Health Plan at this time."

We invited comments on the proposed required limited, minimum QHP details that must be displayed for those QHPs that the web-broker does not facilitate enrollment in through its non-Exchange website and the proposed edits to the plan detail disclaimer text. We also sought comment on whether to require display of any additional elements identified under § 155.205(b)(1) among the limited, minimum information, such as summaries of benefits and coverage. 178

We received public comments on the proposed updates to requirements regarding QHP information display on web-broker non-Exchange websites. The following is a summary of the comments we received and our responses.

Comment: Almost all commenters advocated for requiring that web-broker non-Exchange websites display more OHP information than the proposed rule proposed to require, even in cases when the web-broker non-Exchange website does not support enrollment in a QHP. The vast majority of commenters either advocated for requiring web-broker non-Exchange websites to display all available QHP information for all available QHPs, or generally supported making it easier for consumers to obtain comparative information for all available QHPs when consumers are using web-broker non-Exchange websites. One commenter acknowledged that the proposal (including the proposed updates to the plan detail disclaimer) represented a significant improvement over the status quo and would allow consumers to make more educated comparisons between QHPs when using web-broker non-Exchange websites, but still expressed a preference for requiring that all information for all available QHPs be displayed. Another commenter stated that the "no wrong door" intent of the ACA would be best met by requiring the display of all available QHP information

¹⁷⁵ See 78 FR at 37046 and 78 FR at 54077. ¹⁷⁶ See Patient Protection and Affordable Care Act; Program Integrity: Exchange, SHOP, and Eligibility Appeals; Final Rule, 78 FR 54069 at 54077 (August 30, 2013).

¹⁷⁷ The current plan detail disclaimer states: "[Name of Company] isn't able to display all required plan information about this Qualified Health Plan at this time. To get more information about this Qualified Health Plan, visit the Health Insurance Marketplace® website at HealthCare.gov." See also Section 5.3.2 of the "Federally-Facilitated Exchanges (FFEs) and Federally-Facilitated Small Business Health Options Program (FF–SHOP) Enrollment Manual." Available at https://www.regtap.info/uploads/library/ENR_FFEFFSHOPEnrollmentManual2020_5CR_090220.pdf.

¹⁷⁸ Section 155.205(b)(1) references the following comparative QHP information: Premium and costsharing information, the summary of benefits and coverage, metal level, results of enrollee satisfaction surveys, quality ratings, medical loss ratio information, transparency of coverage measures, and the provider directory.

for all available OHPs on web-broker non-Exchange websites. Another commenter asserted that there is no consumer-oriented rationale for webbroker non-Exchange websites to display limited OHP information now that there is access to APIs that provide the information. One commenter specifically noted that the proposal did not require display of summaries of benefits and coverage and quality information when a web-broker non-Exchange website does not support enrollment in a particular QHP, and that that information is critical for consumers to evaluate and compare QHP options. Two commenters supported the proposal as proposed.

Response: After consideration of the comments received, we are not finalizing the proposed amendments to $\S 155.220(c)(3)(i)(A), (c)(3)(i)(D), or (n).$ We agree that the display of more QHP information on web-broker non-Exchange websites is in the best interest of consumers to aid them in comparing QHP options without having to potentially navigate to multiple websites, and understand why the majority of commenters advocated for web-broker non-Exchange websites displaying all of the comparative information listed in § 155.205(b)(1), including summaries of benefits and coverage and quality information. We also believe requiring web-broker non-Exchange websites to display additional QHP information is reasonable given that QHP information has been more readily accessible for some time, both through public use files and the Marketplace API. In addition, we note that the specific suggestions made by commenters regarding some of the QHP information that should be displayed on web-broker non-Exchange websites (that is, summaries of benefits and coverage and quality information) are part of the QHP information display requirements in § 155.220(c)(3)(i)(A) through its crossreference to § 155.205(b)(1).179

Thus, we intend to further consider these issues and clarify the display requirements for web-broker non-Exchange websites in future rulemaking. In the interim, we also intend to limit our current use of enforcement discretion that permits web-brokers to only display issuer marketing name, plan marketing name, plan type, and metal level for all available QHPs, 180 so that web-broker non-Exchange websites will be required to display all QHP

information consistent with § 155.205(b)(1) and (c), with the exception of medical loss ratio information and transparency of coverage measures under § 155.205(b)(1)(vi) and (vii), for all available OHPs. As such, until these issues are addressed in future rulemaking, beginning at the start of the open enrollment period for plan year 2022, web-broker non-Exchange websites will be required to display all QHP information received from the Exchange or directly from QHP issuers, consistent with the requirements of § 155.205(b)(1) and (c). 181 During this time, we will exercise enforcement discretion and not deem a web-broker non-Exchange website out of compliance with § 155.220(c)(3)(i)(A) and (D) with respect to the display of medical loss ratio information and transparency of coverage measures if the web-broker non-Exchange website displays the other required standardized comparative information consistent with § 155.205(b)(1) and (c). Prior to the start of the open enrollment period for plan year 2022, if a web-broker's non-Exchange website does not display all QHP information consistent with the requirements of § 155.205(b)(1) and (c), other than medical loss ratio information and transparency of coverage measures, it must prominently display the standardized disclaimer provided by HHS and provide a link to the Exchange website. We note that this interim approach applicable beginning with the start of the plan year 2022 open enrollment period does not establish new requirements and instead represents a change in the exercise of enforcement discretion regarding the standardized comparative information web-brokers are required to display under existing regulations following our consideration of comments on the proposed changes to the web-broker QHP display requirements. 182 We intend to continue our collaborative approach of working with web-broker and other enrollment partners to ensure consumers have information to make informed coverage choices while balancing the burdens and costs imposed on our partners.

c. Web-Broker Operational Readiness Review Requirements

We proposed amendments to further clarify the operational readiness requirements applicable to web-brokers

by adding a new proposed § 155.220(c)(6). In the 2018 Payment Notice final rule, we adopted rules to require web-brokers to demonstrate operational readiness, including compliance with applicable privacy and security requirements, prior to participating in the FFE direct enrollment program. 183 Our intent in codifying this requirement was to build on the onboarding and testing processes for a web-broker to be approved to use the direct enrollment pathways. We noted the expectation that additional operational readiness requirements would be established specific to EDE to account for the additional functionality associated with that pathway. 184 At the same time, we established similar requirements for QHP issuers to demonstrate operational readiness and compliance with applicable requirements prior to their use of the direct enrollment pathway. 185 In the 2020 Payment Notice final rule, we consolidated these similar requirements from their prior locations at §§ 155.220(c)(3)(i)(K) and 156.1230(b)(2) into § 155.221(b)(4) as part of our effort to streamline requirements applicable to all direct enrollment entities. 186 In the proposed rule, we proposed to create a new § 155.220(c)(6) to capture operational readiness requirements applicable to web-brokers that host non-Exchange websites to complete QHP selection or the Exchange eligibility application. In proposed paragraph (c)(6), we proposed to include introductory language that reflects the requirement for a web-broker to demonstrate operational readiness and compliance with applicable requirements prior to the web-broker's non-Exchange website being used to complete an Exchange eligibility application or a QHP selection, which may include submission or completion, in a form and manner specified by HHS, of certain information or testing processes. As reflected in proposed paragraphs (c)(6)(i) through (v), HHS may request a web-broker submit a number of artifacts or documents or complete certain testing processes to demonstrate the operational readiness of its non-Exchange website. The required documentation may include operational data including licensure information, points of contact, and third-party relationships; security and privacy assessment documentation, including penetration testing results, security and privacy assessment reports,

¹⁷⁹ See 45 CFR 155.205(b)(1)(ii), (iv), and (v). ¹⁸⁰ "Processes and Guidelines for Becoming a Web-broker in the Federally-facilitated Exchanges: An Overview for New and Existing Web-brokers," October 2017, available at https://www.cms.gov/ files/document/processes-becoming-web-broker.pdf.

¹⁸¹HHS makes QHP information available, including the standardized comparative information under § 155.205(b)(1)(i)—(v) and (viii), through public use files and the Marketplace API.

¹⁸² See 45 CFR 155.220(c)(3)(i)(A) and (D).

¹⁸³ See 81 FR 94176.

¹⁸⁴ See 81 FR 94120.

¹⁸⁵ See 81 FR 94152.

¹⁸⁶ See 84 FR 17524.

vulnerability scan results, plans of action and milestones, and system security and privacy plans; and an agreement between the web-broker and HHS documenting the requirements for participating in the applicable direct enrollment program. The required testing processes may include enrollment testing, prior to approval or at the time of renewal, and website reviews performed by HHS to evaluate prospective web-brokers' compliance with applicable website display requirements prior to approval. To facilitate testing, prospective and approved web-brokers would have to maintain and provide access to testing environments that reflect their prospective or actual production environments. We proposed these amendments to codify in regulation existing program requirements that apply to web-brokers that participate in the FFE direct enrollment program and are captured in the agreements executed with participating web-broker direct enrollment entities and related technical guidance.187 We did not propose to extend the same requirements to QHP issuers participating in the FFE direct enrollment program, because QHP issuers, as HIPAA-covered entities, are subject to longstanding federal requirements and oversight related to the protection of PII and PHI that are not necessarily applicable to web-brokers. With HIPAA privacy and security regulations and oversight in place and applicable to QHP issuers, HHS has adopted a risk acceptance approach for QHP issuers allowing them to participate in the FFE direct enrollment program, in some cases, without imposing certain requirements that are in place for web-brokers. In addition, OHP issuers are subject to more extensive oversight by state regulators than web-brokers.

We sought comment on this proposal. We received one public comment on the proposed updates to web-broker operational readiness review requirements. The following is a summary of the comment we received and our response.

Comment: One commenter indicated they did not object to this proposal because it primarily codifies existing guidelines to which web-brokers are already subject. While acknowledging that similar requirements may not apply to QHP issuers, based in part on their status as HIPAA-covered entities, the

commenter recommended similar requirements apply to non-web-broker QHP issuer direct enrollment technology providers. The commenter went on to state that though these entities may also be subject to HIPAA as issuers' business associates, issuers may not apply the same type of security and privacy oversight that HHS applies to web-brokers.

Response: We are finalizing this proposal as proposed. We appreciate the recommendation to extend similar or identical requirements to non-webbroker OHP issuer direct enrollment technology providers, and may consider proposing such requirements in the future. However, we did not propose and are not finalizing the extension of the same additional operational readiness review requirements to QHP issuers participating in the FFE direct enrollment program. As noted above and explained in the proposed rule, we did not propose to extend the same requirements to QHP issuers because, as HIPAA-covered entities, issuers are subject to longstanding federal privacy and security requirements that are not necessarily applicable to all webbrokers. In recognition of the applicability of the HIPAA privacy and security framework and extensive oversight of issuers by state regulators, HHS adopted a different approach for QHP issuer operational readiness reviews, which includes not imposing certain requirements applicable to webbroker direct enrollment entities. While we continuously review our approach and regularly evaluate whether to enhance program requirements for all direct enrollment entities, we believe the current approach strikes the appropriate balance between the burden associated with program requirements for different types of direct enrollment entities and the risks posed by those entities' participation in the program. In addition, our experience to date has shown that most direct enrollment technology providers that develop technology platforms for purposes of facilitating QHP issuer use of direct enrollment are either facilitating participation in the EDE program or are also web-brokers, and therefore would be subject to the more rigorous EDE operational readiness review requirements or the operational readiness review requirements applicable to web-brokers. To the extent a small number of QHP issuer direct enrollment technology providers are not also web-brokers and are not subject to the more rigorous EDE operational readiness review requirements, those entities are likely subject to HIPAA as

issuers' business associates as the commenter acknowledged. As part of our continuous review and evaluation of direct enrollment requirements, we intend to monitor the types of entities QHP issuers engage with as direct enrollment technology providers and may propose changes to the operational readiness review requirements for QHP issuer direct enrollment technology providers in future rulemaking.

5. Standards for Direct Enrollment Entities and for Third Parties To Perform Audits of Direct Enrollment Entities (§ 155.221)

a. Direct Enrollment Entity Plan Display Requirements

We proposed to revise § 155.221(b)(1) to clarify the requirements that apply when direct enrollment entities want to display and market QHPs 188 and non-QHPs. We proposed that in such circumstances, the web-broker or QHP issuer must display and market QHPs offered through the Exchange, individual health insurance coverage as defined in § 144.103 offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits), and all other products, such as excepted benefits, on at least three separate website pages, with certain proposed exceptions described below.

In the 2020 Payment Notice final rule, we amended § 155.221(b)(1) to require direct enrollment entities to display and market QHPs and non-QHPs on separate website pages on their respective non-Exchange websites. 189 Similarly, we amended paragraph (b)(3) to require direct enrollment entities to limit the marketing of non-QHPs during the Exchange eligibility application and QHP selection process in a manner that will minimize the likelihood that consumers will be confused as to what products are available through the Exchange and what products are not. 190 Under the existing display standards captured at paragraphs (b)(1) and (3), direct enrollment entities are required to offer an Exchange eligibility application and QHP selection process that is free from advertisements or information about non-QHPs and sponsored links promoting health insurance related

¹⁸⁷ See, for example, "Updated Web-broker Direct Enrollment Program Participation Minimum Requirements," May 21, 2020. Available at https:// www.cms.gov/CCIIO/Programs-and-Initiatives/ Health-Insurance-Marketplaces/Downloads/2020-WB-Program-Guidance-052120-Final.pdf.

¹⁸⁸ As detailed in prior rulemaking, with some limited exceptions, stand-alone dental plans certified for sale on an Exchange are considered a type of QHP. See 77 FR 18315. CMS expects direct enrollment entities to follow the same requirements for stand-alone dental plan QHPs as for medical QHPs, including the applicable display and marketing requirements captured in §§ 155.220, 155.221, and 156.1230, except as proposed and finalized at new § 155.221(c)(2) in the context of off-Exchange stand-alone dental plan shopping.

¹⁸⁹ See 84 FR 17523 and 17524.

¹⁹⁰ Id.

products. However, under the current framework, it is permissible for a direct enrollment entity to market or display non-QHP health plans and other off-Exchange products in a section of the entity's website that is separate from the QHP web pages if the entity otherwise complies with the applicable requirements. We explained in the 2020 Payment Notice that we believe marketing some products in conjunction with QHPs may cause consumer confusion, especially as it relates to the availability of financial assistance for QHPs purchased through the Exchanges. 191 We acknowledged at that time that we may need to update these standards as new products come to market and as technologies evolve that can assist with differentiating between QHPs offered through the Exchange and other products consumers may be interested in. We also noted our belief that the convenience of being able to purchase additional products as part of a single shopping experience outweighs potential consumer confusion, if proper safeguards are in place. 192

In the proposed rule, we proposed to amend paragraph (b)(1) to refine the previously adopted policy, consistent with the original intent of minimizing consumer confusion about distinct products with substantially different characteristics, while providing direct enrollment entities with more marketing flexibility and opportunities for innovation. QHPs are required to be offered on- and off-Exchange under the guaranteed availability requirements at § 147.104. The current framework allows for direct enrollment entities to display on- and off-Exchange OHPs on the same website pages, as long as the direct enrollment entity's website makes clear that APTC and CŠRs are only available for QHPs offered through the Exchange. 193 We noted that we have observed various attempts by direct enrollment entities to distinguish between on- and off-Exchange QHPs displayed on the same website pages, but believed that even good faith efforts to inform consumers about this distinction have the potential to cause confusion about which QHP a consumer should select if APTC-eligible when two instances of otherwise identical plans (that is, the on- and off-Exchange versions of the QHP) are displayed on a single website page, but only one is available with APTC. In addition, paragraph (b)(1) currently prohibits the display of off-Exchange QHPs on the

same website pages as comparable non-OHP individual health insurance coverage. This creates a segmented off-Exchange plan shopping experience on direct enrollment entity websites that does not allow consumers to easily comparison shop among comparable major medical health insurance products. As described in the proposed rule and further below, the recent introduction of individual coverage health reimbursement arrangements (HRAs) increases the importance of individual health insurance coverage offered outside of the Exchange for employees whose employers offer such arrangements and also offer the opportunity to make salary reduction contributions through a cafeteria plan under section 125 of the Code, and this is part of the reason we proposed to amend the current display requirements for direct enrollment entities.

We proposed to revise § 155.221(b)(1) to require that direct enrollment entities display and market QHPs offered through the Exchange, individual health insurance coverage as defined in § 144.103 offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits), and all other products, such as excepted benefits, on at least three separate website pages, with certain exceptions. Requiring that these three categories of products be displayed and marketed on separate website pages provides a more precise delineation between the three categories of products with substantially different characteristics, either in the way they can be purchased or the types of benefits they offer, while still allowing substantial flexibility in website design to facilitate the consumer's shopping experience. We proposed the first product category, QHPs offered through the Exchange, must be isolated from the other categories of products to distinguish for consumers the products for which APTC and CSRs are available (if eligible). We proposed the second product category, individual health insurance coverage offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits), must be similarly distinguished from other products, because those plans represent major medical coverage that is subject to the same ACA market-wide requirements as QHPs offered through the Exchange, but that is not available with APTC and CSRs. Therefore, distinguishing between these two categories of products by requiring that they be displayed and marketed on separate website pages would allow consumers to more easily shop for comparable major medical insurance

subject to ACA market-wide rules while maintaining the clear distinction between plans for which APTC and CSRs are and are not available. We proposed that the third product category, which encompasses types of products not in the first two categories, including excepted benefits, must be displayed and marketed on one or more website pages separate from the website pages used for displaying and marketing the first two categories of products to assist consumers in distinguishing them from major medical plans. The range of products in the third category are not subject to ACA market-wide rules and APTC and CSRs are not available for such products, and therefore they are substantially different from the plans that fall into the first two categories.

We also proposed to amend § 155.221(b)(3) to include clarifying edits and to include the same exceptions detailed in this final rule as we proposed for paragraph (b)(1). We proposed to revise paragraph (b)(3) to limit marketing of non-QHPs during the Exchange eligibility application and QHP selection process in a manner that minimizes the likelihood that consumers would be confused as to which products and plans are available through the Exchange and which products and plans are not, except as permitted under new proposed paragraph (c)(1). The proposal also removed a redundant reference to "plan" that was included after "QHP," and added references to "plans" after the references to "products" to use consistent language throughout paragraphs (b)(1) and (3). We proposed the same exceptions for paragraph (b)(3) to align with the proposed changes to paragraph (b)(1) to clarify that displaying QHPs and non-QHPs on the same website page, as would be permitted under the proposed exceptions in certain circumstances, would not constitute a violation of paragraphs (b)(1) or (3).

We proposed certain exceptions in new § 155.221(c) to the proposed updates to paragraphs (b)(1) and (3), because we recognized that, in some limited scenarios, consumers may be best served by being able to directly and easily compare plans offered on- and off-Exchange. As of January 1, 2020, employers may offer employees an individual coverage HRA instead of offering traditional group health coverage. ¹⁹⁴ An individual coverage HRA may reimburse employees for medical expenses, including monthly

¹⁹¹ Id.

¹⁹² Id.

 $^{^{193}\,\}mathrm{See},$ for example, 45 CFR 155.220(j)(2)(i) and 156.1230(a)(1)(iii).

 $^{^{194}\,\}mathrm{See}$ Health Reimbursement Arrangements and Other Account-Based Group Health Plans; Final rule, 84 FR 28888 (June 20, 2019).

health insurance premiums. To use the individual coverage HRA, an employee (and any eligible household members) must enroll in individual health insurance coverage, other than excepted benefits, or Medicare parts A and B or C. To satisfy this requirement, employees (and any eligible household members) can enroll in individual health insurance coverage through the Exchange or outside the Exchange. An employee and any household members offered an individual coverage HRA will be ineligible for APTC if the individual coverage HRA is affordable or if the employee and household members accept the individual coverage HRA even if it is unaffordable. If an employee and any household members offered an individual coverage HRA that is unaffordable decline the individual coverage HRA benefit, they may qualify for APTC (if otherwise eligible) if they enroll in a QHP through the Exchange. Some employees who are offered an individual coverage HRA may also be eligible, through a cafeteria plan under section 125 of the Code, to pay a portion of their health insurance premiums through tax-preferred salary reduction contributions. This type of cafeteria plan benefit may only be used in combination with off-Exchange individual health insurance coverage. Employers have flexibility to offer an employee both the individual coverage HRA and the cafeteria plan benefit instead of providing traditional taxpreferred group health coverage. However, employers may not offer employees a choice of an individual coverage HRA or traditional group health coverage.

Consumers shopping and enrolling in coverage through direct enrollment entity websites may therefore wish to see and consider additional non-QHP individual health insurance coverage (other than excepted benefits) options that are only available off-Exchange. We also noted that we believed consumers may find it difficult to determine their best option, especially when they are part of a tax household with members that may have varying eligibility for APTC, CSRs, Medicaid, CHIP, individual coverage HRAs, and cafeteria plans. For this reason, we proposed to provide an exception to the new proposed display standards in § 155.221(b)(1) and (b)(3) to support the development of innovative and consumer-friendly plan comparison tools by direct enrollment entities to assist consumers in making the best choices among individual health insurance coverage options subject to ACA market-wide rules for themselves

and their families in these complex situations.

In proposed new paragraph (c)(1), we proposed to allow direct enrollment entities to display and market QHPs offered through the Exchange and individual health insurance coverage offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits) on the same website pages when assisting individuals who have communicated, within the website user interface or by communicating to an agent or broker assisting them, they have received an offer of an individual coverage HRA, as a standalone benefit or in addition to an offer of an arrangement under which the individual may pay the portion of the premium for individual health insurance coverage that is not covered by an individual coverage HRA using a salary reduction arrangement under a cafeteria plan, so long as certain conditions are met. As reflected in the new proposed § 155.221(c)(1), the conditions we proposed to adopt included clearly distinguishing between the QHPs offered through the Exchange and the individual health insurance coverage offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits), and prominently communicating that APTC and CSRs are available only for QHPs purchased through the Exchange, that APTC is not available to an individual who accepts an offer of an individual coverage HRA or who opts out of an affordable individual coverage HRA, and that a salary reduction arrangement under a cafeteria plan may only be used toward the cost of premiums for plans purchased outside the Exchange.

We noted that we wished to reduce incentives that may lead to routing consumer households to off-Exchange plan shopping experiences based on overly simplistic factors such as a single member of a multi-member household having an individual coverage HRA and a cafeteria plan offer. Instead we sought to encourage direct enrollment entities to develop blended plan selection user interfaces that incorporate on- and off-Exchange plan options when assisting consumers who have communicated receipt of an offer of an individual coverage HRA while incorporating the proposed conditions that are designed to minimize the chance for consumer confusion about the differences between the different coverage options. For example, a direct enrollment entity exercising the flexibility under the proposed exception in § 155.221(c)(1) could clearly distinguish between onand off-Exchange plan options by using frames, columns, different color

schemes, prominent headings, icons, help text, and other visual aids to increase the chance that consumers are aware of the distinctions between the plan options. We emphasized the proposal's intent was to distinguish and clarify user interface elements to be clear, prominent, and difficult to ignore, and therefore the use of an obscure disclaimer in small text at the bottom of the page or behind a link would not be sufficient, for example. We noted that in addition to the safeguards proposed in the proposed rule, direct enrollment entities in the FFEs are subject to standards of conduct that require they provide consumers with correct information, without omission of material fact, regarding QHPs and insurance affordability programs, and refrain from marketing or conduct that is misleading. 195 We solicited comment on these proposals, as well as comments on alternative approaches through which direct enrollment entities may assist consumers with individual coverage enrollment when they have an offer of an individual coverage HRA.

We proposed an additional exception to § 155.221(b)(1) at proposed paragraph (c)(2) to allow direct enrollment entities to display and market stand-alone dental plans certified by an Exchange but offered outside the Exchange and non-certified stand-alone dental plans on the same off-Exchange dental plan shopping website pages. Stand-alone dental plans certified by an Exchange and non-certified stand-alone dental plans should be largely comparable products among which consumers looking for dental coverage off-Exchange may wish to comparison shop. Since the proposed change at paragraph (b)(1) to allow display of all individual health insurance coverage offered outside the Exchange on the same website pages (including QHPs and non-QHPs other than excepted benefits) excludes standalone dental plans (since stand-alone dental plans are excepted benefits), we proposed this additional exception to allow direct enrollment entities to provide a consumer-friendly off-Exchange stand-alone dental plan shopping experience where consumers can compare the full range of standalone dental plans on a single website page.

¹⁹⁵ See 45 CFR 155.220(j)(2)(i), applicable to webbrokers, and 156.1230(b)(2), applicable to QHP issuers participating in direct enrollment. Also see "Guidance Regarding website Display for Direct Enrollment (DE) Entities Assisting Consumers in States with Federally-facilitated Exchanges (FFEs) and State Exchanges on the Federal platform (SBE-FPs)." Available at https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/DE-Entity-Standards-of-Conduct-website-Display.pdf.

We proposed conforming amendments to redesignate paragraphs (c) through (h) in § 155.221 as paragraphs (d) through (i) and related updates to internal cross references. As detailed in the proposed rule and this final rule, we also proposed certain amendments to the direct enrollment entity operational readiness review requirements in § 155.221(b)(4).

We requested comment on these

proposals.

We received numerous public comments on the proposed amendments to the direct enrollment entity plan display requirements. The following is a summary of the comments we received

and our responses.

Comment: Most commenters supported the proposal to require direct enrollment entities to display and market QHPs offered through the Exchange, individual health insurance coverage as defined in § 144.103 offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits), and all other products, such as excepted benefits, on at least three separate website pages. One commenter stated that guardrails should limit opportunities for consumers to accidentally enroll in or be steered toward a non-subsidized QHP or non-OHP: and therefore, at a minimum. substantially different coverage types should be listed on separate website pages (as proposed) to ensure consumers compare apples-to-apples. Other commenters expressed similar sentiments, and in some cases advocated for the inclusion of additional safeguards to help consumers understand the different products that might be displayed to them (for example, requiring that different products be clearly labeled to aid in differentiation). A few commenters requested clarification about which of the categories would include products or services such as health care sharing ministries, direct primary care arrangements, group association plans, and short-term limited duration insurance, or requested confirmation that such products or services would have to be displayed on the one or more website pages that included excepted benefits and not on the website pages that display on- or off-Exchange QHPs and non-QHPs other than excepted benefits. Several commenters expressed opposition to the proposal. Generally these commenters cited concerns about consumer confusion if and when consumers are presented with numerous substantially different product options, regardless of how those products are displayed and even if they are displayed on separate website pages.

Response: We are finalizing the proposal as proposed, but hope to clarify several issues raised by commenters. We intend to carefully monitor how direct enrollment entities modify their websites in accordance with these requirements and anticipate making updates in future rulemaking if we believe such updates are necessary to mitigate the risk that consumers are confused by how different products are being displayed or marketed to them on direct enrollment entity websites. We agree that guardrails are necessary to help consumers understand their options and minimize the chance they inadvertently choose to enroll in a plan or product that they did not intend to enroll in or that does not meet their needs. As we monitor direct enrollment websites, we will evaluate whether the user interface options direct enrollment entities choose (for example, how they convey to consumers the characteristics of different products or services on different website pages) are adequate in terms of helping consumers distinguish between and understand the advantages and disadvantages of different products or services. When designing their websites, we encourage direct enrollment entities to incorporate clear labels or descriptions of different products or services they offer to assist consumers, and we may require specific labeling or description requirements in future rulemaking if we determine such standardization would be helpful for consumers or if we identify other opportunities to improve the consumer experience and better inform consumers about the important differences between substantially different products or services marketed or displayed on direct enrollment entity websites. We also clarify and confirm that, as applied to the other non-QHP products and services identified by commenters, § 155.221(b)(1) requires that any marketing or display of health care sharing ministries, direct primary care arrangements, group association plans, and short-term limited duration insurance not occur on the same website pages as on- or off-Exchange QHPs and non-QHPs other than excepted benefits. When marketed or displayed on direct enrollment entity websites, those products and services should instead be displayed on the separate website page or pages reserved for all other products, such as excepted benefits. The intent of these amendments is to provide additional clarity to direct enrollment entities regarding the display and marketing of products or services that are not subject to ACA market-wide rules and on- and off-Exchange QHPs, as

well as non-OHP major medical coverage that is subject to ACA marketwide rules. We appreciate the concerns expressed by some commenters that consumers may still be confused when presented with numerous substantially different options for products or services, even if those products or services are displayed on separate website pages in a clear manner. As described in the proposed rule and the preamble above, a significant motivation for adopting this policy was to reduce consumer confusion about distinct products with substantially different characteristics. We acknowledge that this approach may not eliminate all consumer confusion or other risks that may exist for consumers when they use direct enrollment and other non-Exchange websites. We intend to carefully monitor direct enrollment websites and may pursue refinements to these website display requirements in future rulemaking. We are also broadly considering options for future rulemaking intended to address risks to consumers that use direct enrollment websites not addressed by this policy, including evaluating consumer protections adopted by State Exchanges.

Comment: There were several comments received related specifically to the portion of the proposed rule that would allow direct enrollment entities to display and market QHPs offered through the Exchange and individual health insurance coverage offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits) on the same website pages when assisting individuals who have communicated they have received an offer of an individual coverage HRA. Several commenters supported the flexibility provided by this exception. One commenter recognized the need to provide consumers with individual coverage HRA offers information about all relevant coverage options, but expressed concern about consumers being misled or confused about those options and urged HHS to strictly enforce requirements related to the proposed exception. Another commenter acknowledged that consumers offered individual coverage HRAs will need access to information for both on- and off-Exchange options, but opposed the proposed exception, stating that allowing on- and off-Exchange options to be commingled on the same website page would lead to substantial confusion, even with smart design choices to differentiate the plans. One commenter recommended that the exception be modified so that it is available generally (without respect to

whether a specific consumer the entity is assisting has been offered an individual coverage HRA) to entities approved to use EDE that have implemented eligibility application functionality supporting individual coverage HRA offers. The commenter stated this alternative approach would be less burdensome to implement than accounting for specific consumers' situations. One commenter noted this exception as proposed does not apply to consumers provided QSEHRAs, and that if it is modified to account for such plans, a requirement should be included that direct enrollment entities communicate to consumers the need to reduce APTC by any employer contribution.

Response: We appreciate the comments and are finalizing this exception as proposed. We note that the individual coverage HRA market is relatively new and still evolving, and recognize that the flexibility and requirements associated with this exception should be monitored closely and evaluated regularly for potential modifications in future rulemaking. We further recognize there is the potential for confusion, even with strict compliance with the safeguards we are finalizing. We believe this exception and the other related direct enrollment entity plan display requirement proposals finalized in this rule represent a reasonable balance at this time and appropriately take into account the need to also support consumers who may be offered new types of coverage arrangements (for example, individual coverage HRAs). Additionally, we intend to closely monitor implementation of the exception and the accompanying display requirement proposals finalized in this rule through website reviews and will strictly enforce the limitations and requirements related to leveraging this exception, and will make adjustments through future rulemaking if deemed necessary. We further note that most consumers using direct enrollment websites are assisted by agents or brokers who can help their clients understand their options. To help consumers offered individual coverage HRAs navigate their different options and to support agents and brokers providing assistance to these consumers, HHS has developed various education, training, and other materials on individual coverage HRAs. 196 As stated in the proposed rule, we hope that this exception will lead direct enrollment entities to design and

implement innovative and consumerfriendly plan comparison tools to assist consumers offered individual coverage HRAs in making the best choices for themselves and their families in these complex situations. In addition, we sought to reduce incentives that may lead direct enrollment entities to route consumer households to off-Exchange plan shopping experiences based on overly simplistic factors such as a single member of a multi-member household having an individual coverage HRA and a cafeteria plan offer. 197 As a result of the comments received expressing concerns about consumer confusion due to this exception, we encourage any direct enrollment entity considering updates to its website design to leverage this exception to contact us before implementing any updates (by emailing directenrollment@cms.hhs.gov). We are interested in working collaboratively with direct enrollment entities to ensure their planned website designs meet applicable regulatory requirements and intend to carefully monitor implementation under this exception. We would pursue any refinements through rulemaking, and if we deem necessary or appropriate may also consider adopting a mandatory review and approval process before direct enrollment entities could leverage this exception in a future rulemaking.

We do not agree with the one commenter that suggested this exception be made broadly available to EDE entities, without respect to whether a specific consumer the entity is assisting has been offered an individual coverage HRA. This exception is intended to be a targeted measure focused on supporting consumers offered individual coverage HRAs who use direct enrollment entity websites to shop for coverage. 198 In those instances, it would be appropriate to inform consumers about the broader range of individual health insurance coverage options. The same considerations do not exist for consumers who do not receive individual coverage HRA offers. Direct enrollment entities already design different plan shopping interfaces for their websites and route consumers to them based on screening questions

intended to evaluate specific consumers' needs and circumstances. For entities assisting consumers with individual coverage HRA offers, leveraging the flexibility afforded by the exception finalized in this rule could be accomplished using a similar approach of asking consumers questions about whether they have received an individual coverage HRA offer and routing them to different website pages based on their responses. Finally, we note that we did not propose and are not finalizing an extension of the proposed exception to consumers provided QSEHRAs at this time, in part because we have not noted the same interest in serving such consumers from direct enrollment entities. We may consider creating such an exception in a future rulemaking if necessary or appropriate.

Comment: We received a small number of comments related to the proposed exception to § 155.221(b)(1) at proposed paragraph (c)(2) to allow direct enrollment entities to display and market stand-alone dental plans certified by an Exchange but offered outside the Exchange and non-certified stand-alone dental plans on the same off-Exchange dental plan shopping website pages. One commenter stated that dental plans offer a wide variety of plan designs, and suggested that if the proposed stand-alone dental plan exception is finalized, it should include a requirement that direct enrollment entities clearly label different types of dental plans. The commenter also expressed concern that consumers may not be able to differentiate between stand-alone dental plans for which APTC may be used and stand-alone dental plans only available off-Exchange. Another commenter requested implementation of the proposed stand-alone dental plan exception be delayed until testing the approach with consumer focus groups and evaluating its impact based on that testing.

Response: We appreciate the comments and are finalizing this proposal as proposed. As mentioned above, when designing their websites, we encourage direct enrollment entities to incorporate clear labels or descriptions of different plans, products, or services they offer to assist consumers, whether major medical or stand-alone dental plans. We may require specific labeling or description requirements in future rulemaking if we determine such standardization would be helpful for consumers or if we identify other opportunities to improve the consumer experience and better inform consumers about the important differences between substantially

¹⁹⁶ See, for example, https://www.cms.gov/CCIIO/ Programs-and-Initiatives/Health-Insurance-Market-Reforms/Health-Reimbursement-Arrangements.

¹⁹⁷ There are additional complexities for APTCeligible consumers who receive an offer of an individual coverage HRA that is unaffordable in addition to a salary reduction arrangement under a cafeteria plan. See, for example, 85 FR at 78617.

¹⁹⁸ As detailed in the proposed rule, the recent introduction of individual coverage HRAs increases the importance of individual health insurance coverage offered outside of the Exchange for employees offered such arrangements alongside the opportunity to make salary reduction contributions through a cafeteria plan under section 125 of the Code. See 85 FR 78616.

different plans, products, or services. We also clarify that since the standalone dental plan exception is only available to direct enrollment entities with regard to their off-Exchange standalone dental plan shopping websites, the risk that a consumer may inadvertently choose a stand-alone dental plan for which APTC is not available is not relevant since APTC is not available for any off-Exchange stand-alone dental plans. Stated differently, an APTC-eligible consumer seeking to enroll in a stand-alone dental plan on-Exchange that has wound up shopping for stand-alone dental plans on an off-Exchange website has encountered a problem unrelated to the stand-alone dental plan exception in this rule. While we understand the request to delay implementation of the stand-alone dental plan exception until consumer focus group testing can be conducted, we consider multiple factors when developing rules, including risk of consumer harm, impact to the operations of the private business entities we are regulating, and the availability of government resources to conduct testing and oversight, among other factors. We also believe this exception is sufficiently narrow for the proposal to be finalized as part of this rule because it is limited to website pages marketing and facilitating enrollment in off-Exchange plans, products, and services. In addition, until the current rule at § 155.221(b)(1) was finalized in 2019, this exception would not have been required for entities to display stand-alone dental plans in this manner and we suspect many entities were doing so at the time. As mentioned above, we will be closely monitoring and evaluating how direct enrollment entities modify their websites based on these updated rules and will pursue future rulemaking if we believe that is necessary or appropriate. We may also engage in consumer focus group testing in the future, if deemed necessary or appropriate.

b. Direct Enrollment Entity Operational Readiness Review Requirements

We proposed to revise § 155.221(b)(4) to add additional detail on the operational readiness requirements for direct enrollment entities. Similar to the proposed web-broker operational readiness requirement at new proposed § 155.220(c)(6), we proposed these amendments to codify in § 155.221(b)(4) more details about the existing program requirements that apply to direct enrollment entities and are captured in the agreements executed with participating web-broker and QHP issuer direct enrollment entities. We

noted that these proposed requirements are in addition to the operational readiness requirements for web-brokers at new proposed § 155.220(c)(6), although web-brokers may not be required to submit the documentation required under this proposal to revise § 155.221(b)(4) or they may be permitted to use the same documentation to satisfy the requirements of both operational readiness reviews depending on the specific circumstances of their participation in the direct enrollment program and the source and type of documentation. For example, a webbroker seeking to participate only in the Classic DE program would only be required to meet the operational readiness requirements at new proposed $\S 155.220(c)(6)$, whereas a web-broker seeking to participate in the EDE program may be permitted to use its third-party security and privacy audit documentation for EDE to satisfy the security and privacy audit documentation requirements of §§ 155.220(c)(6) and 155.221(b)(4) assuming the Classic DE and EDE systems and functionality were hosted in the same environments subject to the third-party audit.

In paragraph (b)(4), we proposed to continue to require a direct enrollment entity to demonstrate operational readiness and compliance with applicable requirements prior to the direct enrollment entity's website being used to complete an Exchange eligibility application or a QHP selection. We added new proposed paragraphs (b)(4)(i) through (v) to reflect that direct enrollment entities may need to submit or complete, in the form and manner specified by HHS, a number of artifacts, documentation, or various testing or training processes. The documentation may include business audit documentation, including: Notices of intent to participate including auditor information; documentation packages including privacy questionnaires, privacy policy statements, and terms of service; and business audit reports including testing results. The required documentation may also include security and privacy audit documentation including: Interconnection security agreements; security and privacy controls assessment test plans; security and privacy assessment reports; plans of action and milestones; privacy impact assessments; system security and privacy plans; incident response plans; and vulnerability scan results. Submission of agreements between the direct enrollment entity and HHS documenting the requirements for

participating in the applicable direct enrollment program may also be required. Required testing may include eligibility application audits performed by HHS. The direct enrollment entity may also be required to complete online training modules developed by HHS related to the requirements to participate in the direct enrollment program.

We requested comment on this proposal.

We received one public comment on the proposed updates to direct enrollment entity operational readiness review requirements. The following is a summary of the comment we received and our response.

Comment: One commenter expressed support for the proposed updates to the direct enrollment entity operational readiness review requirements.

Response: We appreciate the commenter's support of the proposed updates to the direct enrollment entity operational readiness review requirements and are finalizing this proposal as proposed.

6. Certified Applications Counselors (§ 155.225)

In the proposed rule, we proposed to allow, but not require, CACs to assist consumers with applying for insurance affordability programs and QHP enrollment through web-broker non-Exchange websites under certain circumstances and to the extent permitted by state law. For a discussion of this proposal, along with a summary of comments received and our responses to these comments, please see the preamble for § 155.220.

- 7. Verification Process Related to Eligibility for Insurance Affordability Programs (§ 155.320)
- a. Verification of Eligibility for Employer Sponsored Coverage

Exchanges must verify whether an applicant is eligible for or enrolled in an eligible employer sponsored plan for the benefit year for which coverage and premium assistance (APTC or CSR) are requested using available data sources, if applicable, as described in § 155.320(d)(2). For any coverage year that an Exchange does not reasonably expect to obtain sufficient verification data as described in paragraph (d)(2)(i) through (iii), an alternate procedure applies. Specifically, Exchanges must select a statistically significant random sample of applicants and meet the requirements under paragraph (d)(4)(i). For benefit years 2016 through 2019, Exchanges also could use an alternative process approved by HHS. We are

continuing to explore a new alternative approach to replace the current procedures in paragraph (d)(4)(i), under which an Exchange may design its verification process to confirm that qualified individuals are not eligible for or enrolled in an eligible employer sponsored plan, disqualifying them from receiving APTC or CSRs.

HHS's experience conducting random sampling revealed that employer response rates to HHS's request for information were low. The manual verification process described in § 155.320(d)(4)(i) requires significant resources and government funds, and the value of the results ultimately does not appear to outweigh the costs of conducting the work because only a small percentage of sample enrollees have been determined by HHS to have received APTC or CSRs inappropriately. We believe an approach to verifying an applicant's attestation regarding access to eligible employer sponsored coverage should be rigorous, while posing the least amount of burden on states, employers, consumers, and taxpayers. Based on our experiences with random sampling methodology under paragraph (d)(4)(i), HHS is of the view that this methodology may not be the best approach for all Exchanges to assess the associated risk for inappropriate payment of APTC and CSRs. As such, in 2019, HHS conducted a study to (1) determine the unique characteristics of the population with offers of employersponsored coverage that meets minimum value and affordability standards, (2) compare premium and out-of-pocket costs for consumers enrolled in affordable employersponsored coverage to Exchange coverage, and (3) identify the incentives, if any, that drive consumers to enroll in Exchange coverage rather than coverage offered through their current employer. We are still evaluating the results of this study to ensure the best verification process to ensure that consumers with offers of affordable coverage that meets affordability and minimum value standards through their employer are identified and do not receive APTC or CSRs inappropriately. HHS will consider changes to the verification process outlined under paragraph (d)(4) as part of future rulemaking.

As HHS continues to explore the best options for verification of employer sponsored coverage, we proposed that HHS will continue to refrain from taking enforcement action against Exchanges that do not perform random sampling as required by paragraph (d)(4), as an alternative to performing this verification against the data sources required under § 155.320(d)(2)(i)

through (iii), and will extend this nonenforcement posture from plan year 2021 through plan year 2022. We also proposed that HHS will continue to exercise such discretion as HHS continues to evaluate the results of the employer verification study described in the proposed rule and of the futures changes also discussed.

Comment: The majority of commenters on this topic agreed with HHS's proposal to refrain from taking enforcement action against Exchanges that do not conduct random sampling to verify whether an applicant has access to or received an offer of affordable coverage that meets the minimum value standard through their employer. The commenters agreed with HHS's prior study findings that the random sampling process requires significant resources with little return on investment. Commenters also agreed with HHS that an employer-sponsored coverage verification approach should provide State Exchanges with flexibility and more opportunities to use verification processes that are evidencebased, while imposing the least amount of burden on consumers, states, employers, and taxpayers and ensures that only consumers who are eligible for APTC/CSRs continue to receive them; commenters noted that this is especially important during the current COVID-19 public health emergency and allows states to shift resources to help consumers retain or enroll in QHP coverage. One commenter further noted that an efficient verification process to verify whether an applicant has an offer of affordable coverage through their employer also provided an added benefit as it reduces the employer shared responsibility payment (ESRP) burden for both the Internal Revenue Service (IRS) and employers nationwide. One commenter supported the proposal, but proposed that HHS allow State Exchanges to select their own verification method that would not add significant administrative burden on states and stated that the current proposal does not provide State Exchanges with enough flexibility to make any necessary changes that may result from future rulemaking.

Finally, another commenter suggested that, as HHS reviews the results of the study discussed in the preamble to the proposed rule, we should consider releasing the results of the 2019 study in an effort to provide transparency regarding the demographic patterns that HHS discovered as a result of this research.

Response: We agree that the current random sampling process required under § 155.320(d)(4)(i) is not only

burdensome for states, employers, consumers, and taxpayers, but it also does not provide enough flexibility to all Exchanges to develop a process for employer-sponsored coverage verification that more accurately reflects their respective enrolled Exchange populations. As discussed in the preamble above and in the proposed rule, HHS shares the same concerns regarding the feasibility and effectiveness of random sampling, including the effectiveness of employer and employee notices, and the impact that such a verification process has on Exchanges' appeals processes. We also agree that a verification process should be evidence-based and informed by certain risk-factors for inappropriate payment of APTC/CSRs and that additional flexibilities are important to help states better serve their populations during the current COVID-19 public health emergency. Finally, as HHS continues to evaluate the results of the 2019 study, we will explore the possibility of releasing the results of the study at a later date.

We disagree with the comment that the proposal to extend enforcement discretion to plan year 2022 provides State Exchanges with less flexibility to implement any future process changes for employer-sponsored coverage verification. State Exchanges have existing flexibility under §§ 155.320(a)(2) and 155.315(h) to propose an alternative approach to using the verification procedures under $\S 155.320(d)(2)$, or an alternative to using the random sampling process described under $\S 155.320(d)(4)$, in order to verify whether applicants have received an offer of affordable coverage. We continue to encourage states to use this flexibility to explore evidence or risk-based approaches to conducting this verification. Finally, these changes do not impact State Exchanges that currently verify offers of employersponsored coverage using approved data sources under § 155.320(d)(2)(i) through (iii) or use the random sampling procedures under § 155.320(d)(4), and have determined these methods are the appropriate approaches for their Exchanges to meet requirements under § 155.320(d).

Comment: Two commenters supported the proposal but expressed their ongoing concerns regarding employer-sponsored verification, specifically that the lack of a centralized website or database for employers to provide contact information and other information Exchanges would need to verify whether an employer offers coverage that meets minimum value standards is problematic and has led to

many of the ongoing challenges Exchanges have experienced. These commenters suggested that HHS and IRS should work together to develop a single, streamlined verification process that could be achieved in one of two ways: (1) By establishing a simple, webbased platform or database where employers could provide Exchanges with their contact information which Exchanges could query as part of their verification attempts or (2) provide employers with the option to report their information to IRS well in advance of Open Enrollment so that Exchanges could query this information to verify whether that employer offers coverage that meets the employer shared responsibility affordability and minimum value tests. Commenters also urged IRS and Treasury to allow employers to provide real-time employer coverage data on *HealthCare.gov* to help consumers compare coverage offered through their employers with options offered on Exchanges to make the best coverage decisions based on their needs and budgets.

Response: We did not propose policies or requirements related to future verification processes as HHS is still evaluating the results of the 2019 study to determine the best path forward. HHS appreciates the suggested approaches for consideration and agrees with the commenters that having accurate, up-to-date contact information for employers presents a significant challenge for Exchanges attempting to verify an applicant's attestation that they do not have access to affordable coverage through their employer as outlined under § 155.320(\hat{d})(4)(i)(D). HHS will continue to explore all options to implement a verification process for employer-sponsored coverage that is evidence-based and will continue to work with our federal partners to assess the feasibility of creating such a webbased platform or database to collect employer contact information as outlined above.

 b. Verification Process Related to Eligibility for Insurance Affordability Programs

As noted in section IV of the preamble, on March 4, 2021, the United States District Court for the District of Maryland decided *City of Columbus, et al.* v. *Cochran, No.* 18–2364, 2021 WL 825973 (D. Md. Mar. 4, 2021), vacating certain requirements under 45 CFR 155.320, which provides Exchange income verification requirements for resolving data matching issues related to eligibility for advance payments of premium tax credits. Under the current

regulation, an individual who attests to a household income within 100 percent to 400 percent of the federal poverty level (FPL), but whose income according to trusted electronic data sources is below 100 percent FPL, must submit additional documentation supporting the attested to household income. 199 Given the court's order invalidating this policy, we are finalizing revisions to § 155.320 in this final rule to rescind text implementing the policy.

As explained below in the Implementation of the Decision in *City* of Columbus, et al. v. Cochran section, HHS's systems automatically generate requests for income verification information for those with income data matching issues, and it will take some time to redesign this function. Until that redesign is complete and implemented, however, HHS will be able to identify consumers who receive requests for income verification information as a result of current system logic. We have established a manual process to notify those consumers that they need not provide the requested information.

- 8. Special Enrollment Periods (§ 155.420)
- a. Exchange Enrollees Newly Ineligible for APTC

We proposed to add new flexibility to allow current Exchange enrollees and their dependents to enroll in a new QHP of a lower metal level ²⁰⁰ if they qualify for a special enrollment period due to becoming newly ineligible for APTC. We are finalizing a modified version of this policy to permit Exchange enrollees who qualify for a special enrollment period based on a loss of APTC eligibility to change to a new plan at any metal level, and to require that Exchanges implement this change no later than January 1, 2024.

In 2017, the Market Stabilization Rule addressed concerns that Exchange

enrollees were utilizing special enrollment periods to change plan metal levels based on ongoing health needs during the coverage year, negatively affecting the individual market risk pool. The Market Stabilization Rule set forth requirements at § 155.420(a)(4) to limit Exchange enrollees' ability to change to a QHP of a different metal level when they qualify for, or when a dependent(s) newly enrolls in Exchange coverage through, most types of special enrollment periods.²⁰¹

Generally, § 155.420(a)(4) provides that enrollees who newly add a household member through most types of special enrollment periods may add the household member to their current QHP or enroll them in a separate QHP,202 and that if an enrollee qualifies for certain special enrollment periods, the Exchange must allow the enrollee and his or her dependents to change to another QHP within the same level of coverage (or one metal level higher or lower, if no such QHP is available), as outlined in § 156.140(b). However, even prior to the change that we are finalizing in this rule, § 155.420(a)(4) included certain flexibilities to permit enrollees to change metal levels through a special enrollment period related to a change in financial assistance for coverage through the Exchange. For example, § 155.420(a)(4)(ii)(B) provides that beginning January 2022, if an enrollee and his or her dependents become newly ineligible for cost-sharing reductions in accordance with paragraph (d)(6)(i) or (ii) of this section and are enrolled in a silver-level OHP, the Exchange must allow the enrollee and his or her dependents to change to a QHP one metal level higher or lower, if they elect to change their QHP enrollment, which they may wish to do based on loss of previously-available financial assistance.

Similarly, we proposed to add a new flexibility at § 155.420(a)(4)(ii)(C) to allow enrollees and their dependents who become newly ineligible for APTC in accordance with paragraph (d)(6)(i) or (ii) of this section to enroll in a QHP of

 $^{^{199}\,\}mathrm{See}$ 83 FR 16985–16987 (discussing finalization of new paragraphs \S 155.320(c)(3)(iii)(D) and (E), and modifications to paragraphs (c)(3)(vi)(C), (D), (F), and (G)).

²⁰⁰ Section 1302(d) of the ACA describes the various metal levels of coverage based on AV, and section 2707(a) of the PHS Act directs health insurance issuers that offer non-grandfathered health insurance coverage in the individual or small group market to ensure that such coverage includes the EHB package, which includes the requirement to offer coverage at the metal levels of coverage described in section 1302(d) of the ACA. Consumerfacing HealthCare.gov content explains that metal levels serve as an indicator of "how you and your plan split the costs of your health care," noting that lower levels such as bronze plans have lower monthly premiums but higher out of pocket costs, while higher levels such as gold plans have higher monthly premiums but lower out of pocket costs. See https://www.healthcare.gov/choose-a-plan/ plans-categories/.

 $^{^{201}}$ These limitations do not apply to enrollees who qualify for certain types of special enrollment periods, including those under \S 155.420(d)(4), (8), (9), (10), (12), and (14). While special enrollment periods under paragraphs (d)(2)(i) and (d)(6)(i) and (ii) are excepted from \S 155.420(a)(4)(iii), \S 155.420(a)(4)(i) and (ii) apply other plan category limitations to them

²⁰² Section 155.420(a)(4)(ii), (a)(4)(iii)(B), and (a)(4)(iii)(C) also provide that alternatively, if the QHP's business rules do not allow the newly-enrolling household member to enroll, the Exchange must allow the enrollee and his or her dependents to change to another QHP within the same level of coverage (or one metal level higher or lower, if no such QHP is available), as outlined in § 156.140(b).

a lower metal level. Under this proposal, these special enrollment periods in paragraph (d)(6)(i) and (ii) for becoming newly ineligible for APTC would be addressed in paragraph (a)(4)(ii)(C), and so they will no longer be subject to the separate rules in paragraph (a)(4)(iii). Therefore, we further proposed to revise paragraph (a)(4)(iii) to include them in the list of triggering events excepted from the limitations at paragraph (a)(4)(iii). We are finalizing a modified version of this policy to permit Exchange enrollees who qualify for a special enrollment period based on a loss of APTC eligibility to change to a new plan at any metal level, and to require that Exchanges implement this change no later than January 1, 2024. We expect that that providing Exchanges with more time to implement the change and exempting this special enrollment period from limitations entirely will reduce Exchanges' implementation burden and that this policy will help impacted enrollees' ability to maintain continuous coverage for themselves and for their dependents in spite of a potentially significant change to their out of pocket costs.

We proposed this new flexibility in part because of concerns from agents and brokers that some consumers who qualify for the special enrollment period in accordance with § 155.420(d)(6)(i) or (ii) because they lose eligibility for APTC based on an income increase may lose a significant amount of financial assistance without having gained enough income to continue to afford the coverage they selected when APTC was available to them. In the proposed rule, we provided an example of a qualified individual whose estimated annual household income increases to more than 400 percent FPL due to an income increase of less than \$2,000.203 In this example, the individual's loss of APTC would require them to pay over \$7,000 more annually for their current plan.204 While this individual would qualify for a special enrollment period due to a loss of eligibility for APTC per paragraph (d)(6)(i), under the previous rule they would not be able to change from a gold plan to a silver or bronze plan (or to a catastrophic plan, if they were eligible)

to pay a lower monthly premium, because paragraph (a)(4)(iii)(A) provided that these enrollees may only change to another QHP within their current plan's metal level. The American Rescue Plan Act of 2021 will help some individuals in the situation described above because it allows individuals whose household income exceeds 400 percent FPL to qualify for a premium tax credit if they are otherwise eligible. The new law will make premium tax credits available to these families and caps the amount of household income the family is expected to contribute to their premiums for purposes of calculating the credit at 8.5 percent, based on the cost of their second lowest cost silver benchmark plan. However, this flexibility is also necessary to ensure access to coverage by those who experience circumstances other than a household income increase that may cause consumers to become ineligible for APTC. For example, in the proposed rule, we also noted that Exchange enrollees can lose eligibility for APTC due to a change in tax household size, without experiencing any change in income, and we provided an example of a family of two parents and a 20-year old child with no income and who is not a full-time student. We are updating the example to reflect the changes made for 2021 and 2022 by the American Rescue Plan Act of 2021. If the family applies during open enrollment in 2022 and qualifies for APTC based on a household of three, and during 2023 the child becomes employed and earns enough income so that the parents no longer plan to claim the child as a tax dependent for 2023, their decrease in household size could cause them to lose eligibility for APTC. Loss of eligibility for APTC based on not being permitted to claim as a tax dependent an individual projected at open enrollment to be a tax dependent (loss of a projected tax dependent) is likely a less common challenge, because loss of a projected tax dependent who was previously enrolled in the same plan as other household members may also result in a lower premium for remaining household members. However, in some cases the decrease in premium may not be enough to make up for the loss of APTC.

As discussed in the proposed rule, in many cases individuals enrolling in Exchange coverage during open enrollment will not anticipate experiencing a situation in the middle of the plan year like those described in this final rule. Even if they are aware that they could have a small increase in

household income or lose a projected tax dependent, they may not realize that these changes could make them newly ineligible for APTC. Furthermore, sometimes these changes are not foreseeable. Additionally, it is reasonable for individuals who complete an application and then shop for coverage on HealthCare.gov to select a QHP based on premiums that are reduced by the APTC amount for which they are eligible at the time of plan selection, particularly if they do not realize that their financial assistance could change based on loss of a projected tax dependent or a small household income change during the

coming year.

While this proposal was designed to provide Exchange enrollees who lose APTC with the chance to select lowercost coverage, we recognized that changing to a new QHP mid-plan year may cause enrollees to incur additional out of pocket costs as a new QHP selection typically resets the deductible and other accumulators. We believe that Exchange enrollees who lose APTC eligibility are best able to weigh the trade-off between reset accumulators or maintaining an affordable monthly premium. As discussed in the proposed rule, a change may benefit some consumers because price differences between QHPs of different metal levels can be significant. For example, in states using the federal enrollment platform, on average, silver plan premiums are 34 percent more expensive than bronze plan premiums, and gold plan premiums are 14 percent more expensive than silver plan premiums.205 Further, enrollees who qualify to make a new plan selection for an applicable special enrollment period already must consider this question.

Finally, in the proposed rule we acknowledged that enrollees may lose APTC eligibility and qualify for a special enrollment period due to their APTC loss for a reason other than a change in household income or tax family size. For example, a currentlyenrolled individual or household could lose APTC and qualify for the related special enrollment period due to an expired inconsistency regarding projected annual household income, or because the Exchange has information that they are eligible for or enrolled in other qualifying coverage that is considered MEC such as most Medicaid coverage, CHIP, or the Basic Health

²⁰³ See 85 FR 78623.

²⁰⁴ 26 CFR 1.36B-2(b)(1) provides that to be eligible for a premium tax credit, the taxpayer's household income must be at least 100 percent but not more than 400 percent of the FPL for the taxpayer's family size for the taxable year. Per the HHS Poverty Guidelines for 2020, 400 percent of the FPL for 2020 for an individual in the contiguous 48 states and DC is \$51,040. However, under the American Rescue Plan Act of 2021, for taxable years 2021 and 2022, the upper limit on household income at 400 percent of the FPL has been removed.

²⁰⁵ Calculated based on information in the "Plan Year 2020 Qualified Health Plan Choice and Premiums in HealthCare.gov States" report. Available at https://www.cms.gov/CCIIO/Resources/ Data-Resources/Downloads/2020QHPPremiums ChoiceReport.pdf.

Program (BHP), through the periodic data matching process described in § 155.330(d), and therefore are ineligible for APTC. We sought comment on whether stakeholders had concerns with this possibility, and on how HHS can help ensure that enrollees who lose eligibility for APTC because of failure to provide information to the Exchange to confirm their APTC eligibility can understand and take action on steps needed to do so. Relatedly, we sought comment on whether Exchanges should limit the flexibility proposed in this rule only to enrollees who qualify for a special enrollment period because they lost APTC eligibility due to a change in household income or tax family size, and continue to apply the current rule at 155.420(a)(4)(iii)(A) to enrollees who qualify for a special enrollment period because they lost APTC for any other reason. We also sought comment on whether such a policy would impose significant additional burdens on Exchanges.

HHS believed that this proposal is unlikely to result in adverse selection, and may improve the risk pool by supporting continued health insurance enrollment by healthy individuals who would be forced to end coverage in response to an increase in premium. However, we requested comment on whether there are concerns with permitting newly unsubsidized enrollees to change to any plan of a lower metal level to help them maintain coverage (for example, permitting an individual to change from a gold plan to a bronze plan), or whether we should instead only permit an enrollee to change to a plan one metal level lower than their current QHP. We also requested comment from issuers on whether there are concerns about impacts such as experiencing a decrease in premium receipt from enrollees who opt to change to a lower-cost plan, or whether they view adverse selection as a possibility. We requested comment from Exchanges, in particular, on implementation burden associated with this change to current plan category limitations rules, including on whether we should instead, to reduce this burden, permit current enrollees and currently enrolled dependents who qualify for this SEP to change to a plan of any metal level—that is, simply exempt the special enrollment periods at § 155.420(d)(6)(i) and (ii) due to becoming newly ineligible for APTC from plan category limitations altogether. We also requested comment from all stakeholders, including those who have or represent individuals with preexisting conditions, on whether such a change would significantly increase risk for adverse selection.

Finally, we also considered whether to propose additional flexibility to allow enrollees and their dependents who become newly eligible for APTC in accordance with paragraph (d)(6)(i) or (ii) to change to a QHP of a higher metal level, but we did not propose additional plan flexibility for enrollees who become newly eligible for APTC. We invited comment on whether we should consider additional flexibilities for this population in the future and the anticipated impact of such a policy.

We received public comments on the proposed updates to Exchange enrollees newly ineligible for APTC. The following is a summary of the comments we received and our responses.

Comment: Almost all comments on this proposal were supportive of this change, explaining that allowing enrollees the flexibility to change to a plan of a lower metal level based on a loss of APTC would allow more individuals to maintain coverage. Some commenters also noted that this proposal could improve the on-Exchange risk pool by increasing the likelihood that individuals would maintain coverage in spite of losing financial assistance. One commenter requested a 2021 effective date for this proposal instead of 2022, and two commenters requested that HHS implement this proposal as soon as possible. One commenter opposed the proposal because they preferred that HHS promote continuous coverage by making more financial assistance available to consumers rather than by providing certain consumers with the flexibility to change to a lower metal level plan. One commenter encouraged HHS to bear in mind the risks of adverse selection in general, but did not oppose this proposal and noted that it would help consumers; this commenter and several others also misunderstood the proposal to be for a new special enrollment period for individuals who lose financial assistance rather than a change to plan category limitations that currently apply to an existing special enrollment period.

No commenters raised the concern that this proposal specifically would increase the risk of adverse selection. Several commenters supported also allowing enrollees who newly become APTC eligible to change to a plan of a higher metal level. Many commenters supported allowing individuals who qualify for a special enrollment period based on a loss of APTC eligibility to change to a plan of any metal level, either to provide enrollees with flexibility to change to the best plan for

themselves and their families, to make implementation easier for State Exchanges, or both. One of these commenters requested that instead of applying plan category limitations, HHS require Exchange enrollees to provide documents to confirm their SEP eligibility. Some commenters supported allowing individuals who lose APTC eligibility to change to a plan of a higher or lower metal level rather than just to a plan of a lower metal level. Finally, many commenters disagreed with the need to require plan category limitations in general, and requested that HHS provide Exchanges with flexibility in terms of when or whether to implement plan category limitations at all based on considerations related to their specific State Exchange's market.

Response: We are finalizing a modified version of this policy to permit Exchange enrollees who lose APTC eligibility to change to a new plan at any metal level, and to require that Exchanges implement this change no later than January 1, 2024. We agree with commenters that allowing enrollees to access a plan at any metal level through the existing special enrollment period for those who lose eligibility for APTC will significantly decrease Exchange implementation complexity and cost, and believe that providing Exchanges with the flexibility to implement this change no later than 2024 provides Exchanges with sufficient time to account for this change in their operational planning. We also agree with commenters who stated that providing more flexibility for enrollees who qualify for a special enrollment period due to losing APTC will help consumers who lose eligibility for APTC during the plan year to stay enrolled in coverage by switching to a new QHP that better suits their changed financial situation. While we understand general concerns related to adverse selection, we agree with commenters that this specific policy does not pose this risk because enrollees are likely to access it based on a financial change as opposed to a change in their health care needs. We also clarify that this policy does not create a new special enrollment period qualifying event, but rather is a change to limitations on plan selection that apply to an already-existing special enrollment period for Exchange enrollees who become newly ineligible for APTC per 45 CFR 155.420(d)(6)(i) and (ii).

Additionally, we do not believe that it is necessary to require eligible consumers to submit documentation of the change that resulted in their loss of APTC eligibility, in part because this special enrollment period is triggered

automatically when consumers attest to the related income or household change in the application. That is, there is no separate question asking consumers to attest to no longer being APTC eligible. Further, as discussed in the 2017 Market Stabilization Rule, we have concerns about pending a new enrollment until pre-enrollment verification is conducted for current Exchange enrollees; because they would still have an active policy, the potential overlap of current, active policies and pended new enrollments would cause significant confusion for consumers and create burdens on issuers with respect to managing potential operational issues. 206

We did not propose removing plan category limitations; however, we continue to study potential policies to promote continuous coverage and provide consumers with flexibility. Finally, we acknowledge the potential benefit of requiring Exchanges to implement this change quickly, but we believe that providing Exchanges with flexibility to implement it no later than January 1, 2024 strikes an appropriate balance between allowing early implementation if possible and providing Exchanges with necessary flexibility to plan related system updates based on Exchange-specific competing priorities and resources. While some Exchanges may be able to implement this new flexibility sooner than January 1, 2024, in light of competing priorities such as the need to implement changes to calculating financial assistance established in the American Rescue Plan Act of 2021, we believe that substantial flexibility for Exchanges is appropriate.

Comment: Several commenters supported the proposal but responded to our request for comment on the risk that enrollees changing plans midcoverage year might not realize that their out of pocket costs could increase if their deductible and other accumulators are re-set by noting this is a concern. Some of these commenters requested that HHS provide additional education and outreach to help enrollees to make an informed decision on whether to change to a less expensive plan even though it could require them to meet a new deductible and out-of-pocket maximum without taking into account progress they had made towards these accumulators in their prior coverage. Specific suggestions from commenters included adding pop-up text in the HealthCare.gov application for enrollees changing plans through a special

enrollment period, additional notice content, including in the form of infographics, to illustrate the trade-off between a lower cost plan and re-set accumulators, and adding help text to encourage special enrollment periodeligible enrollees to seek out assistance through Find Local Help for assistance with understanding their options. One commenter suggested that related help text should appear at the time of an APTC-ineligibility determination and should also provide these enrollees with the basis for the determination. One commenter asked that HHS reiterate in the final rule that issuers have the flexibility to waive deductibles for consumers who change mid-year to a plan of a different metal level, and one commenter asked that HHS consider requiring issuers to transfer progress toward accumulators for consumers who change plans through a special enrollment period.

Response: As discussed in the proposed rule, HHS acknowledges these concerns, and will take commenters' suggestions into consideration in our efforts to improve the consumer experience through outreach and education. We also reiterate here that Marketplace issuers have the flexibility to carry over progress towards a previous plan's accumulators for enrollees who change to a different plan mid-year with the same issuer. However, HHS does not have the authority to require that issuers carry over this progress. Issuers must comply with any applicable state requirements regarding accumulators.

Comment: One commenter recommended continuing to apply plan category limitations to enrollees who lose APTC due to a failure to submit documents to confirm their household income, but to provide the additional flexibility to enrollees who lose APTC eligibility for any other reason, citing the difficulties of implementing changes to plan category limitations for different sub-groups of special enrollment period eligible consumers. However, several commenters recommended extending the new flexibility to all enrollees who lose APTC eligibility, including to those who lose APTC due to failure to resolve an inconsistency related to household income. One of these commenters noted that, in addition to a change in household income or a mid-year decision to no longer claim a household member as a tax dependent, enrollees may lose APTC eligibility if a family member is offered employer-sponsored coverage that is considered affordable and the household loses APTC eligibility as a result. Commenters did not express concerns about the

possibility, as discussed in the proposed rule, that this policy would allow or encourage individuals to change to a plan of a lower metal level instead of submitting documentation to resolve an inconsistency to maintain or re-gain their APTC eligibility. However, several commenters expressed concerns about the challenges consumers may face related to submitting documents to resolve an inconsistency and provided recommendations for HHS to improve education and outreach related to document submission. One commenter asked that HHS provide more direct outreach, such as outbound calls and referrals to an enrollment assister, to consumers who fail to resolve inconsistencies and then select lower cost plans to ensure that these enrollees understand their options. Another commenter stated that individuals who lose APTC based on incorrect or out-ofdate income information must have a chance to challenge their determination, and suggested that their special enrollment period not expire until 60 days after they receive notice of a final determination of APTC ineligibility. One commenter suggested that in addition to reminding enrollees of the requirement to update their application with changes including to household income, that HHS proactively notify enrollees whose income may have changed based on information from a data source that HHS uses to verify income information.

Response: We agree with commenters that limiting this change in plan category limitations based on reasons why existing enrollees lose APTC eligibility would be burdensome to implement, and may prevent some enrollees from benefitting from the ability to change to a new plan based on a change in their financial situation. We also agree that individuals who lose APTC eligibility due to a family member's offer of employer-sponsored coverage may benefit from being able to change to a plan of a different metal level if it would be difficult for them to afford to enroll in the employer coverage along with their family member. Further, we believe that for most enrollees, the benefit of receiving APTC combined with extensive outreach that HHS conducts for individuals who must submit documentation to confirm their household income sufficiently motivates these individuals to submit necessary documentation. Additionally, we clarify that applicants to Exchanges on the Federal platform who must submit documentation to confirm their household income are first notified of

^{206 82} FR 18359, https://www.federalregister.gov/d/2017-07712/p-149.

this requirement in the eligibility notice they receive upon completing their application, and that individuals who do not submit documents, or who submit documents that do not provide enough information to confirm the household income that they attested to on their application, receive a series of reminder notices, calls, and emails.²⁰⁷ We continue to investigate opportunities to improve this outreach.

b. Special Enrollment Periods— Untimely Notice of Triggering Event

We proposed to allow a qualified individual, enrollee, or dependent who did not receive timely notice of a triggering event and was otherwise reasonably unaware that a triggering event occurred to select a new plan within 60 days of the date that he or she knew, or reasonably should have known, of the occurrence of the triggering event. We also proposed to allow such persons to choose the earliest effective date that would have been available if he or she had received timely notice of the triggering event. Finally, we proposed conforming amendments to § 147.104(b)(2)(ii) so that these proposals would also apply to off-Exchange individual health insurance coverage. We are finalizing this policy as proposed.

In accordance with $\S 155.410(a)(2)$, an Exchange may allow qualified individuals and enrollees to enroll in or change coverage only during the annual open enrollment period as specified in § 155.410(e), and during special enrollment periods as specified in § 155.420. An Exchange must allow a qualified individual or enrollee to enroll in or change from one qualified health plan to another if one of the triggering events described in § 155.420(d) occurs. Furthermore, under § 155.420(c)(1), a qualified individual or enrollee generally has until 60 days after the date of the triggering event to select a qualified health plan. Section 155.420(c)(2) and (3), provide exceptions to this general rule under which a qualified individual or enrollee may enroll prior to the date of a triggering event. Section 155.420(c)(4) provides a final exception under which a qualified individual or enrollee may have less than 60 days to enroll. Coverage effective dates are outlined in

§ 155.420(b) and vary depending on the special enrollment period triggering event, but in all cases are either on or after the date of the triggering event.

Because the time period during which a qualified individual may enroll through a special enrollment period is determined by the triggering event, a qualified individual who does not know the triggering event has occurred may not have sufficient time to enroll in coverage. Generally, the triggering events described in § 155.420(d) and related plan selection timelines under § 155.420(c) are premised on the assumption that an individual will become aware of a triggering event in time to make a plan selection within the time allotted under § 155.420(c). For example, the rules anticipate that qualified individuals or enrollees will receive timely notice of the day they will lose employer-sponsored coverage or the day they will gain a dependent such that 60 days is ample time for the individual to apply for enrollment through an applicable special enrollment period and select a plan. However, our experience operating the Federally-facilitated Exchange has shown that there are circumstances in which an individual reasonably may not be aware of an event that triggers special enrollment period eligibility until after the triggering event has occurred. This change will allow a qualified individual, enrollee, or dependent who did not receive timely notice of a triggering event or was otherwise reasonably unaware that a triggering event occurred, to qualify for an applicable special enrollment period and select a new plan within 60 days of the date that he or she knew, or reasonably should have known, of the occurrence of the triggering event. This proposal will also allow the qualified individual, enrollee, or dependent to choose the earliest effective date that would have been available if he or she had received timely notice of the triggering event.

For example, an employer fails to pay its share of premium for an insured employer-sponsored health plan and enters a grace period beginning April 1st, which will expire on May 31st. Because the employer intends to satisfy its premium liability before the end of the grace period, the employer does not notify participants and beneficiaries in the plan of the non-payment or the risk of termination of its employersponsored coverage retroactive to April 1st. The employer is does not timely satisfy the premium debt, and the issuer of the employer-sponsored health coverage terminates coverage for the participants and beneficiaries

retroactively to April 1st. Neither the employer nor the issuer of the employer-sponsored health plan notify the participants and beneficiaries of the beginning of the grace period or that coverage would be terminated as of April 1st. On July 10th, the participants and beneficiaries first receive notice from the issuer that their coverage terminated as of April 1st. In accordance with the circumstances described in 26 CFR 54.9801-6(a)(3)(i), due to the employer's failure to timely pay premiums, the participants and beneficiaries of the employer-sponsored health plan lost eligibility for the coverage and are eligible for the special enrollment period provided in § 155.420(d)(1)(i). Per paragraph (d)(1)(i), the triggering event for special enrollment periods due to loss of minimum essential coverage is the last day the consumer would have coverage under his or her previous plan or coverage. But in this scenario, affected participants and beneficiaries, through no fault of their own, were not aware of their loss of minimum essential coverage until more than 60 days following the last day they had coverage. Thus, without the measure we proposed here, the participants and beneficiaries in this example would not be able to use the special enrollment period at paragraph (d)(1)(i), because more than 60 days had passed since the relevant triggering event without their having selected a new plan. Some participants and beneficiaries of employer-sponsored health plans are experiencing similar circumstances during the COVID-19 public health emergency and sought or seek individual health insurance coverage through the FFEs, exposing a perceived gap in current special enrollment period rules.

Another circumstance in which an individual may not be aware that a triggering event occurred involves technical errors that block an individual from enrolling in coverage through an Exchange. Section 155.420(d)(4) specifies that an individual is eligible for a special enrollment period if, among other things, their erroneous non-enrollment in a qualified health plan was due to an error on the part of the Exchange or one of its agents. In this case, the error itself is the triggering event, and the date it occurs serves as the beginning of the special enrollment period. However, as in the case of the loss of employer-sponsored coverage discussed above, an individual may not be aware that an error has occurred. In some cases, the Exchange may not be aware that a technical error has

²⁰⁷ Sample eligibility and reminder notices can be found at https://marketplace.cms.gov/applications-and-forms/notices, and an overview of HHS outreach to individuals who must submit documentation to confirm their household income or other information can be found starting on slide 15 of this presentation: https://marketplace.cms.gov/technical-assistance-resources/complex-cases-data-matching.pdf.

occurred which prevented individuals from enrolling until a subsequent investigation is conducted. This process may take several weeks, during which time an impacted individual may not be aware that they were unable to enroll due to an error and therefore qualify for a special enrollment period. There may even be cases in which an Exchange does not identify the issue and the impacted population and notify them until more than 60 days after the triggering event occurred.

Therefore we proposed to amend $\S 155.420$ by adding paragraph (c)(5) to specifically provide that if a qualified individual, enrollee, or dependent does not receive timely notice of an event that triggers eligibility for a special enrollment period under this section, and otherwise was reasonably unaware that a triggering event occurred, the Exchange must allow them to select a new plan within 60 days of the date that they knew, or reasonably should have known, of the occurrence of the triggering event. Additionally, we proposed to add paragraph (b)(5) to clarify that when a qualified individual, enrollee, or dependent did not receive timely notice of an event that triggers eligibility for a special enrollment period, the Exchange must allow the such persons the option to choose the earliest coverage effective date for the triggering event under paragraph (b) that would have been available if they had received timely notice of the triggering event. In addition, we proposed that the Exchange must also provide the qualified individual, enrollee or dependent the option to choose the effective date that would otherwise be available under the other provisions in

Lastly, we proposed a conforming edit to § 147.104(b)(2) that would incorporate these amendments by reference in the regulations governing limited open enrollment periods for off-Exchange coverage, so that these proposed special enrollment rules would apply to issuers of nongrandfathered individual health insurance, both on and off-Exchange. We also separately proposed a change to § 147.104(b)(2)(ii) to clarify how the special enrollment period in § 155.420(d)(4) applies off-Exchange. This change is discussed in further detail in the preamble to part 147.

We sought comment on these proposals.

We received public comments on the proposed updates to Special Enrollment Periods—Untimely Notice of Triggering Event. The following is a summary of the comments we received and our responses.

Comment: All commenters, except for one, expressed support for the proposal, explaining that it provides flexibility for situations in which a consumer was reasonably unaware that a special enrollment period triggering event occurred. Several commenters stated that this proposal is especially appropriate given the ongoing economic downturn and COVID-19 pandemic, which will increase the number of consumers without coverage. Others stated that it will help promote continuity of coverage, and reduce the uninsured population. Several commenters stated that the proposal would help reduce challenges with special enrollment period enrollment, such as a lack of clear messaging and insufficient time to select an appropriate plan. A few commenter stated that the proposal will allow more people to enroll in special enrollment periods.

Response: We agree that this proposal will have a positive impact by providing consumers who were reasonably unaware of a special enrollment period triggering event with an opportunity to enroll, as well as the other benefits noted by commenters. As a result, we are finalizing this policy as proposed.

Comment: One commenter opposed the proposal, which they characterized as establishing a new special enrollment period, absent a requirement that enrollees provide evidence of the lack of timely notice of a special enrollment period triggering event. This commenter expressed concern that there are insufficient mechanisms currently to verify the lack of timely notice, and that the proposal would create an openended, year-round opportunity to enroll in coverage, thus increasing the likelihood of adverse selection.

Response: We clarify that the proposed rule does not establish new circumstances through which a special enrollment period would be available, but simply provides additional flexibility regarding when existing special enrollment periods can be accessed in the relatively rare circumstances in which a consumer was reasonably unaware that a triggering event occurred. The proposed rule thus would not create an open-ended special enrollment period through which anyone could enroll, and only consumers who attest to being reasonably unaware that they experienced a special enrollment period triggering event would be eligible to avail themselves of this opportunity. We also note that, for Exchanges on the Federal platform, some enrollments under this authority will be subject to special enrollment period verification, though there may be others that require

caseworker review. Finally, we note that we will continue to monitor the implementation of this provision and propose additional policy and operational updates, including expanding the use of special enrollment period verification, if necessary.

Comment: A few commenters expressed support for the proposed rule, but requested that HHS limit enrollments under this authority to prospective coverage effective dates, and not allow retroactive coverage effective dates. These commenters stated that if retroactive coverage effective dates are permitted, the risk of adverse selection and higher premiums for all enrollees will increase. One of these commenters additionally stated that allowing retroactive coverage effective dates makes it more difficult for issuers to contest improper claims. Another commenter expressed concern regarding the burden of providing retroactive coverage for State Exchanges, and about whether consumers enrolling with a retroactive coverage effective date would be required to pay all past due premiums at once, and whether this would lead to a gap in coverage if they were unable to do so. This commenter requested that we clarify the options available to consumers in this scenario if they are unable to pay all past due premiums. Several other commenters expressed support for providing consumers with the earliest effective date that would otherwise have been available to them had they been aware of the triggering event, stating that this will help maintain continuity of coverage.

Response: While we acknowledge the concerns raised by commenters related to potential adverse selection and increased premiums, we believe this risk to be low due to the rare circumstances in which a consumer would not be notified or become reasonably aware of a triggering event until after it has occurred. We further anticipate that instances of consumers experiencing significant delays in notification or awareness of a triggering event are even rarer, thus minimizing the overall risk of adverse selection and burden on State Exchanges to implement. Regarding the concern of one commenter that consumers may not be able to afford to pay all past due premiums if they choose a retroactive coverage effective date, we note that consumers have the option of choosing a prospective coverage effective date instead.

Comment: Several commenters expressed support for the proposal, but requested that, to prevent abuse by consumers and agents and brokers and

to avoid establishing an open-ended opportunity for enrollment, HHS narrow the scope of the proposal to only cover certain special enrollment periods. A few of these commenters requested that HHS limit the proposal to scenarios in which an individual with employersponsored coverage was not informed by their employer of the loss of coverage, such as the first example discussed in the preamble of the proposed rule. These commenters also stated that HHS already has the authority to provide flexible effective dates for special enrollment periods due to error of the Exchange, and so the flexibility provided by the proposal rule is unnecessary for these situations. One commenter requested that HHS limit the proposal to situations in which an individual with employer-sponsored coverage was not informed by their employer of the loss of coverage, plus scenarios in which an individual is unaware of the date they gained a dependent. Another commenter requested that HHS apply parameters to the proposal, such as limiting the duration to a specific time period such as a public health emergency, or limiting it to the examples discussed in the preamble of the proposed rule.

Response: Although we appreciate the concerns raised by commenters, we are finalizing the rule as proposed. Although some commenters state that HHS already has authority under the exceptional circumstances or error of Exchange special enrollment periods to provide enrollees with flexible effective dates, we note that there are other special enrollment period triggering events, not explicitly discussed as examples in the proposed rule, of which an enrollee may be reasonably unaware, and for which there is no current authority to provide for an enrollment outside the normal window of availability. Furthermore, the exceptional circumstances special enrollment period authority noted by commenters is subject to each Exchange's reasonable interpretation regarding what qualifies as "exceptional." The proposed rule, by contrast, establishes a clear mandate to allow enrollees who were reasonably unaware that a special enrollment period triggering event occurred to use the date they became aware as the triggering event, which will provide transparency and consistency in implementation of this rule across Exchanges and for individual health insurance coverage. Finally, we note that, because the proposal was intended to establish a way to make whole consumers who have been harmed

through no fault of their own, limiting its availability to certain special enrollment period types would be inconsistent with the purpose of this proposed rule.

Comment: A few commenters expressed support for the proposal, but requested that enrollments under this authority be subject to document-based verification to prevent abuse by consumers and agents and brokers.

Response: On Exchanges on the Federal platform, some enrollments under this authority will be subject to special enrollment period verification, though others will likely require caseworker review. Because many State Exchanges and off-Exchange issuers already conduct special enrollment period verification, HHS did not set explicit requirements for State Exchanges or off-Exchange issuers regarding special enrollment period verification for enrollments under this provision. Therefore, we cannot say with certainty whether these entities would subject such enrollments to

Comment: Two commenters requested that HHS implement this proposal sooner than the scheduled January 1, 2022 implementation date.

Response: We note that this provision will become effective on the effective date of this rule, and thus the proposal will be implemented sooner than January 1, 2022.

Comment: Two commenters, noting the difficulties that some consumers face in understanding special enrollment period eligibility and gathering supporting documentation within the 60-day window, expressed support for providing consumers with a window of 60 days from the date they are notified of special enrollment period eligibility to enroll.

Response: Although we appreciate the concerns raised regarding the ability of

consumers to understand and comply with the process for enrolling in a special enrollment period within the 60day window, establishing a policy of providing consumers with a 60-day window from the date they become aware of special enrollment period eligibility would be inconsistent with existing rules for special enrollment period eligibility. Currently, eligibility for special enrollment periods on Exchanges on the Federal platform and many State Exchanges is based on the occurrence of a triggering event, such as a loss of minimum essential coverage, rather than the date an enrollee becomes aware of their special enrollment period eligibility. Therefore, to maintain consistency in special enrollment period operations across these

Exchanges, we believe it is appropriate to establish the date an enrollee becomes aware of the occurrence of a triggering event as the triggering event, rather than the date they become aware of their eligibility for a special enrollment period.

Comment: One commenter requested that HHS broadly interpret the phrase "reasonably unaware" in the regulation text for this proposed rule, and stated that HHS should not second-guess a consumer's statement that they were unaware of a special enrollment period triggering event. Another commenter requested that HHS explain the meaning of this phrase, noting that if interpretation is left up to those providing enrollment assistance, it would be burdensome for State Exchange operations and require processes to individually advise consumers on the date that they should have known about a special enrollment period triggering event.

Response: HHS appreciates the concerns raised regarding how the phrase "reasonably unaware" in the regulation text will be interpreted. Although we do not provide an exact definition of this phrase, we note the two examples included in the preamble of the proposed rule, which describe scenarios in which an individual was reasonably unaware that a special enrollment period triggering event had occurred. In addition, to provide further clarity we include the following example, which illustrates a situation in which a consumer would not have been reasonably unaware that a special enrollment period triggering event occurred. The examples in the preamble to the proposed rule make clear that interpretation of the phrase "reasonably unaware" is not entirely up to individuals providing enrollment assistance. In addition, we also note that the legal standard of what constitutes a reasonable person provides objectivity to whether a consumer in this scenario would be reasonably unaware.

Example: A consumer visits HealthCare.gov on December 1 (during the annual open enrollment period), and while filling out an application, is informed that they may be eligible for Medicaid. The consumer then fills out an application with their state Medicaid office. On February 3 of the following year, they receive a letter from the state Medicaid office informing them that they are ineligible for Medicaid, but fail to open the letter. On April 1 the consumer finds the unopened letter and reads it, and then attempts to enroll in a qualified health plan on HealthCare.gov, attesting to eligibility for the Medicaid denial special

enrollment period based on the February 3 letter informing them of their ineligibility for Medicaid. The consumer failed to enroll in the special enrollment period they would have been eligible for under 45 CFR 155.420(d)(11)(i) within the allotted 60-day window because they were unaware of the triggering event, in this case the determination of ineligibility for Medicaid on February 3, when it occurred. However, they are not eligible to avail themselves of the provision in § 155.420(c)(5) because, had they opened the letter informing them of their ineligibility for Medicaid within a reasonable period of time after receiving it, they would have been made aware of the occurrence of a special enrollment period triggering event, and thus they were not reasonably unaware that one had occurred.

Comment: One commenter requested that HHS discuss whether consumers will be able to access this special enrollment period through HealthCare.gov, which they note would be preferable to enrollments through the call center.

Response: Although enrollees under this authority may be able to enroll using the application on HealthCare.gov, there are likely to be cases in which enrollees must access the special enrollment period they are eligible for through the Marketplace Call Center or a caseworker.

Comment: One commenter expressed support for the proposal, and also asked that the Department of Labor consider implementing this proposal for the group insurance market as well.

Response: HHS does not have the authority to change Department of Labor regulations, and so we are unable to finalize such changes. We note that the Department of Labor regulates group health plans under the Employee Retirement Income Security Act of 1974 (ERISA), and that HHS regulates the group health insurance market. We did not propose to apply this provision to the group health insurance market, and will therefore not finalize such a provision here. However, we will continue to monitor this issue and propose changes related to HHS regulations for the group health insurance market in the future, if appropriate.

Comment: One commenter expressed support for the proposal, but also expressed concern regarding the potential for unintentional loss of dental coverage as a result of changes in other health coverage, for example if a consumer enrolls in both a qualified health plan and stand-alone dental plan, but due to an error of the Exchange was prevented from enrolling in the stand-

alone dental plan. They request that HHS allow consumers enrolling under the authority in the proposed rule to also select a dental plan, and suggest that this could be accomplished by removing the link between qualified health plans and stand-alone dental plans on the Federally-facilitated Exchanges.

Response: We appreciate the concern raised regarding the potential impact of the proposed rule on dental insurance, and note that nothing would prevent a consumer from enrolling in a standalone dental plan under the authority in the proposed rule. For this reason we believe that removing the link between qualified health plans and stand-alone dental plans on the Federally-facilitated Exchanges is not necessary, but we will continue to monitor this issue and propose changes in the future if necessary.

Following review of the comments, we are finalizing this policy as proposed.

c. Cessation of Employer Contributions or Government Subsidies to COBRA as Special Enrollment Period Trigger

The Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA) 208 (Pub. L. 99–272, April 7, 1986) provides for a temporary continuation of group health coverage following, among other circumstances, employees' separation from an employer, for reasons other than gross misconduct, in instances where such separation would otherwise cause termination of coverage. Although employees who elect to receive COBRA continuation coverage may be required by their former employer to pay their former employer's share of the premiums as well as their own,209 some employers pay all or a portion of their former employee's premium for part or all of the COBRA coverage period. In addition, government entities will sometimes subsidize COBRA continuation coverage premiums, whether as a direct payment or via a third party such as an employer.

In accordance with the policy currently in place on the Exchanges on the Federal platform, we proposed to amend § 155.420(d)(1) to state that the complete cessation of employer contributions for COBRA continuation coverage serves as a triggering event for

special enrollment period eligibility. We are instead finalizing this policy under new paragraph (d)(15), rather than in paragraph (d)(1)(v) as we proposed. We are also finalizing text providing that the special enrollment period will be available when subsidies from a government entity completely cease. 210 The triggering event for this special enrollment period is the last day of the period for which COBRA continuation coverage was paid for or subsidized, in whole or in part, by an employer or a government entity.

Exchange regulations at $\S 155.420(d)(1)(i)$ provide that when a qualified individual or his or her dependent loses minimum essential coverage as defined by § 155.20, they gain eligibility for a special enrollment period, during which they can enroll in a qualified health plan. Paragraph (e) of § 155.420 states that loss of minimum essential coverage as described in paragraph (d)(1) includes the circumstances listed at 26 CFR 54.9801-6(a)(3)(i) through (iii). These provisions describe conditions under which someone may qualify for a special enrollment period for group health plan coverage, including paragraphs (a)(3)(i), "Loss of eligibility for coverage," and (a)(3)(iii), "exhaustion of COBRA continuation coverage." Exhaustion of COBRA coverage is defined in 26 CFR 54.9801-2(4) as cessation of COBRA coverage for reasons other than failure of the individual to timely pay premiums, and includes coverage ceasing due to "failure of the employer or other responsible entity to remit premiums on a timely basis.

In implementing special enrollment periods for Exchanges on the Federal platform, HHS has provided a loss of minimum essential coverage special enrollment period under § 155.420(d)(1)(i) for individuals whose COBRA costs change because their former employer completely ceases contributions and as a result they must pay the full cost of premiums. However, loss of coverage based on complete cessation of employer contributions for COBRA coverage might not have been treated as a triggering event by issuers of individual health insurance coverage off-Exchange or by State Exchanges.

²⁰⁸ https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/cobra-continuation-health-coverage-consumer.pdf.

²⁰⁹ Individuals electing COBRA may also be required by their former employer to pay a 2 percent administrative fee. See https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/cobracontinuation-health-coverage-consumer.pdf.

²¹⁰ Because employers are not required to charge a 2 percent administrative fee to individuals who elect COBRA, we do not include this fee in the definition of "employer contributions." For purposes of this section, if an individual enrolled in COBRA continuation coverage without employer contributions (so that the individual was responsible for 100 percent of the premiums) was not required to pay a 2 percent administrative fee, this would not be considered an employer contribution for the purposes of the proposed special enrollment period.

HHS believes it is important that individuals have access to a special enrollment period in the individual market when their former employer or a government entity completely ceases contributions or subsidies to COBRA continuation coverage, because the cost of COBRA continuation coverage premiums can be substantial, rendering this type of coverage unaffordable for many people to whom it would be available. 211 Ensuring that this special enrollment period is widely available will help promote continuity of coverage for those who cannot maintain their COBRA continuation coverage without contributions or subsidies from their employer or a government entity. HHS therefore proposed to make this special enrollment period available throughout the individual market.

We proposed to amend § 155.420 by adding paragraph (d)(1)(v) stating that a special enrollment period is triggered when a qualified individual or his or her dependent is enrolled in COBRA continuation coverage for which an employer is paying all or part of the premiums, and the employer completely ceases its contributions, with the triggering event being the last day of the period for which COBRA continuation coverage is paid for, in whole or in part, by the employer. We are instead finalizing proposed paragraph (d)(1)(v) as (d)(15), and in addition we are also finalizing a change to (e)(1) to explicitly exclude (d)(15). In the preamble to the proposed rule, we clarified that the triggering event for this special enrollment period would be based on loss of employer contributions to COBRA continuation coverage, rather than the loss of coverage itself. Thus, eligibility for this special enrollment period does not depend on loss of COBRA coverage, as illustrated by the examples we included. However, proposed paragraph (d)(1)(v), like the rest of paragraph (d)(1), would have been subject to paragraph (e), which states that loss of coverage excludes voluntary termination of coverage, and (e)(1), which states that loss of coverage does not include failure to pay premiums on a timely basis, including COBRA premiums. Although new paragraph (d)(15) will not be subject to the provisions in (e), we are concerned that stakeholders may still be uncertain about whether individuals who voluntarily end COBRA continuation coverage or have such coverage terminated following a loss of employer contributions or government subsidies would still be eligible for this special

enrollment period, given the limitations imposed by paragraph (e)(1). Therefore, we are finalizing proposed paragraph (d)(1)(v) as (d)(15), which is not subject to paragraph (e). In addition, we are also finalizing a change to paragraph (e)(1) to explicitly exclude the special enrollment period trigger in paragraph (d)(15), making clear that individuals who voluntarily end COBRA continuation coverage or have such coverage terminated following a loss of employer contributions or government subsidies are still eligible for this special enrollment period, and to use the term "COBRA continuation coverage" consistently.

Similar to the special enrollment period for termination of employer contributions to employer-sponsored coverage at 26 CFR 54.9801-6(a)(3)(ii), we proposed that the triggering event is the last day of the period for which COBRA continuation coverage is paid for, in part or in full, by an employer. Furthermore, we proposed to clarify that complete cessation of employer contributions toward employersponsored continuation coverage under state mini-COBRA laws 212 also serves as a special enrollment period triggering event. These changes would make explicit HHS's current policy with regard to the Exchanges on the Federal platform, and would ensure that individual health insurance coverage sold off-Exchange and through State Exchanges align with it. In addition, establishing paragraph (d)(15) to explicitly include complete cessation of employer contributions and government subsidies to COBRA continuation coverage as a special enrollment period triggering event will mitigate confusion among employers and employees, as well as other stakeholders, about their options regarding COBRA continuation coverage and special enrollment period

Similar to other special enrollment periods based on loss of minimum essential coverage, in the Exchanges, this special enrollment period would be subject to the provisions in paragraph (a)(4)(iii)(B) and (C), which allow dependents and non-dependent qualified individuals who qualify for a special enrollment period to be added to the QHP of a household member who is already enrolled in Exchange coverage, or to enroll separately in a plan of any metal level. We also proposed that the Exchange must provide the qualified individual, enrollee, or dependent the effective date that would otherwise be

available pursuant to the other provisions at paragraph (b)(2)(iv). To ensure that this provision applies to new paragraph (d)(15), we are also finalizing changes to paragraph (b)(2)(iv) to include paragraph (d)(15) in the list of special enrollment periods that are subject to the paragraph. In addition, we proposed that an individual eligible for this special enrollment period would have 60 days before or after the triggering event (in this case, the last day for which the qualified individual or dependent has COBRA continuation coverage to which an employer or governmental entity is contributing) to select a qualified health plan. Therefore we are also finalizing changes to paragraph (c)(2) to include new paragraph (d)(15). We also proposed that this special enrollment period, which would be incorporated by reference in the guaranteed availability regulations at § 147.104(b)(2), apply with respect to individual health insurance coverage offered through and outside of an Exchange.

To help clarify the circumstances that would trigger the proposed special enrollment period, we included the

following example:

Example 1: An individual is laid off from a job on June 1, and 5 days later enrolls in COBRA continuation coverage for which the employer pays 100 percent of the premiums (the employer does not require payment of a 2 percent administrative fee). On September 3 of that year, the employer informs the individual that it is completely terminating contributions to the individual's COBRA continuation coverage as of September 30, and beginning on October 1, the individual will be responsible for 100 percent of the COBRA continuation coverage premiums. As a result, the individual decides to end COBRA coverage effective October 1. Because September 30 is the last day for which the individual had COBRA continuation coverage for which the employer was contributing, the individual has 60 days before and after September 30 (in this case, through November 29) to select an individual market plan through a special enrollment period.

In addition to this proposal, HHS also considered addressing situations in which an employer reduces, but does not completely cease, its contributions for COBRA continuation coverage. In particular, we considered adding to proposed paragraph § 155.420(d)(1)(v) a provision that a reduction of employer contributions to COBRA continuation coverage would also serve as a special enrollment period trigger. We also sought comment on whether HHS

²¹¹ https://www.kff.org/private-insurance/issuebrief/key-issues-related-to-cobra-subsidies/.

²¹² https://www.dol.gov/sites/dolgov/files/EBSA/ about-ebsa/our-activities/resource-center/faqs/ cobra-continuation-health-coverage-consumer.pdf.

should also adopt a threshold for the level of reduction of employer contributions to COBRA continuation coverage that would be necessary to trigger the special enrollment period. However, we are not finalizing this policy.

Lastly, we note that in addition to employer contributions to COBRA continuation coverage, COBRA coverage is sometimes subsidized by government entities as well, either directly or through a third party such as an employer.²¹³ As noted in the preamble to the proposed rule and earlier in this preamble, HHS believes it is important that individuals have access to a special enrollment period in the individual market when contributions to COBRA continuation coverage cease, because the cost of COBRA continuation coverage premiums are substantial, rendering this type of coverage unaffordable for many people to whom it would be available. This issue applies equally to cessation of employer contributions and cessation of government subsidies. As with employer contributions to COBRA continuation coverage, providing individuals with a special enrollment period when subsidies from a government entity completely cease will promote continuity of coverage among those who could not maintain their coverage without such subsidies. Therefore, we are also finalizing in new paragraph § 155.420(d)(15) the provision that a special enrollment period is triggered when subsidies from a governmental entity to COBRA continuation coverage, whether paid directly or through a third party, completely cease. The triggering event is the last day of the period for which COBRA continuation coverage is paid for or subsidized, in whole or in part, by an employer or government entity.

We also provide the following example to illustrate how the special enrollment period would work with regard to government subsidies of COBRA continuation coverage premiums.

Example 2: Same scenario as in the first example, except that, as under the American Rescue Plan Act of 2021, the COBRA continuation coverage the individual is receiving is fully subsidized by the federal government, so that the individual does not have to pay any portion of the COBRA premium. The federal subsidy is set to expire on September 30, and as a result,

beginning October 1 the individual will be responsible for the full amount of the COBRA continuation coverage premiums. The individual decides to end their coverage effective October 1, and as a result will have 60 days before and after the last day for which they have COBRA continuation coverage with federal subsidies (in this case, through November 29) to enroll in individual health insurance coverage through a special enrollment period.

We received public comments on the proposed updates to cessation of employer contributions to COBRA as special enrollment period trigger. The following is a summary of the comments we received and our responses.

Comment: No commenters opposed this proposal, and many supported it, explaining that codifying this special enrollment period in regulation would enhance transparency regarding the availability of this special enrollment period on Exchanges on the Federal platform, and mitigate confusion among employers and employees about their options regarding COBRA continuation coverage and special enrollment period eligibility. Several commenters agreed that, since consumers who lose employer contributions to COBRA continuation coverage face a financial calculation that is different than the one they made when originally enrolling in COBRA coverage, a special enrollment period is appropriate. Several others stated that this proposal is especially appropriate given the ongoing economic downturn and COVID-19 pandemic. Other commenters stated that this proposal will help promote continuity of coverage, and noted that this is especially important given that individuals with COBRA are more likely to have higher medical expenses. A few commenters stated that this special enrollment period is especially appropriate given the limited options faced by consumers who choose to maintain their COBRA continuation coverage once employer contributions end. Another agreed that it is important to provide flexibility for consumers who are in a situation over which they have no control. One commenter stated that this special enrollment period is especially important for individuals with chronic health conditions, such as HIV. Another commenter noted that special enrollment periods such as this provide a critical safety net for consumers outside of the annual open enrollment period. Another stated that the proposed rule would likely encourage employers to assist laid-off workers with contributions to COBRA. Finally, one commenter stated that the proposal will have the beneficial effect

of allowing more individuals to enroll through special enrollment periods.

Response: We agree that the proposed changes would enhance transparency and mitigate confusion regarding an existing policy of the Exchanges on the Federal platform and options for consumers regarding special enrollment period eligibility, in addition to the other benefits noted by commenters. Accordingly, we are finalizing this policy as proposed (but with the additional provision regarding government subsidies).

Comment: Several commenters expressed support for the proposal, and in addition supported designating partial reductions in employer contributions to COBRA continuation coverage as a special enrollment period triggering event. These commenters noted that due to the high cost of COBRA continuation coverage, even a partial reduction in employer contributions could make such coverage unaffordable for many consumers. In addition, they noted that including partial reduction of employer contributions as a special enrollment period trigger would promote access to health insurance by providing another pathway by which individuals can enroll in coverage. Several commenters also expressed support for establishing a threshold amount by which employer contributions must decrease in order to trigger special enrollment period eligibility. A few of these commenters expressed support for defining a threshold based on affordability to the consumer. One commenter suggested using a threshold of 10 percent as an approximation of a material reduction in employer contributions. Another commenter noted the IRS' threshold for evaluating affordability of employersponsored coverage of 9.83 percent, which they are concerned may be too high for the purposes of COBRA coverage given the financial challenges faced by consumers following a loss of employment. Finally, a few other commenters opposed establishing a threshold, arguing that it would be unnecessarily burdensome to consumers and noting that even partial reductions can render COBRA coverage unaffordable. These commenters instead supported designating a reduction in employer contributions to COBRA of any amount as a special enrollment period triggering event.

Response: HHS recognizes the concerns raised by commenters regarding the high cost of COBRA continuation coverage, even with partial employer contributions. However, because the number of COBRA enrollees with employer subsidies is already low

²¹³ For example, the American Rescue Plan Act of 2021 provides individuals enrolled in COBRA continuation coverage with subsidies that cover 100 percent of premiums through September 30, 2021.

relative to the rest of the individual insurance market,214 we believe it is likely that situations in which employer contributions to COBRA continuation coverage are reduced significantly enough to render such coverage unaffordable affect only a very small number of consumers. Accordingly, we are not finalizing reduction of employer contributions to COBRA continuation coverage as a special enrollment period trigger, but will continue to monitor this situation in the future.

Comment: Two commenters requested that HHS implement this special enrollment period sooner than the scheduled 2022 implementation date.

Response: We note that the requirement to provide this special enrollment period goes into effect on the effective date of this rule, which is sooner than the 2022 implementation date.

Comment: Two commenters expressed support for applying this special enrollment period to off-Exchange individual health insurance coverage and on State Exchanges. One of these commenters noted that establishing more consistent special enrollment period rules on and off-Exchange would help reduce the on-Exchange disadvantage.

Response: We agree that it is appropriate to apply this special enrollment period market-wide to individual health insurance coverage. including for coverage offered off-Exchange and on State Exchanges, and thus we are finalizing this policy as proposed (but with the additional provision regarding government

subsidies).

Comment: Two commenters expressed support for the proposal, and also suggested that HHS establish a special enrollment period for individuals, and their dependents, who voluntarily terminate their COBRA coverage, regardless of whether they are receiving employer contributions. These commenters also added that not doing so would penalize an enrollee who chooses to enroll in COBRA in an effort to maintain their coverage. One of the commenters suggested this policy as a way of expanding the number of ways in which consumers can enroll in Exchange coverage.

Response: Although we appreciate the concerns raised regarding the availability of a special enrollment period for individuals who are not receiving employer contributions to COBRA coverage, we do not believe that establishing such a special enrollment

period is necessary. In general, when a consumer has the opportunity to elect COBRA continuation coverage, they also will have the opportunity to enroll in a qualified health plan on the Exchanges on the Federal platform or a State Exchange as well as off-Exchange, as they will likely be eligible for a loss of minimum essential coverage special enrollment period. In addition, special enrollment periods are generally based on triggering events that do not include voluntary termination of coverage, which would introduce concerns regarding adverse selection in the individual market.

Comment: One commenter expressed support for the proposal, but requested that HHS implement stronger verification mechanisms, such as provision of a letter indicating the termination of employer contributions to COBRA. This commenter also noted that verification would benefit the enrollee by ensuring they do not pay out-of-pocket for coverage already covered through employer contributions.

Response: This special enrollment period has been subject to special enrollment period verification on Exchanges on the Federal platform, subject to the loss of minimum essential coverage special enrollment period attestation. Similarly, many State Exchanges already conduct special enrollment period verification. With respect to off-Exchange enrollments using special enrollment periods, subject to applicable state law, issuers may implement reasonable procedures to verify eligibility for special enrollment periods, and because these Exchanges and issuers are able to determine for themselves whether verification is needed, we do not believe it is necessary to require them to establish specific verification procedures for this special enrollment period.

Comment: One commenter requested that HHS discuss whether consumers will be able to access this special enrollment period through HealthCare.gov, which they note would be preferable to enrollments through the

Response: This special enrollment period has been, and will continue to be, available to enrollees on Exchanges on the Federal platform through the application on HealthCare.gov.

Comment: One commenter expressed support for the proposal, and requested that HHS allow enrollees through this special enrollment period to select a plan of any metal level when they enroll.

Response: Enrollments through this special enrollment period on Exchanges on the Federal platform and State Exchanges are subject to plan category limitations, including metal level restrictions, under 45 CFR 155.420(a)(4)(iii). We note, however, that because plan category limitations apply only to current Exchange enrollees, consumers enrolling through this special enrollment period on an Exchange would only be subject to them in situations where they were added to an existing policy. Although we appreciate the concern raised regarding allowing enrollees to select a plan of any metal level, because we did not propose to exempt enrollments through this special enrollment period from plan category limitations in the proposed rule, we are not finalizing such a change here. However, we will continue to monitor this issue in the future. We also note that enrollments in off-Exchange coverage are not subject to plan category limitations, and thus consumers enrolling through this special enrollment period off-Exchange could select a plan of any metal level.

Comment: One commenter requested that HHS provide resources to make the public aware of the opportunity to enroll during a special enrollment period when employer contributions to

COBRA coverage cease.

Response: HHS will leverage existing *HealthCare.gov* content to ensure that enrollees are aware of their options regarding cessation of employer contributions to COBRA coverage and special enrollment period eligibility.

Comment: One commenter requested that HHS also establish a special enrollment period for enrollees who experience a decrease in APTC that renders coverage unaffordable to them.

Response: We appreciate the concerns raised regarding individuals who experience a decrease in APTC that renders their coverage unaffordable. As described earlier in this section of the preamble, in this rule we decided not to finalize a special enrollment period where employer contributions to or government subsidies of COBRA coverage are reduced but do not completely cease. We will continue to monitor this situation in the future, and will consider it for future rulemaking.

As a result of the comments, we are finalizing this policy as proposed, except that we are finalizing proposed paragraph (d)(1)(v) as paragraph (d)(15), with the additional provision that cessation of government subsidies to COBRA continuation coverage will also result in a special enrollment period trigger, and with other conforming changes discussed in this section of the

²¹⁴ https://www.cbo.gov/system/files/2021-02/ hEdandLaborreconciliationestimate.pdf.

preamble. However, we are not finalizing the proposal to include reduction of employer contributions to COBRA continuation coverage as a special enrollment period trigger.

d. Special Enrollment Period Verification

In 2017, the HHS Market Stabilization Rule preamble explained that HHS would implement pre-enrollment verification of eligibility for certain special enrollment periods in all FFEs and SBE-FPs and encouraged states to do the same in State Exchanges.

Since 2017, Exchanges on the Federal platform have implemented preenrollment special enrollment period verification for special enrollment period types commonly used by consumers to enroll in coverage. Consumers who are not already enrolled through the Exchange and who apply for coverage through a special enrollment period type that requires pre-enrollment verification by the Exchange must have their eligibility electronically verified using available data sources, or they must submit supporting documentation to verify their eligibility for the special enrollment period before their enrollment can become effective. As stated in the HHS Marketplace Stabilization Rule, special enrollment period verification is only conducted for new enrollees due to the potential for additional burden on issuers and confusion for consumers if required for existing enrollees.

In implementing pre-enrollment verifications for special enrollment periods in the Market Stabilization Rule, HHS did not establish a regulatory requirement that all Exchanges conduct special enrollment period verifications, in order to allow State Exchanges with flexibility to adopt policies that fit the needs of their state.215 Currently, all State Exchanges now conduct either pre- or post-enrollment verification of at least one special enrollment type.

We proposed to amend § 155.420 to add paragraph (f) to require all Exchanges to conduct eligibility verification for special enrollment periods. Specifically, we proposed to require that Exchanges conduct special enrollment period verification for at least 75 percent of new enrollments through special enrollment periods for consumers not already enrolled in coverage through the applicable Exchange.

We also proposed that under § 155.315(h), State Exchanges would have the flexibility to propose

We sought comment on these proposals. With respect to Special Enrollment Period Verification, we sought comment from States about the 75 percent verification threshold and whether it should be based on past year or current year special enrollment period enrollments, understanding that unforeseen events may occur that may drive up or down enrollments from year-to-vear.

We received public comments on the proposed updates to require Exchanges to conduct Special Enrollment Period verification. The following is a summary of the comments we received and our

responses.

Comment: Several commenters supported the proposed policy. However, the majority of commenters opposed the policy due to the administrative burden to consumers and the financial and administrative burden on State Exchanges. Several commenters stated that State Exchanges have the best understanding of their needs around special enrollment period verification and are best able to determine their SEP verification strategy and thresholds. Several commenters did not think that CMS provided justification for the 75 percent threshold or the policy change by citing evidence of a negative risk pool impact, abuse of SEPs, or ongoing problems with Exchanges' current practices. A few commenters expressed concern that the proposal could negatively affect the risk pool by deterring younger and healthier enrollees from completing enrollment. One commenter asked for further guidance on the flexibility for states and what constitutes alternative means. One commenter suggested to waive this requirement until additional research can be conducted to ensure that the policy does not create an undue burden on individuals. One commenter noted that stricter SEP enforcement mechanisms have the potential to improve the risk profile, but any requirements regarding SEP enrollment should not be onerous enough to reduce participation among those legitimately eligible.

Response: We agree with commenters who expressed concerns about imposing administrative or financial burden on State Exchanges or administrative

burden on consumers at this time with additional new requirements. We estimate that there are only four State Exchanges that conduct more limited special enrollment period verification than the Exchanges on the Federal platform, but these State Exchanges still conduct some form of special enrollment period verification. These also include the 3 smallest State Exchanges in terms of numbers enrolled and issuer participation. These State Exchanges have reported to HHS that, based on regular communications they have with their issuers about special enrollment periods, they do not have evidence to suggest there is misuse of special enrollment periods occurring.

Following review of the comments, we are not finalizing this proposal.

9. Required Contribution Percentage (§ 155.605(d)(2))

HHS calculates the required contribution percentage for each benefit year using the most recent projections and estimates of premium growth and income growth over the period from 2013 to the preceding calendar year. Accordingly, we proposed the required contribution percentage for the 2022 benefit year, calculated using income and premium growth data for the 2013 and 2021 calendar years.

Under section 5000A of the Code, an individual must have MEC for each month, qualify for an exemption, or make an individual shared responsibility payment. Under § 155.605(d)(2), an individual is exempt from the requirement to have MEC if the amount that he or she would be required to pay for MEC (the required contribution) exceeds a particular percentage (the required contribution percentage) of his or her projected household income for a year. Although the Tax Cuts and Jobs Act reduced the individual shared responsibility payment to \$0 for months beginning after December 31, 2018, the required contribution percentage is still used to determine whether individuals above the age of 30 qualify for an affordability exemption that would enable them to enroll in catastrophic coverage under § 155.305(h).

The initial 2014 required contribution percentage under section 5000A of the Code was 8 percent. For plan years after 2014, section 5000A(e)(1)(D) of the Code and Treasury regulations at 26 CFR 1.5000A-3(e)(2)(ii) provide that the required contribution percentage is the percentage determined by the Secretary of HHS that reflects the excess of the rate of premium growth between the preceding calendar year and 2013, over the rate of income growth for that

alternative methods for conducting required verifications to determine eligibility for enrollment in a QHP under subpart D, and to allow State Exchanges to request HHS approval for use of alternative processes for verifying eligibility for special enrollment periods as part of determining eligibility for special enrollment periods under § 155.305(b).

^{215 82} FR at 18356.

period. The excess of the rate of premium growth over the rate of income growth is also used for determining the applicable percentage in section 36B(b)(3)(A) of the Code and the required contribution percentage in section 36B(c)(2)(C) of the Code.

As discussed elsewhere in this preamble, we are finalizing as the measure for premium growth the 2022 premium adjustment percentage of 1.3760126457 (or an increase of about 37.6 percent over the period from 2013 to 2021). This reflects an increase of about 1.6 percent over the 2021 premium adjustment percentage (1.3760126457/1.3542376277).

As the measure of income growth for a calendar year, we established in the 2017 Payment Notice that we would use per capita personal income (PI). Under the approach finalized in the 2017 Payment Notice and proposed for use in the 2022 Payment Notice, the rate of income growth for 2022 is the percentage (if any) by which the NHEA Projections 2019–2028 value for per capita PI for the preceding calendar year (\$61,156 for 2021) exceeds the NHEA Projections 2019–2028 value for per capita PI for 2013 (\$44,948), carried out to ten significant digits. The ratio of per capita PI for 2021 over the per capita PI for 2013 is estimated to be 1.3605944647 (that is, per capita income growth of about 36.1. percent).²¹⁶ This rate of income growth between 2013 and 2021 reflects an increase of approximately 3.9 percent over the rate of income growth for 2013 to 2020 $(1.3605944647 \div 1.3094029651)$ that was used in the 2021 Payment Notice. Per capita PI includes government transfers, which refers to benefits individuals receive from federal, state, and local governments (for example, Social Security, Medicare, unemployment insurance, workers' compensation, etc.).²¹⁷

Using the 2022 premium adjustment percentage finalized in this rule, the excess of the rate of premium growth over the rate of income growth for 2013 to 2021 is $1.3760126457 \div$

1.3605944647, or 1.0113319445. This results in the 2022 required contribution percentage under section 5000A of the Code of 8.00×1.0113319445 or 8.09 percent, when rounded to the nearest one-hundredth of one percent, a decrease of 0.18 percentage points from 2021 (8.09066 - 8.27392).

Finally, beginning with the 2023 benefit year, we proposed to publish the required contribution percentage, along with the premium adjustment percentage and the annual cost-sharing limitation parameters, in guidance separate from the annual notice of benefit and payment parameters, unless HHS were to propose a change to the methodology for calculating the parameters, in which case, we would do so through notice-and-comment rulemaking. For a discussion of that proposal, please see the preamble for Publication of the Premium Adjustment Percentage, Maximum Annual Limitation on Cost Sharing, Reduced Maximum Annual Limitation on Cost Sharing, and Required Contribution Percentage (§ 156.130).

We received public comments on the proposed updates to the required contribution percentage (§ 155.605(d)(2)) for plan year 2022. Please see our summary of comments on the premium adjustment percentage (§ 156.130(e)) for a summary of comments on the required contribution percentage.

10. Excluding the Special Enrollment Period Trigger in § 155.420(d)(1)(v) From Applying to SHOP Plans (§ 155.726)

Special enrollment periods due to cessation of employer contributions to COBRA continuation coverage are generally not available in the group insurance market. Therefore, to maintain consistency between SHOP and the rest of the group insurance market, we proposed to amend § 155.726(c)(2)(i) to exclude the special enrollment period trigger in proposed paragraph § 155.420(d)(1)(v) from applying to SHOP plans. However, because proposed paragraph (d)(1)(v) is instead being finalized as paragraph (d)(15), which is not included in § 155.726(c)(2)(i), SHOP plans would no longer be subject to the requirement to offer this special enrollment period. Therefore, there is no need to finalize this provision.

We sought comment on this proposal.

We did not receive public comments on this provision, but are not finalizing this policy as changes to the final regulation at § 155.420 make this unnecessary.

E. Part 156—Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges

1. User Fee Rates for the 2022 Benefit Year (§ 156.50)

The user fee rates for the 2022 benefit year for issuers on the FFE and SBE-FPs were initially finalized in the final rule published on January 19, 2021 (86 FR 6138 at 6152). However, as a result of a change in administration priorities, enrollment increases due to legislation and emergency action, and technical improvements we expect increases in the costs of activities related to consumer outreach and Navigators for 2022. Therefore, upon review, we now estimate that the user fees rates established in the January 19, 2021 final rule (86 FR 6138 at 6152) will need to be slightly increased to sustain essential Exchange-related activities and ensure robust outreach to support long-term operational health. HHS intends to propose to increase FFE and SBE-FP user fee rates for the 2022 benefit year through future notice-and-comment rulemaking. HHS intends to propose a 2022 benefit year user fee rate for all participating FFE issuers at 2.75 percent of total monthly premiums, and a 2022 benefit year user fee rate for all participating SBE-FP issuers at 2.25 percent of total monthly premiums. These user fee rates continue to be lower than the 2021 user fee rates of 3.0 percent of total monthly premiums for all participating FFE issuers and 2.5 percent of total monthly premiums for all participating SBE-FP issuers, but higher than the recently finalized rates of 2.25 percent of total monthly premiums for FFE issuers and 1.75 percent of total monthly premiums for SBE-FP issuers.

a. State User Fee Collection Administration (§ 156.50(c)(2))

We proposed to eliminate the state user fee collection flexibility that HHS had previously offered to states in the 2017 Payment Notice. We proposed that HHS would not collect an additional user fee, if a state so requests, from issuers at a rate specified by the state to cover costs incurred by the state for the functions the state retains. HHS previously provided this flexibility to states to help reduce the administrative burden on states of collecting additional user fees. However, our subsequent

 $^{^{216}}$ The 2013 and 2021 per capita personal income figures used for this calculation reflect the NHE Projections 2019-2028, published on March 24, 2020. The series used in the determinations of the adjustment percentages can be found in Tables 1 and 17 on the CMS website, which can be accessed by clicking the "NHE Projections 2019-2028-Tables" link located in the Downloads section at http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/National HealthExpendData/NationalHealthAccounts Projected.html. A detailed description of the NHE projection methodology is available at https:// www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/National HealthExpendData/Downloads/Projections Methodology.pdf.

²¹⁷ U.S. Department of Commerce Bureau of Economic Analysis (BEA) Table 3.12 Government Social Benefits. Available at https://apps.bea.gov/ iTable/iTable.cfm?reqid=19&step=3&isuri= 1&categories=survey&nipa_table_list=110.

internal analysis demonstrated that the process of collecting the state portion of the user fee and remitting it to the state, would increase the operational burden and cost incurred by HHS and no states currently rely on this mechanism. Therefore, we are amending § 156.50(c)(2) to remove this alternate user fee collection mechanism. We noted that this proposal does not change the ability of an SBE-FP to request that HHS collect from the SBE-FP state regulatory entity the total amount that would result from the percent of monthly premiums charged for enrollment through the Federal platform, instead of HHS collecting the fee directly from SBE-FP issuers.

We did not receive public comments on this provision, and therefore, we are finalizing it as proposed.

b. Eligibility for User Fee Adjustments for Issuers Participating Through SBE– FPs (§ 156.50(d))

We proposed to amend § 156.50(d) to clarify that issuers participating through SBE-FPs are eligible to receive adjustments to their federal user fee amounts that reflect the value of contraceptive claims they have reimbursed to third-party administrators (TPAs) that have provided contraceptive coverage on behalf of an eligible employer. In the final rules "Coverage of Certain Preventative Services Under the Affordable Care Act," 218 these relationships were established as a method of both providing contraceptives for women and accommodating the religious beliefs of employers. In the 2017 Payment Notice,²¹⁹ we allowed State Exchanges to enter into agreements to rely on the Federal platform for certain Exchange functions to enhance efficiency and coordination between the state and federal programs, and to leverage the systems established by the FFEs to perform certain Exchange functions. Although we recognized that issuers participating in these types of Exchanges were subject to a federal user fee, § 156.50(d) was not amended to reflect the SBE-FP Exchange model. As such, we proposed to amend § 156.50(d) to explicitly include the issuers offering QHPs through SBE-FPs. We also proposed to make conforming changes throughout the regulation text at § 156.50(d) to reflect the user fees applicable to FFEs and SBEs that adopt the DE option, as further discussed elsewhere in this rulemaking.

We sought comment on these proposals.

We received public comments on the proposed updates to eligibility for user fee adjustments for issuers participating through SBE–FPs (§ 156.50(d)). The following is a summary of the comments we received and our responses.

Comment: All commenters supported the proposal for SBE–FP issuers to be eligible to receive adjustments to their user fee amounts for contraceptive claims reimbursed to third-party administrators. Specifically, a commenter noted their approval of the proposed change because it ensures that issuers in SBE–FP states are not treated less advantageously than issuers in FFE states.

Response: We appreciate the supportive comments on this proposal and are finalizing the policy to amend § 156.50(d) to explicitly include the issuers offering QHPs through SBE–FPs as proposed.

c. Request for Comments on Alternatives to Exchange User Fees (§ 156.50)

In the proposed 2022 Payment Notice, we solicited comment on the appropriateness of an alternative revenue source to Exchange user fees to ensure Exchanges can cover the costs of the Exchange in an effective, appropriate, and fair manner. We appreciate the comments received on this issue, but are not taking any action at this time in relation to Exchange revenue sources. Should we propose future administrative action on this topic, we will review and consider responsive comments at that time.

- 2. State Selection of EHB-Benchmark Plan for Plan Years Beginning on or After January 1, 2020 (§ 156.111)
- a. Annual Reporting of State-Required Benefits

We proposed July 1, 2022 as the deadline for states to submit to HHS their annual reports on state-required benefits pursuant to § 156.111(d) and (f). We are finalizing this deadline as proposed for 2022.

We also intend to exercise enforcement discretion with regard to the first annual reporting submission deadline of July 1, 2021 under current regulation. Pursuant to this enforcement posture, we will not take enforcement action against states that do not submit an annual report in 2021. Rather, we will begin enforcing the annual reporting requirement on July 1, 2022, when states must notify HHS in the manner specified by HHS, of any benefits in addition to EHB and any

benefits the state has identified as not in addition to EHB and not subject to defrayal, describing the basis for the state's determination, that QHPs in the individual or small group market are required to cover in plan year 2022 or after plan year 2022 by state action taken by May 2, 2022 (60 days prior to the annual submission deadline).

In the 2021 Payment Notice, we amended § 156.111(d) and added paragraph (f) to require states to annually notify HHS in a form and manner specified by HHS, and by a date determined by HHS, of any staterequired benefits applicable to QHPs in the individual or small group market that are considered to be "in addition to EHB" in accordance with § 155.170(a)(3) and any benefits the state has identified as not in addition to EHB and not subject to defrayal, describing the basis for the state's determination. Under this requirement, a state's submission must describe all benefits requirements under state mandates applicable to QHPs in the individual or small group market that were imposed on or before December 31, 2011, and that were not withdrawn or otherwise no longer effective before December 31, 2011, as well as all benefits requirements under state mandates that were imposed any time after December 31, 2011, applicable to the individual or small group market. The state's report is also required to describe whether any of the state benefit requirements in the report were amended or repealed after December 31, 2011. Information in the state's report is required to be accurate as of the day that is at least 60 days prior to the annual reporting submission deadline set by HHS.

We also finalized § 156.111(d)(2) to specify that if the state does not notify HHS of its required benefits considered to be in addition to EHB by the annual reporting submission deadline, or does not do so in the form and manner specified by HHS, HHS will identify which benefits are in addition to EHB for the state for the applicable plan year. HHS's identification of which benefits are in addition to EHB will become part of the definition of EHB for the applicable state for the applicable plan year. In the 2021 Payment Notice, we finalized that we would begin implementation of the annual reporting policy in 2021. Specifically, we finalized that states would be required to notify HHS by July 1, 2021, of any benefits in addition to EHB and any benefits the state has identified as not in addition to EHB and not subject to defrayal, describing the basis for the state's determination, that QHPs in the individual or small-group market are

²¹⁸ 78 FR 39870 (July 2, 2013); 80 FR 41318 (July 14, 2015).

²¹⁹81 FR 12203 at 12293 (March 8, 2016).

required to cover in plan year 2021 or after plan year 2021 by state action taken by May 2, 2021 (60 days prior to the annual submission deadline).

We are finalizing as proposed a July 1, 2022 deadline for states to submit to HHS a complete reporting package for the second year of annual reporting. As finalized, states are required to notify HHS in the manner specified by HHS by July 1, 2022, of any benefits in addition to EHB and any benefits the state has identified as not in addition to EHB and not subject to defrayal, describing the basis for the state's determination, that QHPs are required to cover in plan year 2022 or after plan year 2022 by state action taken by May 2, 2022 (60 days prior to the annual submission deadline). However, as noted earlier in this section, we also intend to exercise enforcement discretion with regard to the first annual reporting submission deadline of July 1, 2021. Pursuant to this enforcement posture, we will not be actively collecting or requiring submission of annual reports in 2021.

Comment: Many commenters objected to the proposed reporting deadline and asked for a delay in implementation of this policy. Many commenters were against implementation of the annual reporting requirement during the CÔVID-19 PHE. Commenters explained that imposing this new reporting requirement during a time when states are already required to expend substantial resources to respond to the COVID-19 PHE would add unnecessary burden on states and require states to divert already limited resources away from addressing the COVID-19 PHE. Commenters requested that HHS eliminate the burdensome reporting requirement or, at a minimum, delay reporting until 2023 assuming the end of the COVID-19 PHE in 2021 and economic recovery in 2022.

Other commenters also urged HHS to delay the reporting requirement, arguing that HHS should not implement the annual reporting requirement until HHS releases additional guidance clarifying its defrayal policies as HHS promised it would in the 2021 Payment Notice. These commenters requested that any implementation of the annual reporting policy only occur after states have an opportunity to review the annual reporting process and associated templates in more depth that HHS will be requiring states to use for annually reporting state mandates to HHS. These commenters noted that states have not yet seen or had an opportunity to review or comment on the proposed annual reporting templates, reiterating the request for HHS to specify with more clarity the reporting and determination

mechanisms required of states. Commenters urged HHS to immediately make available the proposed templates that states are expected to use when submitting annual reports.

Commenters also expressed concern about the lack of transparency around the annual reporting and review process, requesting that HHS delay the reporting requirement until HHS provides further clarification. These commenters specifically requested that HHS clarify whether HHS will accept a state's determination as to whether a state mandate is in addition to EHB, who will be the final arbiter of such determinations, and whether there will be any avenue for states to appeal HHS's decisions in situations where there is disagreement between HHS and a state surrounding the scope of a benefit mandate or its status as being in an addition to EHB.

Response: Section 1311(d)(3)(B) of the ACA permits a state to require QHPs offered in the state to cover benefits in addition to the EHB, but requires the state to make payments, either to the individual enrollee or to the issuer on behalf of the enrollee, to defray the cost of these additional state-required benefits. Further, section 36B(b)(3)(D) of the Code specifies that the portion of the premium allocable to state-required benefits in addition to EHB shall not be taken into account in determining premium tax credits. We continue to believe that requiring states to annually notify HHS of state-required benefits in the manner specified at § 156.111(d) and (f) will promote compliance with section 1311(d)(3)(B) of the ACA and its implementing regulations at § 155.170. We also believe it will enhance program integrity and potentially reduce improper federal expenditures by supporting HHS efforts to ensure that APTC is paid in accordance with federal law. We also believe the annual reporting policy will increase transparency for issuers, enrollees, and other stakeholders as to which staterequired benefits are in addition to EHB. We are proceeding with implementation of the annual reporting policy and finalizing the second annual reporting deadline of July 1, 2022 as proposed. As finalized, states are required to notify HHS in the manner specified by HHS by July 1, 2022, of any benefits in addition to EHB and any benefits the State has identified as not in addition to EHB and not subject to defrayal, describing the basis for the state's determination, that QHPs are required to cover in plan year 2022 or after plan year 2022 by state action taken by May 2, 2022 (60 days prior to the annual submission deadline).

Although we continue to support implementation of the annual reporting policy, we also acknowledge the validity of commenters' concerns regarding the timing and implementation of annual reporting of state-required benefits as planned in 2021. Therefore, although we are finalizing the second annual reporting deadline of July 1, 2022 as proposed, we also intend to exercise enforcement discretion in relation to the upcoming first annual reporting submission deadline of July 1, 2021. Specifically, HHS will not take enforcement action against states that do not submit an annual report on state-required benefits by the July 1, 2021 submission deadline; and HHS will not identify state-required benefits in addition to EHB for states that do not submit a report to HHS by the July 1, 2021 submission deadline. Accordingly, because HHS is not enforcing the collection of state-required benefits reports in 2021, HHS will not publish on the CMS website in 2021 any annual reports on state-required benefits. We note that the obligation for a state to defray the cost of QHP coverage of state-required benefits in addition to EHB is an independent statutory requirement from the annual reporting policy finalized at § 156.111(d) and (f). Therefore, although this enforcement posture effectively relieves states of state-required benefit reporting requirements until July 1, 2022, it does not pend or otherwise impact the defrayal requirements under section 1311(d)(3)(B) of the ACA, as implemented at § 155.170. Under this enforcement posture, states remain responsible for making payments to defray the cost of additional required benefits and issuers are still responsible for quantifying the cost of these benefits and reporting the cost to the state.

Under this enforcement posture, HHS will begin enforcing the annual reporting requirement on states in 2022. States are required to notify HHS in the manner specified by HHS by July 1, 2022, of any benefits in addition to EHB that QHPs are required to cover in plan year 2022 or after plan year 2022 by state action taken by May 2, 2022 (60 days prior to the annual submission deadline). As part of this reporting, states must also identify which staterequired benefits are not in addition to EHB and do not require defrayal in accordance with § 155.170, and provide the basis for the state's determination, by the July 1, 2022 reporting submission deadline. States are permitted to submit their annual report at any time during the May 2-July 1, 2022, submission window.

In the 2021 Payment Notice, we indicated that we would continue engaging in technical assistance with states to help ensure state understanding of when a state-benefit requirement is in addition to EHB and requires defrayal. We continue to work on additional technical assistance that we believe will further assist states with their defrayal analyses and believe such technical assistance will bolster state compliance with defrayal requirements, as well as result in a smoother annual reporting process for states and review process for HHS. However, we also believe these additional technical assistance documents will best serve state needs if made available to states far enough in advance of the first annual reporting deadline. It is important that states have an opportunity to ask HHS any clarifying questions after reviewing these technical assistance documents and make any necessary adjustments to state policy. We believe that exercising enforcement discretion for the first year of annual reporting in the manner we described will ensure that states have these opportunities before the July 1, 2022 submission deadline. We also believe our enforcement posture will promote a smoother annual reporting process overall in 2022 and beyond as states will be able to utilize the additional technical assistance documents as a tool to identify which state mandates are in addition to EHB in a manner that reflects federal policy.

We also believe the additional technical assistance efforts will help address commenter concerns around potential disagreements between HHS and states as to which state-required benefits are in addition to EHB and require defrayal. The purpose of this additional technical assistance and outreach is to clarify the defrayal policy more generally and to provide states with a more precise understanding of how HHS analyzes and expects states to analyze whether a state-required benefit is in addition to EHB pursuant to § 155.170. We encourage states to review state-required benefits in the context of this additional technical assistance and take the appropriate steps to update policy decisions regarding which state-required benefits are in addition to EHB and require defrayal ahead of the July 1, 2022 annual reporting deadline.

We also acknowledge that states continue to express concern regarding how HHS plans to enforce § 155.170 after reviewing state reports or identifying mandates in a non-reporting state that are in addition to EHB for which the non-reporting state is not defraying. We stated in the 2021

Payment Notice that we would not be adopting any policy with regard to whether enforcement of the defrayal requirement will be retrospective or prospective in relation to the submission of § 156.111 reports. However, we are concerned that declining to adopt an enforcement policy has caused unnecessary confusion and concern for states. We are therefore clarifying that HHS does not intend to retroactively enforce the defrayal requirement against states for plan years prior to 2022 in relation to the submission of § 156.111 reports. With regards to resolving any disagreements that may arise between a state and HHS as to whether a mandated benefit is in addition to EHB, we intend to work closely with the state to address the disagreement without engaging in a formal appeals process. We also intend to provide non-reporting states with an opportunity to review our identifications of state-required benefits that are in addition to EHB prior to releasing the annual reports on the CMS website an effort to mitigate the potential for disagreement between the state and HHS.

As stated in the 2021 Payment Notice, HHS will provide the templates that states are required to use for annually reporting the information required pursuant to § 156.111(f)(1) through (6). We continue to believe that the descriptions of the required data elements at § 156.111(f)(1) through (6) provide sufficient detail to states regarding the types of information states will be required to include in the annual reports. States and other stakeholders reviewing those requirements should be able to review § 156.111(f)(1) through (6) to better understand the scope of the information states are required to include in their annual reports without reviewing the actual reporting templates. However, we also believe it is important to provide states with ample time to review the precise format, instructions, and content of the annual reporting templates for state-required benefits ahead of submission. As stated in the 2021 Payment Notice, the precise templates that HHS will require states to use are available for review as part of the information collection amended under OMB control number: 0938–1174 (Essential Health Benefits Benchmark Plans (CMS-10448)). Although OMB approved that information collection on February 25, 2021, this approval took longer than anticipated and we agree with commenters that this delay resulted in increasingly limited time for states to review the templates ahead of the July 1, 2021 deadline for the first

year of annual reporting of state-required benefits. By exercising enforcement discretion in the manner described, we would provide states that are concerned about having ample time to review the templates ahead of submitting an annual report the option to choose to delay submitting their first annual report until July 1, 2022 without HHS identifying which state-required benefits are in addition to EHB for the applicable plan year in the state.

We also understand that states have an immediate need to devote limited resources to responding to the COVID-19 PHE and that commenters feel that preparing an annual report on staterequired benefits in 2021 is competing with that urgent priority. We continue to believe that the information we are requiring that states report to HHS as part of this annual reporting requirement should already be readily accessible to states, as every state should already be defraying the costs of state-required benefits in addition to EHB. Thus, states should already have ready access to the information the annual reports require and the reporting itself should therefore be complementary to the process the state already has in place for tracking and analyzing state-required benefits. Moreover, states need not report to HHS if they choose not to. Specifically, § 156.111(d)(2) provides that, HHS will identify the state-required benefits it believes are in addition to EHB for the applicable plan year for any state that does not submit an annual report by the annual submission deadline, or does not do so in the form and manner specified by HHS. However, when coupled with the delays in finalizing the reporting templates and issuing additional technical assistance, we believe the added burden of the COVID-19 PHE on states is yet an additional factor that supports exercising enforcement discretion. We believe our enforcement posture for 2021 will allow states that have concerns about the upcoming July 1, 2021 deadline in the context of the COVID-19 PHE sufficient time to prepare their annual reports on staterequired benefits before the July 1, 2022 submission deadline.

Comment: Many commenters continue to oppose or be concerned about the annual reporting policy overall and asked HHS for clarity on why HHS has placed a burdensome reporting requirement on states. Commenters stated that HHS has not defined the scope of the problem the reporting seeks to address and asked HHS to provide additional transparency regarding the value that HHS seeks to add in requiring this additional

reporting, especially given that some states already conduct defrayal analyses of their own and posts these publicly. Commenters again expressed that the annual reporting requirement is unnecessary, as existing regulation has already established robust requirements for insurers to, in coordination with states and marketplaces, perform actuarially sound analyses of costs associated with state-mandated benefits for use when calculating federal tax credits. Commenters also noted the importance of setting a deadline that allows issuers time to make changes to rate filings. For example, one commenter supported the overall annual reporting policy but requested that HHS adjust the timing and deadlines for the annual reporting to ensure that issuers are aware of any state-mandated benefits that states must defray in advance of rate-setting timelines. This commenter specifically noted that requiring states to file reports by July 1 of the same benefit year does not provide plans with the time necessary to work such benefits and defrayals into premium calculations for that year.

Response: We disagree with commenters that we have not yet provided adequate justification for why HHS is implementing the annual reporting requirement. When finalizing the annual reporting requirement in the 2021 Payment Notice, we explained the reasoning for the new policy in detail. We also explained that, although we acknowledge that some states may already be appropriately identifying which state-required benefits are in addition to EHB and require defrayal, we believe that many other states may not be doing so. In such states, QHP issuers may be covering benefits as EHB that actually require state defrayal under federal requirements, but for which the state is not actively defraying costs, resulting in improper expenditures of APTC paid by the federal government. Furthermore, requiring states to provide information regarding their state benefit requirements to HHS properly aligns with federal requirements for defraying the cost of state-required benefits; improves transparency with regard to the types of benefit requirements states are enacting; and that it provides the necessary information to HHS for increased oversight over whether states are appropriately identifying which state-required benefits require defrayal and whether QHP issuers are properly allocating the portion of premiums attributable to EHB for purposes of calculating PTCs. For a more detailed discussion of why the annual reporting

policy is justified, please refer to the 2021 Payment Notice.

With regards to the timing of the annual reporting submission deadline, we acknowledge that a July 1 deadline of any given reporting year may not perfectly align with other state and issuer deadlines, such as issuer ratesetting deadlines. However, we remind commenters that states must defray benefits in addition to EHB in accordance with § 155.170 independent of any reporting requirement or reporting timeline and regardless of whether the state benefit requirement is included in that plan year's annual reporting submission. We therefore also conclude that states newly identifying state-required benefits as being in addition to EHB after rate-setting has concluded is likely not a new issue. In the event that a state newly identifies a state-required benefit as being in addition to EHB and this determination affects issuer rates for the plan year during which the reporting is taking place or for a future plan year, we will work with the state on how to address that situation on a state-by-state basis. We believe that our additional technical assistance and outreach to states will assist in preventing such situations from arising by ensuring that states can analyze pending legislation and staterequired benefits in a manner consistent with federal defrayal policy and in advance of rate filing deadlines. However, states that have still concerns about such a situation arising are encouraged to ask HHS in advance of annual reporting submission deadlines for input on whether a state-required benefit is in addition to EHB.

b. States' EHB-Benchmark Plan Options

The 2019 Payment Notice stated that we would propose EHB-benchmark plan submission deadlines in the HHS annual Notice of Benefit and Payment Parameters. In the proposed 2022 Payment Notice, we proposed May 6, 2022, as the deadline for states to submit the required documents for the state's EHB-benchmark plan selection for the 2023 plan year and as the deadline for states to notify HHS that they wish to permit between-category substitution for the 2023 plan year. A typographical error appeared in the proposed rule related to these deadlines. Both proposed deadlines should have read May 6, 2022, for the 2024 plan year, not for the 2023 plan year. The correct meaning of the proposed rule as applying to the 2024 plan year should have been clear from the context of the rulemaking, and the prior rulemaking in the 2021 Payment Notice establishing deadlines for this purpose.

We are finalizing these deadlines with minor revisions to correct the typographical error such that May 6, 2022, is the deadline for states submitting EHB-benchmark plan selections for the 2024 plan year and May 6, 2022, is the deadline for states to permit between-category substitution for the 2024 plan year.

Comment: Commenters requested clarification regarding the proposed submission deadlines. These commenters noted that issuers need sufficient time to review and respond to changes a state may make to its EHBbenchmark plan, and expressed concern that the proposed deadline would occur when issuers are filing plans for 2023. One commenter noted that the proposed reporting deadline is earlier than in prior years and, out of concern for public notice, urged CMS to require states to provide a significant amount of time for the public to comment on any changes that states are planning to make to their EHB-benchmark plans. Another commenter objected to the proposed reporting deadline because it permits EHB-benchmark plan selections to occur on an annual cycle, arguing that by granting states expansive power to alter their EHB-benchmark plans so dramatically every year, the EHBbenchmark plan selection flexibility threatens any hope of predictability of coverage for consumers from year-tovear and state-to-state. We also received several out of scope comments.

Response: We are finalizing as proposed May 6, 2022 as the deadline for states to submit the required documents for the state's EHBbenchmark plan selection for the 2024 plan year and as the deadline for states to notify HHS that they wish to permit between-category substitution for the 2024 plan year, with minor revisions to correct the typographical error that referred to plan year 2023 in the proposed rule. Fixing this typographical error aligns the deadlines with those finalized in prior years and addresses the concerns commenters raised regarding providing issuers sufficient time to review changes states make to the EHB-benchmark plan and providing the public advance notice of such changes. As in prior years, states are required to provide reasonable public notice and an opportunity for public comment on the state's selection of an EHB-benchmark plan that includes posting a notice on its opportunity for public comment with associated information on a relevant state website. As finalized, the deadlines also allow issuers sufficient time to develop plans that adhere to their state's new EHBbenchmark plan.

As discussed in more detail in the 2019 Payment Notice, the purpose of this policy is to allow for state flexibility in selecting an EHB-benchmark plan, which is why we allow states to make such changes on an annual basis. Furthermore, because of the level of effort needed by the state and its issuers to make changes to a state's EHBbenchmark plan, we believe that in only very limited cases will a state choose to make EHB-benchmark plan changes on an annual basis, a scenario that has not vet occurred since finalizing the EHBbenchmark plan selection flexibility. If a state does decide to make changes annually, there may be a specific reason for needing an annual change such as for a medical innovation where such benefits would outweigh any potential for consumer confusion.

We continue to emphasize that the deadlines for EHB-benchmark plan selection and permitting betweencategory substitution are firm, and that states should optimally have one of their points of contact who has been predesignated to use the EHB Plan Management Community reach out to us using the EHB Plan Management Community well in advance of the deadlines with any questions. Although not a requirement, we recommend states submit applications for EHB-benchmark plan selections at least 30 days prior to the submission deadline to ensure completion of their documents by the proposed deadline. We also remind states that they must complete the required public comment period for EHB-benchmark plan selection and submit a complete application by the finalized deadline.

3. Premium Adjustment Percentage (§ 156.130(e))

We proposed the 2022 benefit year annual premium adjustment percentage using the most recent estimates and projections of per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) from the NHEA, which are calculated by CMS' Office of the Actuary. For the 2022 benefit year, the premium adjustment percentage will represent the percentage by which this measure for 2021 exceeds that for 2013. However, in light of the overwhelming comments received, we are readopting as the measure of premium growth for the 2022 benefit year and beyond the NHEA projections of average per enrollee employer-sponsored insurance (ESI) premium, which was the measure used for benefit years 2015 through 2019.

Section 1302(c)(4) of the ACA directs the Secretary to determine an annual

premium adjustment percentage, a measure of premium growth that is used to set three other parameters detailed in the ACA: (1) The maximum annual limitation on cost sharing (defined at § 156.130(a)); (2) the required contribution percentage used to determine eligibility for certain exemptions under section 5000A of the Code (defined at § 155.605(d)(2)); and (3) the employer shared responsibility payment amounts under section 4980H(a) and (b) of the Code (see section 4980H(c)(5) of the Code). Section 1302(c)(4) of the ACA and § 156.130(e) provide that the premium adjustment percentage is the percentage (if any) by which the average per capita premium for health insurance coverage for the preceding calendar year exceeds such average per capita premium for health insurance for 2013, and the regulations provide that this percentage will be published in the annual HHS notice of benefit and payment parameters.

The 2015 Payment Notice final rule and 2015 Market Standards Rule established a methodology for estimating the average per capita premium for purposes of calculating the premium adjustment percentage for the 2015 benefit year and beyond. In those rules, HHS used the NHEA ESI premium measure to estimate premium growth. As noted in the 2022 Payment Notice proposed rule, the 2020 Payment Notice final rule changed this methodology and, for benefit years 2020 and 2021, we instead calculated the average per capita premium as private health insurance premiums minus premiums paid for Medicare supplement (Medigap) insurance and property and casualty insurance, divided by the unrounded number of unique private health insurance enrollees, excluding all Medigap enrollees. Additionally, as finalized in the 2021 Payment Notice final rule, we finalized that we would calculate the payment parameters that depend on NHEA data based on the NHEA data available at the time of the applicable proposed rule.

As such, we proposed that the premium adjustment percentage for 2022 would be the percentage (if any) by which the most recent NHEA projection available at the time of the applicable proposed rule of per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) for 2021 (\$7,036) exceeds the most recent NHEA estimate available at the time of the applicable proposed rule of per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) for

2013 (\$4,883).²²⁰ Using this formula, the proposed premium adjustment percentage for the 2022 benefit year was 1.4409174688 (\$7,036/\$4,883), which represents an increase in private health insurance (excluding Medigap and property and casualty insurance) premiums of approximately 44.1 percent over the period from 2013 to 2021.

We received numerous public comments on the proposed updates to premium adjustment percentage (§ 156.130(e)). Many comments on the premium adjustment percentage were presented alongside comments on related parameters such as the required contribution percentage, maximum annual limitation on cost sharing, and reduced annual limitation on cost sharing. As such, we address comments on all of these parameters in this section. The following is a summary of the comments we received and our responses.

Comment: As has been typical since the change to the methodology was adopted in the 2020 Payment Notice, the majority of commenters requested that we not implement the annual increase to the premium adjustment percentage, or at least one of the parameters derived from this value (for example, the maximum annual limitation on cost sharing, the reduced maximum annual limitations on cost sharing, the required contribution percentage published by HHS), or that the IRS not increase the applicable percentage used to determine premium tax credits, or required contribution percentage for purposes of determining affordability of employer-sponsored minimum essential coverage for determining eligibility for premium tax credits for the 2022 benefit year, and instead requested that HHS revert to the use of the NHEA ESI premium measure to estimate premium growth. Numerous commenters expressed concern with the rate of increase in the premium adjustment percentage and related payment parameters. These commenters specifically opposed the changes made to the premium adjustment percentage calculation in the 2020 Payment Notice, which based this parameter and the maximum annual limitation on cost sharing, reduced maximum annual limitations on cost sharing, and required contribution percentage on a premium measure that includes individual market premium changes, instead of maintaining the methodology established in the 2015 Payment Notice 221 and 2015 Market Standards

²²⁰ 79 FR 13743.

Rule. 222 These commenters were concerned that the use of a measure that includes individual market premiums has led to more rapid increases in consumer costs than would have occurred had HHS retained the NHEA ESI-only premium measure utilized to calculate the premium adjustment percentage and related parameters prior to the 2020 benefit year.

Commenters also expressed concerns that more rapid increases in the premium adjustment percentage would lead to higher costs to consumers and lower enrollment. A significant majority of these commenters requested that HHS reverse the policy finalized in the 2020 Payment Notice. A few commenters suggested alternatives, including a cap on increases to the maximum annual limitation on cost sharing of 3 percent year-to-year, or a hybrid approach between the pre-2020 and current methodologies. Under the suggested hybrid policy, ESI premiums would be used to calculate the growth in premiums between 2013 and 2019, while all private health insurance premiums minus Medigap and the medical portion of property and casualty insurance would be used to calculate the growth in premiums between 2019 and the current benefit year. These two growth estimates would be multiplied to arrive at the premium adjustment percentage.

Some of these commenters suggested that consumer burden connected to the increases in these parameters has been exacerbated by the COVID–19 PHE and its economic implications. These commenters maintained that these parameters should not be raised during the COVID–19 PHE. However, one commenter specified that they support the flexibility provided by the increase in the maximum annual limitation on cost sharing, which is a result of the increase in the premium adjustment percentage.

Response: After considering the overwhelming comments received, we are reverting to using the NHEA ESI premium measure previously used for the 2015 through 2019 benefit years to estimate premium growth for the 2022 benefit year and beyond. We believe using the NHEA ESI premium measure aligns with the statutory language at section 1302(c)(4) of the ACA, as ESI meets the definition of "health insurance coverage" and represents the vast majority of the market, overlapping very significantly with the private

health insurance data used for benefit years 2020 and 2021.²²³

With these considerations, we believe this change is consistent with the will and interest of stakeholders and will mitigate the uncertainty regarding premium growth during the COVID-19 PHE. Reverting to the NHEA ESI premium measure also aligns with the policy objectives in the January 28, 2021 Executive Order on Strengthening the Affordable Care Act and Medicaid 224 and the American Rescue Plan Act of 2021,225 which both emphasize making health coverage accessible and affordable for consumers of all income levels. Moreover, this policy is consistent with reducing premium growth so that consumers are not required to pay high premiums or costsharing that is subsequently rebated pursuant to MLR requirements, particularly since we have seen record high MLR rebates in recent years.²²⁶ ESI premiums have grown at a slower rate from 2013 through 2019 as compared to the private insurance premium growth rate, and when used as a measure of premium growth, ESI premium growth will make more individuals eligible for an affordability exemption that will enable them to enroll in catastrophic coverage under § 155.305(h), will decrease the rate of growth of cost sharing parameters such as the annual maximum limitation on cost sharing, and, if the IRS adopts this measure of premium growth for purposes of indexing under the premium tax credit provision in section 36B of the Code going forward, also will increase consumer eligibility for premium tax credits.227

In addition to aligning with the policy priorities expressed in the recent executive order and statute, reverting to NHEA ESI data as a measure of premium was an explicit interest expressed by commenters to the proposed rule. As noted earlier in this section, the overwhelming majority of commenters specifically opposed the changes made to the premium adjustment percentage calculation in the 2020 Payment Notice and asked HHS to revert to the NHEA ESI premium. We agree with these commenters' concerns.

Furthermore, reverting to NHEA ESI premium data is consistent with changing circumstances related to the potential uncertainty of the private health insurance premium measure that includes the individual market. Private health insurance premiums are more likely to be influenced by risk premium pricing, or premium pricing based on changes in benefit design and market composition in the individual market. Particularly during times of economic uncertainty, such as that experienced as a result of the COVID-19 PHE, private health insurance premium growth could reflect issuer uncertainty in market developments and could be reflected in the NHEA private insurance premium measure (excluding Medigap and property and casualty insurance). NHEA ESI premium data provides a more stable premium measure because it will exclude premiums from the individual market, which are likely to be most affected by the significant changes in benefit design, or risk premium pricing. By using the NHEA ESI premium measure for the 2022 benefit year and beyond, we will provide a more appropriate and fair measure of average per capita premiums for health insurance coverage when considering the goal of consumer protection.

As such, using the NHEA Projections 2019–2028 ESI data available at the time of the proposed rule, the premium adjustment percentage for 2022 is the percentage (if any) by which the NHEA Projections 2019–2028 value for per enrollee ESI premiums for 2021 (\$6,964) exceeds the NHEA Projections 2019–2028 value for per enrollee ESI

²²³ The data used to calculate per capita ESI premiums overlaps significantly with the data used to calculate the current measure—according to the CMS Office of the Actuary, approximately 86 percent of enrollees in 2022 will be covered by employer-sponsored insurance.

²²⁴ 86 FR 7793 (February 2, 2021).

 $^{^{225}\,\}mathrm{American}$ Rescue Plan Act of 2021, Public Law 117–2.

²²⁶ See https://www.cms.gov/CCIIO/Resources/ Data-Resources/Downloads/2019-Rebates-by-State.pdf.

²²⁷ Section 36B(b)(3)(A)(ii) of the Code generally provides that the applicable percentages are to be adjusted after 2014 to reflect the excess of the rate of premium growth over the rate of income growth for the preceding year. Section 36B(c)(2)(C) of the Code provides that the required contribution percentage is to be adjusted after 2014 in the same manner as the applicable percentages are adjusted in section 36B(b)(3)(A)(ii) of the Code. Following HHS's establishment of the methodology for calculating premium growth for purposes of the premium adjustment percentage using NHEA ESI for benefit years 2015–2019, and NHEA private health insurance (excluding Medigap and property and casualty insurance), the Department of the Treasury and the IRS issued guidance providing that the rate of premium growth for purposes of the section 36B provisions would be based on the same

measures HHS selected. Following this rulemaking, we expect the Department of the Treasury and the IRS to issue additional guidance to adopt the same premium measure for purposes of future indexing of the applicable percentage and required contribution percentage under section 36B of the Code. The effects of this change would not be seen in 2022, as the American Rescue Plan Act of 2021 amends the Code to temporarily supersede the indexing for 2021 and 2022, but if the same premium measure was adopted in future tax years, this would result in more individuals being eligible for premium tax credits than would be the case if the current premium measure were maintained.

premiums for 2013 (\$5,061). Using this formula, the premium adjustment percentage for the 2022 benefit year is 1.3760126457 (\$6,964/\$5,061) which represents an increase in ESI premiums of approximately 37.6 percent over the period from 2013 to 2021. As described in further detail elsewhere in this preamble, this premium adjustment percentage will be used to index the maximum annual limitation on cost sharing and the required contribution percentage used to determine eligibility for certain exemptions under section 5000A of the Code. It will also be used to index the employer shared responsibility payment amounts under section 4980H(a) and (b) of the Code.

Comment: A few commenters asked HHS to coordinate with the Internal Revenue Service (IRS) in setting the maximum annual limitation on cost sharing for high deductible health plans (HDHPs) that would allow enrollees to be eligible to contribute to a Health Savings Account (HSA) so the IRS values match those set in the annual HHS notice of benefit and payment parameters. These commenters were concerned that the differences in these values were confusing to consumers and would lead to an inability for issuers to offer HSA-eligible plans in the bronze metal level.

Response: The Department of the Treasury and the IRS have jurisdiction over HSAs and HSA-eligible HDHPs and the applicable maximum out-of-pocket under section 223 of the Code. Annual adjustments to the maximum annual limitation on cost sharing for HSAeligible HDHPs are determined under section 223(g) of the Code, which by statute provides for a different annual adjustment than the premium adjustment percentage provided under section 1302(c) of the ACA. As both of these adjustments are defined in statute, it is not within the authority of HHS to align the premium adjustment percentage with the index used by the IRS for HSA-eligible HDHPs.

Comment: One commenter requested that we reverse the policy we finalized in the 2016 Payment Notice,²²⁸ which clarified that the maximum annual limitation on cost sharing for self-only coverage applies to all individuals regardless of whether the individual is covered by a self-only plan or is covered by a plan that is other than self-only.

Response: We did not propose and are not finalizing any changes to the policy that the maximum annual limitation on cost sharing for self-only coverage applies to all individuals regardless of whether the individual is covered by a

self-only plan or is covered by a plan that is other than self-only. As we stated in the 2016 Payment Notice,²²⁹ we believe that this policy is an important consumer protection, as we were aware that some consumers were confused by the applicability of the annual limitation on cost sharing in other than self-only plans. As such, for all benefit years since 2016, an individual's cost sharing for EHB may never exceed the self-only annual limitation on cost sharing.

Based on the comments received, we are finalizing the premium adjustment percentage for the 2022 benefit year as 1.3760126457 (\$6,964/\$5,061) which represents an increase in ESI premiums of approximately 37.6 percent over the period from 2013 to 2021.

a. Maximum Annual Limitation on Cost Sharing for Plan Year 2022

We proposed to increase the maximum annual limitation on cost sharing for the 2022 benefit year based on the proposed value calculated for the premium adjustment percentage for the 2022 benefit year. As finalized in the EHB final rule ²³⁰ at § 156.130(a)(2), for the 2022 calendar year, cost sharing for self-only coverage may not exceed the dollar limit for calendar year 2014 increased by an amount equal to the product of that amount and the premium adjustment percentage for 2022. For other than self-only coverage, the limit is twice the dollar limit for self-only coverage. Under § 156.130(d), these amounts must be rounded down to the next lowest multiple of \$50.

Using the proposed premium adjustment percentage, and the 2014 maximum annual limitation on cost sharing of \$6,350 for self-only coverage, which was published by the IRS on May 2, 2013, 231 we proposed that the 2022 benefit year maximum annual limitation on cost sharing would be \$9,100 for self-only coverage and \$18,200 for other than self-only coverage. This would have represented an approximately 6.4 percent (\$9,100 \div \$8,550) increase above the 2021 parameters of \$8,550 for self-only coverage and \$17,100 for other than self-only coverage.

We received public comments on the proposed updates to the maximum annual limitation on cost sharing for plan year 2022. Please see our summary of comments on the premium adjustment percentage (§ 156.130(e)) for a summary of comments on the

maximum annual limitation on cost sharing.

We are not finalizing the 2022 maximum annual limitation on cost sharing as proposed. Based on the comments received and as explained above, we are finalizing a 2022 maximum annual limitation on cost sharing of \$8,700 for self-only coverage and \$17,400 for other than self-only coverage. Using the premium adjustment percentage of 1.3760126457 for 2022 finalized in this rule, and the 2014 maximum annual limitation on cost sharing of \$6,350 for self-only coverage, which was published by the IRS on May 2, 2013,232 the 2022 maximum annual limitation on cost sharing is \$8,700 for self-only coverage and \$17.400 for other than self-only coverage. This represents an approximately 1.8 percent (\$8,700 ÷ \$8,550) increase above the 2021 parameters of \$8,550 for self-only coverage and \$17,100 for other than selfonly coverage.

b. Reduced Maximum Annual Limitation on Cost Sharing (§ 156.130)

We proposed for the 2022 benefit year and beyond, unless changed through notice-and-comment rulemaking, to use the reductions in the maximum annual limitation on cost sharing for cost-sharing plan variations determined by the methodology we established beginning with the 2014 benefit year, as further described later in this section of the preamble.

Sections 1402(a) through (c) of the ACA direct issuers to reduce cost sharing for EHBs for eligible individuals enrolled in a silver-level QHP. In the 2014 Payment Notice, we established standards related to the provision of these CSRs. Specifically, in part 156 subpart E, we specified that QHP issuers must provide CSRs by developing plan variations, which are separate costsharing structures for each eligibility category that change how the cost sharing required under the QHP is to be shared between the enrollee and the federal government. At § 156.420(a), we detailed the structure of these plan variations and specified that QHP issuers must ensure that each silverplan variation has an annual limitation on cost sharing no greater than the applicable reduced maximum annual limitation on cost sharing specified in the annual HHS notice of benefit and payment parameters. Although the amount of the reduction in the maximum annual limitation on cost sharing is specified in section

²²⁹ Ibid.

²³⁰ See 78 FR 12847 through 12848.

 $^{^{231}}$ See Revenue Procedure 2013–25, 2013–21 IRB 1110. http://www.irs.gov/pub/irs-drop/rp-13-25.pdf.

 $^{^{232}}$ See Revenue Procedure 2013–25, 2013–21 IRB 1110. http://www.irs.gov/pub/irs-drop/rp-13-25.pdf.

1402(c)(1)(A) of the ACA, section 1402(c)(1)(B)(ii) of the ACA states that the Secretary may adjust the costsharing limits to ensure that the resulting limits do not cause the AV of the health plans to exceed the levels specified in section 1402(c)(1)(B)(i) of the ACA (that is, 73 percent, 87 percent, or 94 percent, depending on the income of the enrollee).

As we stated earlier in this final rule, the proposed 2022 maximum annual limitation on cost sharing was \$9,100 for self-only coverage and \$18,200 for other than self-only coverage. We analyzed the effect on AV of the reductions in the maximum annual limitation on cost sharing described in the statute to determine whether to adjust the reductions so that the AV of a silver plan variation will not exceed the AV specified in the statute. Below, we describe our analysis for the 2022 plan year and our proposed results.

Consistent with our analysis for the 2014 through 2021 benefit years' reduced maximum annual limitation on cost sharing, we developed three test silver level QHPs, and analyzed the impact on AV of the reductions described in the ACA to the proposed estimated 2022 maximum annual limitation on cost sharing for self-only coverage (\$9,100). The test plan designs are based on data collected for 2021 plan year OHP certification to ensure that they represent a range of plan designs that we expect issuers to offer at the silver level of coverage through the Exchanges. For 2022, the test silver level QHPs included a PPO with typical cost-sharing structure (\$9,100 annual limitation on cost sharing, \$2,775 deductible, and 20 percent in-network coinsurance rate); a PPO with a lower annual limitation on cost sharing (\$7,400 annual limitation on cost sharing, \$3,050 deductible, and 20 percent in-network coinsurance rate); and an HMO (\$9,100 annual limitation on cost sharing, \$4,800 deductible, 20 percent in-network coinsurance rate, and the following services with copayments that are not subject to the deductible or coinsurance: \$500 inpatient stay per day, \$500 emergency department visit, \$30 primary care office visit, and \$55 specialist office visit). Based on the parameters in the proposed rule, all three test QHPs meet the AV requirements for silver level health plans.

We then entered these test plans into a draft version of the 2022 benefit year AV Calculator 233 and observed how the reductions in the maximum annual

limitation on cost sharing specified in the ACA affected the AVs of the plans. As with prior years, we found that the reduction in the maximum annual limitation on cost sharing specified in the ACA for enrollees with a household income between 100 and 150 percent of FPL (2/3 reduction in the maximum annual limitation on cost sharing), and 150 and 200 percent of FPL (2/3 reduction), would not cause the AV of any of the model QHPs to exceed the statutorily specified AV levels (94 and 87 percent, respectively).

However, as with prior years, we continue to find that the reduction in the maximum annual limitation on cost sharing specified in the ACA for enrollees with a household income between 200 and 250 percent of FPL (1/2 $\,$ reduction), would cause the AVs of two of the test QHPs to exceed the specified AV level of 73 percent. Furthermore, as with prior years, for individuals with household incomes of 250 to 400 percent of FPL, without any change in other forms of cost sharing, the statutory reductions in the maximum annual limitation on cost sharing would cause an increase in AV that exceeds the maximum 70 percent level in the statute.

The calculation of the reduced maximum annual limitation on cost sharing has remained consistent since the 2014 Payment Notice due to yearover-year consistency of the results of our analysis regarding the effects of the reduced maximum annual limitation on cost sharing on the AV of silver plan variations. Therefore, as a result of the apparent stability of those results, and consistent with prior Payment Notices, we proposed to continue to use the maximum annual limitation on cost sharing reductions of 2/3 for enrollees with a household income between 100 and 200 percent of FPL, 1/5 for enrollees with a household income between 200 and 250 percent of FPL, and no reduction for individuals with household incomes of 250 to 400 percent of FPL for the 2022 benefit year and beyond. We would continue to review the effects of these reductions annually, and should we determine that this approach should be changed to better reflect the statutorily specified AVs for silver plan variations, we would propose to change these reductions through notice-and-comment rulemaking.

Specifically, we proposed to continue to use the methodology described above for analyzing the effects of the reduced maximum annual limitations on cost sharing on the AV of silver plan variations to verify that the reductions do not result in unacceptably high AVs

before we publish these values in guidance for a given benefit year. Subsequently, if a future analysis using this methodology supports a modification to the reduced maximum annual limitation for any of the household income bands for a future benefit year, we would propose those modifications to the reduced maximum annual limitations through notice-andcomment rulemaking, as appropriate.

We noted that selecting a reduction for the maximum annual limitation on cost sharing that is less than the reduction specified in the statute would not reduce the benefit afforded to enrollees in the aggregate. This is because QHP issuers are required to meet specified AV levels that require the plan's cost-sharing to be within a

limited range.

We sought comment on this analysis and the proposed reductions in the maximum annual limitation on cost sharing calculation methodology for the 2022 benefit year and beyond. We also sought comment on the proposed reduced annual limitations on cost sharing for the 2022 benefit year.

We noted that for 2022, as described in § 156.135(d), states are permitted to request HHS's approval for state-specific datasets for use as the standard population to calculate AV. No state submitted a dataset by the September 1. 2020 deadline.

We received no comments on the reductions in the maximum limitations on cost sharing apart from those already discussed in the preamble to the premium adjustment percentage (§ 156.130(e)). In this regard, please see our summary of comments on the premium adjustment percentage (§ 156.130(e)) for a summary of comments pertaining to the reduced maximum annual limitation on cost sharing.

In light of our decision to finalize the 2022 premium adjustment percentage using the NHEA ESI premium measure to estimate premium growth, we are not finalizing the 2022 reduced maximum annual limitation on cost sharing parameters as proposed (in Table 9 of

the proposed rule ²³⁴).

To confirm consistency with the analysis for the reduced maximum annual limitation on cost sharing, we tested the reductions to the maximum annual limitation for cost sharing which we are finalizing in this rule, and we analyzed the impact on AV of the reductions described in the ACA to the 2022 maximum annual limitation on cost sharing that we are finalizing (\$8,700). For 2022, the test silver level

²³³ Available at https://www.cms.gov/cciio/ resources/regulations-and-guidance/index.

^{234 85} FR 78572 at 78635.

OHPs included a PPO with typical costsharing structure (\$8,700 annual limitation on cost sharing, \$2,600 deductible, and 20 percent in-network coinsurance rate); a PPO with a lower annual limitation on cost sharing (\$7,700 annual limitation on cost sharing, \$2,800 deductible, and 20 percent in-network coinsurance rate); and an HMO (\$8,700 annual limitation on cost sharing, \$4,100 deductible, 20 percent in-network coinsurance rate, and the following services with copayments that are not subject to the deductible or coinsurance: \$1200 inpatient stay per day, \$500 emergency department visit, \$30 primary care office visit, and \$60 specialist office

visit). All three test QHPs meet the AV requirements for silver level health plans based on the parameters that we are finalizing in this rule.

We then entered these test plans into a draft version of the 2022 benefit year AV Calculator ²³⁵ and observed how the reductions in the maximum annual limitation on cost sharing specified in the ACA affected the AVs of the plans. We found that the reduction in the maximum annual limitation on cost sharing specified in the ACA for enrollees with a household income between 100 and 150 percent of FPL (²/₃ reduction in the maximum annual limitation on cost sharing), and 150 and 200 percent of FPL (²/₃ reduction),

would not cause the AV of any of the model QHPs to exceed the statutorily specified AV levels.

Therefore, we are finalizing as proposed the reductions of ½3 for enrollees with a household income between 100 and 200 percent of FPL, ½5 for enrollees with a household income between 200 and 250 percent of FPL, and no reduction for individuals with household incomes of 250 to 400 percent of FPL for the 2022 benefit year and beyond, as well as the methodology we use to ensure that these reductions do not result in unacceptably high AVs. The resulting final 2022 reduced maximum annual limitations on cost sharing are available in Table 10 below.

TABLE 10: Reductions in Maximum Annual Limitation on Cost Sharing for 2022

Eligibility Category	Reduced Maximum Annual Limitation on Cost Sharing for Self-only Coverage for 2022	Reduced Maximum Annual Limitation on Cost Sharing for Other than Self-only Coverage for 2022
Individuals eligible for CSRs under § 155.305(g)(2)(i) (100-150 percent of FPL)	\$2,900	\$5,800
Individuals eligible for CSRs under § 155.305(g)(2)(ii) (151-200 percent of FPL)	\$2,900	\$5,800
Individuals eligible for CSRs under § 155.305(g)(2)(iii) (201-250 percent of FPL)	\$6,950	\$13,900

c. Publication of the Premium Adjustment Percentage, Maximum Annual Limitation on Cost Sharing, Reduced Maximum Annual Limitation on Cost Sharing, and Required Contribution Percentage (§ 156.130)

Since the 2014 benefit year, HHS has published the premium adjustment percentage, maximum annual limitation on cost sharing, reduced maximum annual limitation on cost sharing, and required contribution percentage parameters through notice-andcomment rulemaking. Beginning with the 2023 benefit year, we proposed to publish these parameters in guidance by January of the year preceding the applicable benefit year, unless HHS is changing the methodology for calculating the parameters, in which case, we would do so through noticeand-comment rulemaking. We additionally proposed to publish in guidance the premium adjustment percentage and related parameters using the most recent NHEA income and premium data that is available at the time these values are published in guidance or, if HHS is changing the methodology for calculating these parameters, at the time these values are

proposed in notice-and-comment rulemaking. Publication of these parameters prior to the release of updates to the NHEA data, which typically (but not always) occurs in February or March, is consistent with the 2021 Payment Notice policy to finalize the premium adjustment percentage, maximum limitation on cost sharing, reduced maximum limitation on cost sharing, and required contribution percentage using NHEA data that would be available at the time that the proposed rule would have been published.

In the EHB final rule,²³⁶ HHS established at § 156.130(e) that HHS will publish the annual premium adjustment percentage in the annual HHS notice of benefit and payment parameters. Additionally, in the 2014 Payment Notice final rule,²³⁷ HHS established at § 156.420(a)(1)(i), (2)(i), and (3)(i), that the reduced annual limitations on cost sharing would be published in the applicable benefit year's annual HHS notice of benefit and payment parameters. Due to the timing of publication of the annual HHS notice of benefit and payment parameters final rule in past years, stakeholders have

suggested that when HHS is not changing the calculation methodology for these parameters, HHS should publish earlier the premium adjustment percentage, maximum limitation on cost sharing, reduced maximum limitation on cost sharing, and required contribution percentage. These stakeholders asserted that an earlier publication would allow issuers to incorporate these parameters for rate setting and the submission of QHP benefit templates earlier than would be possible if the parameters were published in the applicable benefit year's notice of benefit and payment parameters.

In addition, once the methodologies used to calculate the premium adjustment percentage, required contribution percentage, and maximum annual limitation on cost sharing have been established through rulemaking, the calculation of these amounts is a function of entering the applicable figures into the established equations, and therefore, does not require rulemaking to establish in subsequent benefit years. Furthermore, the methodology used to calculate the reduced maximum annual limitation on

²³⁵ Available at https://www.cms.gov/cciio/resources/regulations-and-guidance/index.

²³⁶ 78 FR 12834 through 12833.

²³⁷ 78 FR 15409.

cost sharing has remained consistent since the 2014 Payment Notice final rule. Therefore, as discussed earlier in this final rule, we are finalizing for the 2022 benefit year and beyond the reduction rates for the reduced maximum annual limitation on cost sharing as well as the methodology for determining whether these reductions raise plan AVs above acceptable levels for the 2022 benefit year and beyond.

With these methodologies in place we proposed to amend §§ 156.130(e) and 156.420(a) to reflect that, beginning with the 2023 benefit year, we would publish the premium adjustment percentage, along with the maximum annual limitation on cost sharing, the reduced maximum annual limitation on cost sharing, and the required contribution percentage, in guidance by January of the year preceding the applicable benefit year (for example, the 2023 premium adjustment percentage would be published in guidance no later than January 2022), unless HHS is amending the methodology to calculate these parameters, in which case HHS would amend the methodology and publish the parameters through notice-andcomment rulemaking.

We believed that publishing the final premium adjustment percentage and associated final parameters in guidance annually instead of through notice-and-comment rulemaking is consistent with our efforts to provide information to stakeholders in a timely manner.

We received public comments on the proposal to publish the premium adjustment percentage, maximum annual limitation on cost sharing, reduced maximum annual limitation on cost sharing (§ 156.130), and required contribution percentage (§ 155.605(d)(2)) in guidance. The following is a summary of the comments we received and our responses.

Comment: We received multiple comments expressing general support for publishing the premium adjustment percentage, maximum annual limitation on cost sharing, reduced maximum annual limitation on cost sharing, and required contribution percentage in guidance by January of the year proceeding the applicable benefit year, when we are not proposing any changes to the methodologies used to calculate these values. Commenters largely agreed that this publication timeline would reduce confusion and would provide information to stakeholders in a more timely manner.

However, a few commenters expressed concern that publication in guidance would reduce their opportunities to review and comment on these parameters. Some of these

commenters pointed out that their concerns regarding the 2020 Payment Notice change in the premium adjustment percentage calculation ²³⁸ have not been addressed and feared that publishing these parameters in guidance would remove opportunity to comment on the current methodology. For this reason, one commenter asked that we publish the parameters in guidance in draft form seeking public comment prior to finalizing the parameters for the applicable benefit year.

Response: We are finalizing our ability to publish the premium adjustment percentage, maximum annual limitation on cost sharing, reduced maximum annual limitation on cost sharing and required contribution percentage in guidance. Therefore, for the 2023 benefit year and beyond, the values calculated based on the methodologies established in rulemaking will generally be published in guidance by January of the year preceding the benefit year to which they apply, unless we are proposing changes to the methodology used to calculate these values or otherwise wish to discuss or obtain significant feedback on the methodology. As a general matter, we do not believe that comments to such guidance will be necessary since the methodology will have been set pursuant to statute and through noticeand-comment rulemaking, and the guidance would merely be announcing the published measures and showing the calculations based on the established methodology and published measures. We reiterate that if we do propose changes to the methodology, we will propose the values of these parameters alongside the changes in methodology through notice-andcomment rulemaking.

As mentioned in previous sections of this final rule, we have addressed comments concerned about the methodology change for calculating the premium adjustment percentage that was finalized in the 2020 Payment Notice, and are reverting back to the methodology used prior to 2020 Payment Notice. Therefore, we are relying on NHEA ESI premium data, not premium data from other private health insurance markets, in our calculation of premium growth and the premium adjustment percentage, maximum annual limitation on cost sharing, reduced maximum annual limitation on cost sharing, and required contribution

percentage for the 2022 benefit year and beyond.

4. Termination of Coverage or Enrollment for Qualified Individuals (§ 156.270)

In the 2021 Payment Notice, we finalized a requirement that under § 156.270(b)(1), QHP issuers must send termination notices with effective dates and reason for the termination to enrollees for all termination events. We finalized this policy as proposed, noting that all commenters who weighed in on this topic supported our proposal. This policy became effective July 13, 2020. In the 2022 Payment Notice proposed rule, we did not propose, and we are not finalizing, any changes to paragraph (b)(1) beyond what we finalized in the 2021 Payment Notice for the reasons discussed below.

In finalizing the change to § 156.270(b)(1) in the 2021 Payment Notice, we inadvertently omitted discussion of two comments opposing the proposal. These comments raised concerns about unnecessary additional administrative costs and IT builds, and noted that a termination notice could be confusing in certain scenarios—for example, if the enrollee switches between QHPs offered by the same issuer, a termination notice from their issuer could cause confusion. These commenters proposed instead that Exchanges should be required to clearly convey the eligibility termination reason and effective date in the Exchange's own eligibility notices, consistent with the data conveyed to issuers on 834 termination transactions.

We are sensitive to commenters' concerns that issuers need sufficient time to build IT systems to implement this policy. In response, we issued guidance allowing issuers using the Federal platform enforcement discretion until February 1, 2021 to implement the new termination notice requirement.²³⁹

However, the comments in opposition to the proposal do not change our policy goals underlying our decision to finalize the rule as proposed. FFEs do not send termination notices for any termination scenario other than citizenship datamatching issue expirations and terminations associated with Medicare PDM when the enrollee has elected at plan selection to terminate Exchange coverage when found dually enrolled. FFEs also do not send termination notices in enrollee-initiated

²³⁸ In the 2020 Payment Notice, HHS changed the methodology for calculating the premium adjustment percentage from using ESI premiums to using all individual health insurance premiums minus Medigap and the medical portion of property and casualty insurance. See 84 FR 17454.

²³⁹ "Enforcement Safe Harbor for Qualified Health Plan Termination Notices During the 2019 Benefit Year," August 26, 2020. Available at https:// www.cms.gov/CCIIO/Programs-and-Initiatives/ Health-Insurance-Marketplaces/Downloads/ Termination-Notices-Enforcement-Discretion.pdf.

terminations which must be requested at the Exchange. Similarly, FFEs do not send termination notices when an enrollee switches QHPs within the same issuer. This is all appropriate, because the issuer is the primary communicator to the enrollee about their coverage. We still believe that termination notices would be helpful in these scenarios, even in plan selection changes, because an enrollee switching QHPs could have their premium, cost sharing, and provider network affected. As one of the comments in support of the new termination notice requirement in the 2021 Payment Notice noted, it is important for the enrollee to have in writing the actual termination date for their records, in case of miscommunication with the issuer about the preferred date or to later dispute an inaccurate Form 1095–A. Another commenter agreed that issuers should send termination notices during voluntary terminations associated with Medicare PDM as it would help the enrollee confidently transition to

Complaints about terminations are one of the largest sources of casework. More consistent communication is part of the solution. We believed consumers should be notified of these changes, even if they initiated them, so that enrollees have a record that the issuer completed the request. Issuers are the proper messenger of termination noticing for many reasons. For example, Exchange issuers historically are the senders of termination notices, and some issuers acknowledged in their comments on the 2021 Payment Notice that they already do send termination notices in all scenarios. Furthermore. the issuer has record of the termination date needed for the termination notice before the Exchange in some cases, such as some retroactive termination requests handled through casework, and State Exchange issuer terminations described in $\S 155.430(d)(iv)$. One reason we regulated in this area is that we were receiving detailed questions from issuers about which termination scenarios required issuer notices; we believe requiring issuer termination notices for all scenarios in the long run makes the requirement simpler.

Therefore, we did not propose, and are not finalizing, any changes to § 156.270(b)(1) beyond what we finalized in the 2021 Payment Notice.

Comment: One commenter appreciated that we did not propose any changes beyond what we finalized in the 2021 Payment Notice. Another commenter supported our 2021 Payment Notice provision requiring issuers to send termination notices to

consumers in all termination scenarios, but suggested that HHS work with consumer advocates to provide simpler, more easily understandable termination templates that could help with readability for individuals with low literacy.

Response: HHS does not proscribe language that issuers must use in their termination notices. We believe that issuers, as the primary communicators to enrollees about their coverage, are in the best position to decide the appropriate termination notice content and wording for their enrollees, as long as they comply with applicable requirements, including those in §§ 156.270 and 156.250. Under those regulations, because issuers are required to send these termination notices to enrollees, issuers must use plain language in any such notices they send to consumers, so that the information can easily be understood and is useful to consumers with low literacy, low health literacy, or limited English proficiency.

Comment: One commenter said that FFEs, as the systems of record, should be responsible for sending termination notices, particularly because FFEs already send eligibility notices, 1095–A forms, and other documentation.

Response: As we explained in the preamble to the proposed rule, issuers are the proper messenger of termination noticing for many reasons. Exchange issuers historically are the senders of termination notices, and some issuers acknowledged in their comments on the 2021 Payment Notice that they already do send termination notices in all scenarios. Furthermore, the issuer has record of the termination date needed for the termination notice before the Exchange in some cases, such as some retroactive termination requests handled through casework, and State Exchange issuer terminations described in § 155.430(d)(iv).

5. Prescription Drug Distribution and Cost Reporting by QHP Issuers (§ 156.295)

Section 6005 of the ACA added section 1150A(a)(2) of the Act to require a PBM under a contract with a Medicare Part D plan sponsor or Medicare Advantage plan that offers a Medicare Part D plan, or with a QHP offered through an Exchange established by a state under section 1311 of the ACA ²⁴⁰ to provide certain prescription drug information to the Secretary, at such

times, and in such form and manner, as the Secretary shall specify. Section 1150A(b) of the Act addresses the information that a QHP issuer or their PBM must report.²⁴¹ Section 1150A(c) of the Act requires the information reported to be kept confidential and not to be disclosed by the Secretary or by a plan receiving the information, except that the Secretary may disclose the information in a form which does not disclose the identity of a specific PBM, plan, or prices charged for drugs for certain purposes.²⁴²

In the 2012 Exchange Final Rule, we codified the requirements contained in section 1150A of the Act with regard to QHPs at § 156.295. In that rule, we interpreted section 1150A of the Act to require QHP issuers to report the information described in section 1150A(b) of the Act and did not specify the responsibilities of PBMs that contract with QHP issuers to report this information. On January 28, 2020 243 and on September 11, 2020,244 we published notices in the Federal Register and solicited public comment on collection of information requirements detailing the proposed collection envisioned by section 1150A of the Act to HHS.245

²⁴⁰ This includes an FFE, as a Federal Exchange may be considered an Exchange established under section 1311 of the ACA. *King v. Burwell*, 576 U.S. 988 (2015).

 $^{^{241}}$ This information is: The percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed (generic dispensing rate), by pharmacy type (which includes an independent pharmacy, chain pharmacy, supermarket pharmacy, or mass merchandiser pharmacy that is licensed as a pharmacy by the state and that dispenses medication to the general public), that is paid by the health benefits plan or PBM under the contract; the aggregate amount, and the type of rebates, discounts, or price concessions (excluding bona fide service fees, which include but are not limited to distribution service fees inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs)) that the PBM negotiates that are attributable to patient utilization under the plan, and the aggregate amount of the rebates, discounts, or price concessions that are passed through to the plan sponsor, and the total number of prescriptions that were dispensed; and, the aggregate amount of the difference between the amount the health benefits plan pays the PBM and the amount that the PBM pays retail pharmacies and mail order pharmacies, and the total number of prescriptions that were dispensed.

²⁴² The purposes are: As the Secretary determines to be necessary to carry out Section 1150A or part D of title XVIII; to permit the Comptroller General to review the information provided; to permit the Director of the Congressional Budget Office to review the information provided; and, to States to carry out section 1311 of the ACA.

²⁴³ 85 FR 4993 through 4994.

²⁴⁴ 85 FR 56227 through 56229.

²⁴⁵ Pharmacy Benefit Manager Transparency. CMS–10725. Available at https://www.cms.gov/regulations-and-guidancelegislationpaperworkreductionactof1995pra-listing/cms-10725.

a. QHP Issuer Responsibilities

In the proposed rule, we proposed to add new part 184 to address the responsibilities of PBMs under the ACA and to add § 184.50 to codify in regulation the statutory requirement that PBMs that are under contract with an issuer of one or more OHPs report the data required by section 1150A of the Act. Accordingly, we proposed to revise § 156.295(a) to state that where a QHP issuer does not contract with a PBM to administer the prescription drug benefit for QHPs, the QHP issuer will report the data required by section 1150A of the Act to HHS. We proposed corresponding revisions throughout § 156.295 to remove the applicability of the reporting requirement for PBMs under this section and propose revising the title to "Prescription drug distribution and cost reporting by QHP

As explained in the proposed rule and in the preamble for $\S 184.50$ in this final rule, we acknowledge that section 1150A places responsibility on both the QHP issuer and their PBMs to report this prescription drug data. Generally, where a QHP issuer contracts with a PBM, the PBM is more likely to be the source of the data that must be reported. Therefore, to reduce overall burden, rather than requiring the QHP issuer to serve as a conduit between its PBM and HHS, or unnecessarily requiring both the PBM and the QHP issuer to submit duplicated data, we proposed to implement section 1150A to make QHP issuers responsible for reporting this data directly to the Secretary only when the QHP issuer does not contract with a PBM to administer the prescription drug benefit for their QHPs. Where a QHP contracts with a PBM, the PBM is responsible for reporting data to the Secretary as required by § 184.50.

We stated that although we were unaware of any QHP issuer that does not currently utilize a PBM, we believed that, together, the proposals to revise § 156.295 and to add § 184.50 would ensure the collection of data required by section 1150A of the Act in all circumstances, including when a QHP issuer does not use a PBM to administer its prescription drug benefit. Retaining the requirement for QHP issuers to report data at § 156.295 when they do not contract with a PBM would ensure that the data is consistently collected every plan year.

We also proposed to remove § 156.295(a)(3) to remove the requirement for QHP issuers to report spread pricing amounts when the QHP issuer does not contract with a PBM to administer the prescription drug benefit for their QHPs. Spread pricing amounts are only present where a PBM acts as an intermediary between the QHP issuer and a drug manufacturer. If a QHP issuer does not contract with a PBM, no such intermediary exists and it is not possible for QHP issuers to report this data.

We sought comment on these proposals.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to collect this data directly from the PBMs that QHP issuers contract with to administer the drug benefit for their QHPs, as PBMs are best positioned to report the data with the least amount of burden. A few commenters asserted that section 1150A(a)(2) of the Act does not grant HHS the authority to collect this data directly from PBMs.

Response: We agree with commenters that where QHP issuers utilize PBMs to administer their prescription drug benefit, PBMs are best suited to report this data. Section 1150A(a)(2) of the Act grants the Secretary the authority to specify the time, form, and manner of this collection. We exercise this authority to specify the manner of this collection by finalizing this policy as proposed: PBMs will submit this data to HHS when a QHP issuer contracts with the PBM to administer the drug benefit for their QHPs. If a QHP issuer does not contract with a PBM to administer the drug benefit for their QHPs, the QHP issuer will submit the data to HHS. However, given our understanding that all QHP issuers currently use a PBM, with the limited exception of QHP issuers with integrated delivery systems as discussed below, we believe that it is reasonable to expect that PBMs are best suited to report this data given their contractual role in the primary administration of prescription drug benefits.

Comment: Citing the burden to make contractual modification and operational upgrades, many commenters requested that we delay implementation of the collection until 2022 or later.

Response: We are aware of the timing concerns expressed by commenters in response to the policies finalized here and at part 184 below, as well as those expressed in response to the collection of information requirement notices displayed in 2020. However, this collection is statutorily required, and, as noted in the collection of information requirement notices, we have previously delayed its implementation in order to accommodate concerns regarding

burden. We are sensitive to commenters' concerns about burden and timing, and, this data collection is not imposed lightly; we understand that the implementation of a new data collection during a pandemic may impose additional challenges on the industry. However, its disclosure has never been more vital, as all aspects of the prescription drug delivery chain continue to contribute to rising prescription drug costs in this country. Additionally, we believe that this data is essential for the implementation of policies that seek to improve the coverage landscape of prescription drugs. We therefore intend to begin collection as soon as reasonably possible. However, to minimize burden during a pandemic, and to allow for additional time to provide technical assistance to reporting entities for a new collection, we do not intend to require submission sooner than December 31.

Comment: Multiple commenters asserted that section 1150A(a)(2) of the Act does not grant HHS the authority to collect some of this data at the National Drug Code (NDC) level of detail.

Commenters also expressed concern that HHS did not describe the level of detail for this collection in regulation.

Response: Section 1150A(a)(2) of the Act grants the Secretary the authority to specify the time, form, and manner of this collection. We have specified the form and manner of this collection as part of the collection of information requirement notices displayed in 2020. In collecting some of this data at the NDC level of detail, we are interpreting section 1150A in a manner consistent with previous rulemaking by CMS.²⁴⁶ Additionally, we sought comment on the form and manner of the collection twice in the collection of information requirement notices displayed in 2020,

²⁴⁶ See "Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes; Final Rule" at 77 FR 22094. In that final rule, CMS interpreted section 1150A of the Act to impose no additional reporting requirements for entities subject to Direct and Indirect Remuneration (DIR) reporting, except for PBM spread amount aggregated to the plan benefit package level. The existing DIR reporting required data reporting at the NDC. As such, CMS has previously interpreted that section 1150A authorizes collection at an NDC level of reporting. For consistency with previous rulemaking by CMS and to reduce the burden of creating different CMS, collection requirements, we will collect some of this data at the NDC level. We recognize that DIR reporting requirements under Part D are partly based on statutory authority that is not applicable to this collection, and we do not claim to rely on any authority other than section 1150A of the Act as the basis for this collection. We do, however, rely on that final rule insofar as CMS strives to interpret the same statute consistently.

including the level of detail of the collection.

Comment: Some commenters expressed concern that a federal requirement to report prescription drug data for QHPs may conflict or overlap with state requirements to collect similar data. One commenter voiced concern that this collection is unduly similar to the Transparency in Coverage final rule,²⁴⁷ a rule for which the commenter seeks regulatory clarifications.

Response: While we agree with commenters that we should endeavor to minimize burden and avoid conflict or duplication of efforts with state reporting requirements, we have conducted research and held discussions with states to understand existing state reporting requirements. In addition, no state submitted comments to the collection of information requirement notices displayed in 2020 or to this proposal indicating any concern about conflict or overlap with this reporting requirement. As a result, we believe that there is no significant conflict or duplication between this collection and any state reporting requirement.

We also note that, after the proposed rule displayed, Congress passed the Consolidated Appropriations Act, 2021,²⁴⁸ which includes certain reporting requirements on pharmacy benefits and drug costs.²⁴⁹ We are aware that some of the data envisioned for reporting under the Consolidated Appropriations Act may, to an extent, be similar to some of the data sought by collection under § 1150A of the Act. While we are finalizing this collection as proposed, we, along with the Departments of Treasury and Labor, intend to issue future guidance that will explain the interaction between this collection and the future collection envisioned by the Consolidated Appropriations Act, if necessary.

Comment: One commenter requested clarification whether the collection applies to QHP issuers with integrated delivery systems; that is, QHP issuers that do not use a network of outside providers and do not use outside PBMs to manage their prescription drug benefits. This commenter asserted that there is limited rationale to collect data from such plans, as § 1150A is intended to increase transparency on relationships and transactions across the prescription drug supply chain,

particularly between health plans, PBMs, and pharmacies.

Response: We recognize that not all data elements that must be reported under this requirement would apply equally to integrated delivery systems. Nonetheless, we believe that it is important for these QHP issuers with integrated delivery systems to report the data elements that are applicable, since these issuers are also part of the drug supply chain and their different model provides an important point of comparison. In this instance, the QHP issuer would be responsible for reporting this data, as they do not utilize a PBM to administer their prescription drug benefit. We plan to provide technical assistance to all reporting entities to minimize the burden of this collection.

Comment: One commenter requested clarification regarding the collection's applicability to off-Exchange plans.

Response: This collection applies to QHPs only. We interpret the statute as requiring reporting for QHPs, regardless of whether the QHPs are sold on-Exchange or off-Exchange. The collection does not apply to any other plans.

Comment: A few commenters addressed the confidentiality provision of section 1150A and their codification in regulation. A few commenters requested that the data be released to the public in Public Use Files (PUFs). A few commenters noted that we should share this data with states upon their request to bolster their transparency efforts. One commenter asserted that the confidentiality restrictions required by statute may be too limiting to have an appreciable impact on reducing health care costs for patients, employers and other purchasers.

Response: Section 1150A of the Code, codified previously at § 156.295 and also finalized below at § 184.50 states that information disclosed by a plan or PBM under this collection is confidential and shall not be disclosed by the Secretary or by a plan receiving the information, except that the Secretary may disclose the information in a form which does not disclose the identity of a specific PBM, plan, or prices charged for drugs, for certain purposes, including to states to carry out section 1311 of the ACA.²⁵⁰

Comment: We received a number of comments that were out-of-scope of the

two specific proposals in the proposed rule, including suggestions for improving the definition of "bona fide service fees" used in the appendices of the previously posted ICRs, suggestions on how we might automate the reporting mechanisms, and comments regarding the transparency in coverage requirement under PHS Act section 1311(e)(3).

Response: We appreciate these suggestions and will consider them for future action for this collection and its associated regulations. However, as they are out-of-scope with regards to these specific proposals, we decline to comment further on them at this time.

As a result of the comments, we are finalizing this policy as proposed.

b. Reporting of Data by Pharmacy Type

Section 1150A(b)(1) of the Act requires the Secretary to collect certain QHP prescription drug data ²⁵¹ by pharmacy type (which includes an independent pharmacy, chain pharmacy, supermarket pharmacy, or mass merchandiser pharmacy that is licensed as a pharmacy by the state and that dispenses medication to the general public). This requirement was previously codified at § 156.295(a)(1). In the Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes final rule, we recognized that it is not currently possible to report such data by pharmacy type because pharmacy type is not a standard classification currently captured in industry databases or files.²⁵² We understand that these types continue not to be standard classifications currently captured in industry databases or files, as indicated by comments submitted in response to the January 28, 2020 notice in the Federal Register soliciting public comment on the collection of information requirements of this collection.²⁵³ To reduce the burden of this collection, we proposed to revise § 156.295(a)(1) to remove the requirement to report the data described at section 1150A(b)(1) of the Act by pharmacy type. We intended to collect this information at a time when this requirement would impose reasonable burden. We sought comment on ways that we may collect the data by pharmacy type without creating

²⁴⁷ 85 FR 72158.

²⁴⁸ Public Law 116–260, enacted on December 27,

²⁴⁹ See section 2799A-10.

²⁵⁰ The other purposes described in statute are: As the Secretary determines to be necessary to carry out section 1150A or part D of title XVIII; to permit the Comptroller General to review the information provided; and, to permit the Director of the Congressional Budget Office to review the information provided.

²⁵¹ Section 1150A(b)(1) requires the reporting of the percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed.

²⁵² See 77 FR 22072 at 22093.

²⁵³ See 85 FR 4993 through 4994.

unreasonable burden and any existing definitions that may exist that could be leveraged for this purpose. We also sought comment on the time and costs required for PBMs to begin reporting by pharmacy type, if definitions were finalized.

We received public comments on the proposed updates to reporting of data by pharmacy type. The following is a summary of the comments we received and our responses.

Comment: Nearly all commenters supported the proposal to remove the requirement to report the data described at section 1150A(b)(1) of the Act by pharmacy type, agreeing that it is not a data point that is collected on a widespread basis by the industry and that the implementation would cause unreasonable burden. One commenter disagreed, explaining that that industry is currently capable of reporting this data.

Response: We agree with the majority of commenters that pharmacy type data is currently not readily collected by industry. While we will continue to consider ways to implement its collection, we agree that removal of this requirement from the regulation is warranted at this time.

Following review of the comments, we are finalizing this policy as proposed.

6. Oversight of the Administration of the Advance Payments of the Premium Tax Credit, Cost-Sharing Reductions, and User Fee Programs (§ 156.480)

a. Application of Requirements to Issuers in State Exchanges and SBE–FPs

In the second Program Integrity Rule, we finalized general provisions related to the oversight of QHP issuers in relation to APTC and CSRs.254 We explained that since APTC and CSR payments are federal funds which pass from HHS directly to QHP issuers, it is necessary for HHS to oversee QHP issuer compliance in these areas, regardless of whether the QHP is offered through a State Exchange or an FFE. As such, to effectively oversee the payment of APTC and CSRs by QHP issuers, HHS established standards in part 156, subpart E for QHP issuers participating in FFEs and State Exchanges. We also noted that in states with State Exchanges, the state would have primary enforcement authority over QHP issuers participating in the state's individual market exchange that were not in compliance with the standards set forth in part 156, subpart E.255

However, if the State Exchange does not enforce such standards, HHS would enforce compliance with these requirements, including the imposition of CMPs on QHP issuers participating in State Exchanges using the same standards and processes for QHP issuers participating in FFEs set forth in part 156, subpart I.²⁵⁶ In the second Program Integrity Rule, we also finalized general provisions that require issuers offering QHPs in an FFE maintain all documents and records and other evidence of accounting procedures and practices, which are critical for HHS to conduct activities necessary to safeguard the financial and programmatic integrity of the FFEs.²⁵⁷ As finalized in 45 CFR 156.705(a)(1), this includes the authority for HHS to include periodic auditing of the QHP issuer's financial records related to the participation in an FFE. To date, we have leveraged this authority to conduct user fee audits of QHP issuers participating in an FFE.

In the proposed rule, we proposed amendments to consolidate HHS audit authority regarding APTC, CSR, and user fee audits by expanding the audit authority under § 156.480(c) to also capture user fees audits by HHS, or its designee, of QHP issuers participating in an FFE. Additionally, as part of determining whether APTC and CSR amounts were properly paid to issuers, and whether user fee amounts were properly collected, we explained that HHS regularly identifies discrepancies in issuer records caused by issuer noncompliance with other applicable Exchange operational standards. Examples include failure to correctly effectuate or terminate coverage, or to correctly calculate premiums. In addition, we proposed to apply the same framework to QHP issuers participating in SBE-FP states. As such, QHP issuers in SBE-FP states would be required to comply with HHS audits under § 156.480(c) to confirm compliance with the applicable standards established in part 156, subpart E for APTC and CSRs and § 156.50 for user fees.

We further proposed that in situations where the state fails to substantially enforce such standards, HHS would enforce compliance, including imposing CMPs using the same standards set forth in part 156, subpart I. Based on our experience conducting audits of APTC, CSRs, and user fees, we also proposed several amendments to § 156.480(c) to ensure we can effectively oversee the payment of these amounts by QHP issuers, regardless of Exchange type (for

example, FFE, State Exchange, or SBE–FP).

As detailed below, to further support our program integrity efforts in these areas, we proposed to amend § 156.480(c) to codify additional details regarding HHS audits and to capture authority for HHS to conduct compliance reviews of QHP issuer compliance with the applicable federal APTC, CSR, and user fee standards,²⁵⁸ including the consequences for the failure to comply with an audit. In addition, we proposed amendments to §§ 156.800 and 156.805 to set forth the framework for HHS enforcement of the applicable federal APTC, CSR, and user fee standards in situations where state authorities fail to substantially enforce those standards with respect to the QHP issuers participating in State Exchanges and SBE-FPs.

We sought comment on these proposals, including with respect to how HHS could coordinate with State Exchanges and SBE-FPs to address noncompliance by QHP issuers with applicable federal APTC, CSRs, and user fee standards. We sought comment on ways to balance enforcement by State Exchanges and SBE-FPs and the protection and oversight of federal funds by HHS. We are finalizing the proposal to apply the same audit requirements to QHP issuers participating in SBE-FP states as for QHP issuers participating in FFE states. As such, QHP issuers in SBE-FP states will be required to comply with HHS audits under § 156.480(c) to confirm compliance with the applicable standards established in part 156, subpart E for APTC and CSRs and § 156.50 for user fees. We are also finalizing the APTC, CSR, and user fee audit requirements at § 156.480(c) with slight modifications to certain audit timeframes, as well as HHS's authority to impose CMPs on issuers in State Exchanges and SBE-FPs when the State Exchange or SBE-FP fails to substantially enforce the applicable federal APTC, CSR, and user fee standards at §§ 156.800 and 156.805. We are also finalizing the accompanying amendments to establish authority for HHS to conduct compliance reviews to confirm QHP issuer compliance with the federal APTC, CSR, and user fee standards.

We received public comments on the proposed updates and policies regarding

²⁵⁴ See 78 FR 65077 and 65078.

 $^{^{255}\,\}mathrm{See}$ the proposed Program Integrity Rule, 78 FR 37058. Also see 78 FR 65077 and 65078.

²⁵⁶ Ibid.

²⁵⁷ See 78 FR 65078 and 65079.

²⁵⁸ The applicable federal standards for APTC and CSRs are found in part 156, subpart E, which apply to QHP issuers participating in all Exchanges types (FFEs, State Exchanges, and SBE–FPs). The applicable federal standards for user fees are found in 45 CFR 156.50, which apply to QHP issuers in FFEs and SBE–FPs.

the application of federal APTC, CSR, and user fee requirements to issuers in State Exchanges and SBE-FPs. The majority of the comments we received to this section were also made to the sections regarding HHS's enforcement of the applicable federal APTC, CSR, and user fee standards if a State Exchange or SBE-FP is not enforcing or fails to substantially enforce one or more of these requirements ($\S 156.480(c)(6)$); subpart I—enforcement remedies in the Exchanges, available remedies, and scope (§ 156.800); and the bases and process for imposing CMPs in the Exchanges (§ 156.805). We respond to these parallel comments in the bases and process for imposing CMPs in the Exchanges (§ 156.805) preamble section below. However, we received some comments that were specific to this section, suggesting ways for HHS to coordinate with State Exchanges and SBE-FPs to address non-compliance by QHP issuers with applicable federal APTC, CSRs, and user fee standards. The following is a summary of these comments and our responses.

Comment: Commenters emphasized that HHS should collaborate with State Exchanges and SBE-FPs and keep them informed of and involved in HHS's audits of QHP issuers that operate in their respective State Exchange or SBE-FP. They noted that State Exchanges and SBE-FPs should also be informed of upcoming issuer audits and compliance reviews, as well as audit and compliance review findings, including any amounts recouped by HHS and any enforcement action taken against issuers in their states. These commenters offered specific suggestions for how HHS could collaborate with State Exchanges and SBE-FPs. One commenter stated that HHS should provide technical assistance to the state and coordinate with the state on corrective action required of any issuers in the state, if necessary. Another commenter asked that HHS reconsider the role of State Exchanges in audits and revise the audit process accordingly. This commenter suggested creating one audit process for FFE issuers and a different one for State Exchange and SBE-FP issuers, and further suggested HHS could consider creating different processes for State Exchange and SBE-FP issuers, as well as different processes among State Exchanges, as necessary.

Response: HHS generally intends its approach to audits, compliance reviews, and enforcement activities of issuers to be collaborative processes with issuers, states, State Exchanges, and SBE–FPs. HHS will continue to coordinate with State Exchanges and SBE–FPs, including notifying State Exchanges and

SBE-FPs when an audit or compliance review involves an issuer in their state. Additionally, HHS will also consider taking a different approach for conducting APTC, CSR, and user fee audits and compliance reviews for State Exchange issuers, such that HHS more closely involves State Exchanges in the process, to the extent possible and appropriate based on the specific State Exchange and the circumstances involved. This includes HHS considering how best to coordinate APTC, CSR, and user fee audits for State Exchange issuers with existing independent external audit activities that State Exchanges are required to conduct annually, under 45 CFR 155.1200, that cover similar or related Exchange functions such as eligibility determinations, enrollments, and the reporting of eligibility and enrollment data to HHS. State Exchanges are required to report the results of these external audits to HHS and establish corrective action plans for findings, which are jointly monitored by the State Exchange and HHS. In addition, HHS will continue to work with State Exchanges and SBE-FPs to enforce the applicable federal APTC, CSR, and user fee standards, as detailed in the below section on bases and process for imposing CMPs in the Exchanges (§ 156.805).

We appreciate commenters' suggestions and agree that HHS may provide technical assistance to the state and coordinate with the state on corrective action required of any issuers in the state, if necessary, to help guide collaboration efforts with State Exchanges and SBE-FPs with respect to ensuring issuer compliance with federal APTC, CSR, and user fee standards and audits. We intend to consider the various recommendations for potential enhancements to the process for HHS audits and compliance reviews of federal APTC, CSR, and user fee standards, including potential ways to further enhance the collaboration with state regulators, State Exchanges, and SBE-FPs. However, as explained in the proposed rule, the proposed updates were intended to build on the existing framework established in the second Program Integrity Rule and clarify HHS's authority with respect to oversight and enforcement of compliance with federal APTC, CSR, and user fee standards in State Exchange and SBE-FP states. 259 We also remind stakeholders that the APTC, CSR,²⁶⁰ and user fee programs are

federal funds, and the focus of these audits will be on issuer compliance with applicable federal standards.

HHS will consider recommendations to enhance the QHP issuer audit and compliance review processes to take into consideration existing audit activities that HHS requires State Exchanges to conduct annually under § 155.1200, the variation between FFE, SBE-FP, and State Exchange issuers, as well as the variation among issuers participating in the different State Exchanges. In all cases, HHS will continue to collaborate with the State Exchange or SBE-FP to enforce the applicable federal APTC, CSR, and user fee standards. Further, one of the goals of these amendments is to ensure the timely and accurate completion of audits of federal funds under the APTC, CSR, and user fee programs. Therefore, based on our experience to date conducting 2014 benefit year CSR audits, to ensure the protection of federal funds and compliance with applicable federal requirements, HHS will generally lead the efforts to audit compliance with federal APTC, CSR, and user fee standards (where applicable) under § 156.480(c).

After consideration of the comments received on these proposals, we are finalizing the provision to apply the same audit requirements to QHP issuers participating in SBE-FP states as for QHP issuers participating in FFE and State Exchange states as proposed. As such, QHP issuers in SBE-FP states will be required to comply with HHS audits and compliance reviews under § 156.480(c) to confirm compliance with the applicable standards established in part 156, subpart E for APTC and CSRs and § 156.50 for user fees. We are also finalizing the APTC, CSR, and user fee audit requirements at § 156.480(c), as well as HHS's authority to impose CMPs on issuers in State Exchanges and SBE-FPs when the State Exchange or SBE-FP fails to substantially enforce the applicable federal APTC, CSR, and user fee standards at $\S\S\,156.800$ and 156.805.

b. Audits and Compliance Reviews of APTC, CSRs, and User Fees (§ 156.480(c))

In prior rulemaking, we codified authority for HHS to audit an issuer that offers a QHP in the individual market through an Exchange to assess compliance with the requirements of part 156, subpart E.²⁶¹ We also previously codified general authority for HHS to periodically audit a QHP

²⁵⁹ See 78 FR 65077 and 65078.

 $^{^{260}\,\}mathrm{The}$ CSR program was 100 percent federal funds prior to October 2017, when CSR payments

to issuers were discontinued due to lack of a Congressional appropriation.

^{261 78} FR 65077 and 65078.

issuer's financial records related to its participation in an FFE.262 Recently, HHS completed the audits for the 2014 benefit year CSR payments. During these audits, HHS encountered challenges working with some issuers. Specifically, HHS experienced difficulties receiving requested audit data and materials in a timely fashion and receiving data in a format that is readily usable for purposes of conducting the audit. As such, similar to the proposals related to audits of issuers of reinsurance-eligible plans and risk adjustment covered plans discussed earlier in the proposed rule, we proposed to amend § 156.480(c) to provide more clarity around the issuer requirements for APTC, CSR, and user fee audits. The proposed amendments codify more details about the audit process and clarify issuer obligations with respect to these audits, including what it means to comply with an audit and the consequences for failing to comply with such requirements. Additionally, we proposed to amend § 156.480(c) to also capture and clarify HHS's ability to audit FFE and SBE–FP user fees and the accompanying issuer requirements for such audits. As such, we proposed to rename § 156.480, "Oversight of the Administration of the Advance Payments of the Premium Tax Credit, Cost-sharing Reductions, and User Fee Programs." HHS currently reviews compliance with applicable federal user fee standards when conducting APTC audits because the same data is used for both purposes; as such, we explained, there would be minimal increased burden as a result of these proposals.

We also proposed several amendments to § 156.480(c) to expand the oversight tools available to HHS beyond traditional audits to also provide authority for HHS to conduct compliance reviews of QHP issuers to assess compliance with the applicable federal APTC, CSR, and user fee standards. We explained that these proposed HHS compliance reviews would follow the standards set forth for compliance review of QHP issuers participating in FFEs established in 45 CFR 156.715. However, compliance reviews under this section would be conducted to confirm QHP issuer compliance with the federal APTC, CSR, and user fee standards in subpart E of part 156 and 45 CFR 156.50 for user fees, as applicable, and they would generally extend to QHP issuers

participating in all Exchanges.²⁶³ A compliance review may be targeted at a specific potential error and conducted on an ad hoc basis.²⁶⁴ For example, HHS may require an issuer to submit data pertaining to specific data submissions. We explained that we believed this flexibility is necessary and appropriate to provide HHS a mechanism to address situations in which a systematic error or issue is identified during the random and targeted auditing of a sample of QHP issuers, and HHS suspects similarly situated issuers may have experienced the same systematic error or issue but were not selected for audit in the year in question. We further noted that we intend to continue our collaborative oversight approach and coordinate with State Exchanges and SBE-FPs to ensure OHP issuer compliance with the applicable standards in part 156, subpart E and 45 CFR 156.50.

First, we proposed to rename § 156.480(c) to "Audits and Compliance Reviews' to clarify that the authority described in this section would apply to audits and the proposed HHS compliance reviews to evaluate QHP issuer compliance with the applicable federal APTC, CSR, and user fee standards. We similarly proposed to update the introductory language in § 156.480(c) to incorporate a reference to HHS compliance reviews. As amended, § 156.480(c) would provide that HHS or its designee may audit and perform compliance reviews to assess whether an issuer that offers a QHP in the individual market through an Exchange is in compliance with the applicable requirements of subpart E, part 156, and 45 CFR 156.50. We proposed to capture in a new sentence in the amended § 156.480(c) that HHS would conduct these compliance reviews consistent with the standards set forth in 45 CFR 156.715. As detailed earlier in this preamble, these oversight tools would be available to HHS to evaluate compliance by OHP issuers participating in all Exchanges with the applicable federal APTC, CSR, and user fee standards.

Second, we proposed to add new § 156.480(c)(1) to establish notice and conference requirements for these audits. Proposed new paragraph (c)(1) states that HHS would provide at least 15 calendar days advance notice of its intent to conduct an audit of an QHP issuer under § 156.480(c). Under

proposed paragraph (c)(1)(i), HHS proposed to codify that all audits would include an entrance conference at which the scope of the audit would be presented and an exit conference at which the initial audit findings would be discussed.

Third, HHS proposed to add new paragraph (c)(2) to capture the requirements issuers must meet to comply with an audit under this section. Under the proposed paragraph (c)(2)(i), we proposed to require the issuer to ensure that its relevant employees, agents, contractors, subcontractors, downstream entities, and delegated entities cooperate with any audit or compliance review under this section. In new proposed paragraph (c)(2)(ii), we proposed to require issuers to submit complete and accurate data to HHS or its designees that is necessary to complete the audit, in the format and manner specified by HHS, no later than 30 calendar days after the initial deadline communicated and established by HHS at the entrance conference described in proposed paragraph (c)(1)(i). For example, for CSR audits, HHS may request that QHP issuers provide a re-adjudicated claims data extract for the selected sample of policies to verify accuracy of the readjudication process and reported amounts (this would include verification of all elements necessary to perform accurate re-adjudication) and a data extract containing incurred claims for the selected sample of policies to verify accuracy of actual amount the enrollee(s) paid for EHBs via an Electronic File Transfer. As another example, for APTC audits, issuers may be asked to provide data to validate and support APTC payments received for the applicable benefit year.

Fourth, under proposed § 156.480(c)(2)(iii), HHS proposed to require that issuers respond to any audit notices, letters, and inquires, including requests for supplemental or supporting information, no later than 15 calendar days after the date of the notice, letter, request, or inquiry. We explained that we believe that the proposed requirements in paragraph (c)(2) are necessary and appropriate to ensure the timely completion of audits and to protect the integrity of the APTC, CSR, and user fee programs and the payments made thereunder.

Fifth, recognizing that there may be situations that warrant an extension of the timeframes under paragraph (c)(2)(ii) or (iii), as applicable, we proposed to also add a new paragraph (c)(2)(iv) to establish a process for an issuer to request an extension. To request an extension, we proposed to

²⁶² See 45 CFR 156.705(a)(1). Also see 78 FR 65078 and 65079.

²⁶³ HHS does not intend to conduct user fee compliance reviews of QHP issuers participating in State Exchanges that do not rely on the Federal platform. Such reviews would be limited to QHP issuers participating in FFE and SBE–FP states.
²⁶⁴ See 78 FR 65100.

require the issuer to submit a written request to HHS within the applicable timeframe established in paragraph (c)(2)(ii) or (iii). The written request would have to detail the reasons for the extension request and the good cause in support of the request. For example, good cause may include an inability to produce information in light of unforeseen emergencies, natural disasters, or a lack of resources due to a PHE. If the extension is granted, the issuer must respond within the timeframe specified in HHS's notice granting the extension of time.

Sixth, under § 156.480(c)(3), HHS proposed that it would share its preliminary audit findings with the issuer, and further proposed that the issuer would then have 30 calendar days to respond to such findings in the format and manner as specified by HHS. HHS would describe the process, format, and manner by which an issuer can dispute the preliminary audit findings in the preliminary audit report sent to the issuer. For example, if the issuer disagrees with the findings set forth in the preliminary audit report, HHS would require the issuer to respond to such findings by submitting written explanations that detail its dispute(s) or additional rebuttal information via Electronic File Transfer. HHS proposed under paragraph (c)(3)(i) that if the issuer does not dispute or otherwise respond to the preliminary findings within 30 calendar days, the audit findings would become final. In new proposed paragraph (c)(3)(ii), if the issuer timely responds and disputes the preliminary audit findings within 30 calendar days, HHS would review and consider such response and finalize the audit findings after such review. HHS would provide contact and other information necessary for an issuer to respond to the preliminary audit findings in the preliminary audit report sent to the issuer.

Seventh, HHS proposed to add a new section at § 156.480(c)(4) to capture the process and requirements related to final audit findings and reports. If an audit results in the inclusion of a finding in the final audit report, the issuer would be required to comply with the actions set forth in the final audit report in the manner and timeframe established by HHS. We noted that the actions set forth in the final audit report could require an issuer to return APTC or CSRs or make additional user fee payments. HHS further proposed that (1) the issuer must provide a written corrective action plan to HHS for approval within 30 calendar days of the issuance of the final audit report; (2) the issuer must implement

the corrective action plan; and (3) the issuer must provide HHS with written documentation demonstrating the adoption and completion of the required corrective actions.

If an issuer fails to comply with the audit requirements set forth in new proposed § 156.480(c), HHS proposed in paragraph (c)(5)(i) that HHS would notify the issuer of payments received that the issuer has not adequately substantiated, and in new proposed paragraph (c)(5)(ii), HHS would notify the issuer that HHS may recoup any payments identified as not adequately substantiated. Therefore, the continued failure to respond to or cooperate with an audit under paragraph (c) and provide the necessary information to substantiate the payments made could result in HHS recouping up to 100 percent of the APTC or CSR payments made to an issuer for the benefit year(s) that are the subject of the audit.

We clarified in the proposed rule that APTC and CSR amounts recovered by HHS as a result of an audit under § 156.480(c) would be paid to the U.S. Treasury. We further noted that user fee amounts recovered by HHS as a result of an audit under § 156.480(c) would be paid to the ACA Marketplace user fee program collection account.

Lastly, HHS proposed to add a new paragraph (c)(6) to § 156.480 to codify HHS's ability to enforce the applicable federal APTC, CSR, and user fee standards if a State Exchange or SBE-FP is not enforcing or fails to substantially enforce one or more of these requirements. In instances where HHS enforces compliance with the applicable APTC, CSR, and user fee standards with respect to QHP issuers participating in State Exchanges or SBE-FPs, HHS proposed to use the same standards and processes as outlined in §§ 156.805 and 156.806 for QHP issuers participating in an FFE with respect to the imposition of CMPs. This would include the proposed extension of the process outlined in § 156.901, et seq., for the QHP issuer to appeal the imposition of CMPs. For a discussion of the framework and proposed accompanying penalties for non-compliance in situations where HHS is responsible for enforcement of these requirements, see the following discussion of proposed changes to §§ 156.800 and 156.805.

We sought comment on these proposals, including HHS's clarification of its compliance review authority, the proposed timeframes and processes for issuers to respond to audit notices and requests for information and for issuers to request extensions of those timeframes, and the proposals related to HHS's authority to enforce compliance

with the federal APTC, CSR, and user fee requirements if a State Exchange or SBE-FP is not enforcing or fails to substantially enforce one or more of these requirements. We are finalizing these provisions as proposed, with slight modifications to certain audit timelines in response to comments stating that issuers need more time during audits to provide complete and accurate data. HHS will provide at least 30 calendar days advance notice of its intent to conduct an audit, rather than the proposed 15 calendar days. If HHS determines the need for a corrective action plan as the result of an audit, the issuer must provide a written corrective action plan to HHS for approval within 45 calendar days of the issuance of the final audit report, rather than the proposed 30 calendar days. As noted in the above sections on audits of issuers of reinsurance-eligible plans and risk adjustment covered plans (§§ 153.410(d) and 153.620(c)), these modified timeframes apply across the parallel HHS audit provisions for reinsurance, risk adjustment, ATPC, CSR, and user fee audits.

We also clarify that we will recoup monies owed due to a finding as the result of a reinsurance, risk adjustment, APTC, CSR, or user fee audit using the same method with which we collect all debts. That is, we will first net using the process set forth in 45 CFR 156.1215, and we will then invoice issuers for the remaining debt.

We received public comments on the proposed updates to audits and compliance reviews of federal APTC, CSR, and user fee standards (§ 156.480(c)). The majority of the comments we received to the proposed updates outlined in this section were also made to the sections regarding audits and compliance reviews of issuers of reinsurance-eligible plans (§ 153.410(d)) and audits and compliance reviews of issuers of risk adjustment covered plans (§ 153.620(c)). We respond to all of these parallel comments in this section. As noted above, the comments we received to the proposed § 156.480(c)(6) were also made to the sections regarding the application of requirements to issuers in State Exchanges and SBE-FPs (§ 156.480), enforcement remedies in the Exchanges (§ 156.800), and bases and process for imposing CMPs in the Exchanges (§ 156.805). We summarize and respond to those parallel comments in the § 156.805 preamble section below.

The following is a summary of the parallel general comments we received to all of the audits and compliance review proposals in this rule and the specific comments on the proposed

updates to § 156.480(c), with the exception of the comments submitted on § 156.480(c)(6), and our responses.

Comment: Several commenters supported the various audit and compliance review proposals, noting that they will clarify expectations and requirements, ensure compliance, and protect federal funds. Other commenters opposed the proposals and asked HHS to put audit standards in guidance, rather than regulation, as this would maintain flexibility and make it easier for HHS to revise requirements and improve the audit process.

Response: We agree that these provisions will provide clarity for issuers and better facilitate compliance with any HHS audits, as well as enable HHS to protect federal funds. Many of the provisions are merely a codification of the current audit processes that have been used in prior reinsurance, APTC, CSR, and user fee audits.²⁶⁵ We maintain our commitment to working with issuers to meet these requirements, and we note that we proposed and are finalizing a process to allow issuers to submit written requests to extend certain audit response deadlines with good cause.²⁶⁶

We also note that, to provide clear and enforceable standards, we proposed and are finalizing the codification of these procedures in regulation.

Comment: A few commenters requested more flexibility regarding the data format issuers must use.

Response: In order for HHS to complete an audit, we must receive data from issuers in a set format communicated to issuers at the audit entrance conference to be able to analyze data from all issuers using the same procedures. As we explained in the proposed rule, HHS experienced difficulties receiving requested audit data in a format that is readily usable for purposes of conducting the audit. Therefore, we believe it is appropriate and necessary to codify in regulation a requirement that issuers must submit complete and accurate data to HHS or its designees that is necessary to complete the audit, in the format and manner specified by HHS. For example, for CSR audits, HHS may request that OHP issuers provide a re-adjudicated claims data extract for the selected sample of policies to verify accuracy of the re-adjudication process and reported amounts (this would include verification of all elements necessary to

perform accurate re-adjudication) and a data extract containing incurred claims for the selected sample of policies to verify accuracy of actual amount the enrollee(s) paid for EHBs via an Electronic File Transfer. For APTC audits, issuers may be asked to provide data to validate and support APTC payments received for the applicable benefit year. To reduce burden on issuers, we anticipate being able to continue to review compliance with applicable federal user fee standards when conducting APTC audits because the same data is used for both purposes. We also note that if more time is needed to compile the requested data in the required format, an issuer could request an extension under §§ 153.410(d)(2)(iv), 156.620(c)(2)(iv), or 156.480(c)(2)(iv), as applicable.

Comment: Many commenters requested longer timelines for audit notice and issuer responses to HHS to the various audit requests, noting that issuers would need more time than what was proposed in order for issuers to provide complete and accurate data or otherwise respond to HHS requests. Some commenters requested that HHS provide 30 calendar days advance notice of its intent to conduct an audit, rather than the proposed 15 calendar days. Other commenters requested that HHS set the deadline for issuers to submit corrective action plans at either 45 or 60 calendar days, rather than the proposed 30 calendar days. One commenter requested that HHS set the initial data submission deadline at 45 calendar days and subsequent request deadlines at 30 calendar days, rather than the proposed 30 calendar days and 15 calendar days, respectively. Other commenters asked that HHS permit extensions to the timeframes set forth for these audits. A couple of commenters asked that HHS be more timely with respect to performing audits.

Response: We appreciate these comments and acknowledge that our experience with 2014 benefit year CSR and reinsurance audits demonstrated that issuers need sufficient time to provide complete and accurate data for audits, and we acknowledge that some issuers will face difficulties in retrieving and properly formatting data from prior benefit years. We also recognize that it would be beneficial for all stakeholders if issuers could receive more advance notice of an upcoming audit or compliance review to allow the issuer (and HHS or its designee) to begin preparation and coordination efforts earlier. Therefore, in response to these comments, we are modifying the timeframe in § 156.480(c)(1) to require

HHS to provide at least 30 calendar days advance notice of its intent to conduct an APTC, CSR, or user fee audit rather than the proposed 15 calendar days. Similarly, we are modifying the timeframes in §§ 153.410(d)(1) and 153.620(c)(1) to require HHS to provide at least 30 calendar days advance notice of its intent to conduct an audit of a reinsurance-eligible plan or a risk adjustment covered plan, respectively, rather than the proposed 15 calendar days. As for the time allowed to provide the initial audit submission, HHS will continue to maintain the 30 calendar day deadline. HHS believes that in order to complete the audit process in a timely manner and based on prior audit experience, after giving issuers 30 calendars days advance notice of the audit, which is 15 days longer than initially proposed, an additional 30 days to provide the initial data submission for the audit is more than reasonable. We note that as stated in §§ 153.410(d)(2)(iv), 153.620(c)(2)(iv), and 156.480(c)(2)(iv), we proposed and are finalizing the flexibility for issuers to seek extensions for reinsurance, risk adjustment, and APTC, CSR, and user fee audit-related requests from HHS under §§ 153.410(d)(2)(ii) or (iii), 153.620(c)(2)(ii) or (iii), and 156.480(c)(2)(ii) or (iii), respectively, but believe the 30 calendar day timeline to provide the initial audit submission strikes the appropriate balance and will allow HHS to work with issuers to ensure the proper data is provided and the audit can be conducted and completed more efficiently. We are also maintaining the 30 calendar day timeframe for issuers to respond to preliminary audit findings.²⁶⁷ We similarly believe that this timeframe strikes the appropriate balance and ensures these audits can be completed more efficiently.

Additionally, in response to comments suggesting a 45 calendar day deadline for issuers to provide written corrective action plans rather than the proposed 30 calendar day deadline, we will finalize a 45 calendar day timeframe to submit a corrective action plan if an audit results in the inclusion of a finding in the final audit report, rather than a 30 calendar day timeframe, at § 153.410(d)(4)(i) for reinsurance program audits, § 153.620(c)(4)(i) for risk adjustment program audits, and § 156.480(c)(4)(i) for APTC, CSR, and user fee audits. We are persuaded by these comments and agree that issuers would benefit from the extension of this timeframe because the development of a

²⁶⁵ HHS has not yet conducted any risk adjustment audits under 45 CFR 153.620(c).

 $^{^{266}}$ See 45 CFR 153.410(d)(2)(iv), 156.620(c)(2)(iv) and 156.480(c)(2)(iv), which we are finalizing as proposed.

 $^{^{267}\,\}mathrm{See}$ 45 CFR 153.410(d)(3), 153.620(c)(3), and 156.480(c)(3).

corrective action plan may require a significant amount of coordination and discussion between HHS, the state (if applicable), and the issuer in order to finalize the appropriate corrective action(s) and plan for implementation. Therefore, as finalized, the issuer must provide a written corrective action plan to HHS for approval within 45 calendar days of the issuance of the final audit report, rather than the proposed 30 calendar days, for those situations where one or more findings are included in the final audit report.²⁶⁸

HHS makes every effort to conduct audits in an efficient and timely manner and will continue to do so. The audit proposals addressed in the proposed rule and this final rule are aimed at making the audit process more efficient so that audits may be completed in a shorter length of time. However, HHS is flexible and willing to work with issuers who keep us informed of their progress but may need more time. Therefore, as we proposed, we are also finalizing at § 153.410(d)(2)(iv) for reinsurance program audits, § 153.620(c)(2)(iv) for risk adjustment program audits and § 156.480(c)(2)(iv) for APTC, CSR, and user fee audits that issuers may request an extension to certain audit deadlines by submitting a written request to HHS within the applicable timeframe(s) 269 for reinsurance program audits, risk adjustment program audits, and APTC, CSR, and user fee audits. For all of these audits, the written request would have to detail the reasons for the extension request and the good cause in support of the request and must be submitted within the applicable timeframe for responding to the HHS request.

Comment: A few commenters asked that HHS avoid audits during the annual open enrollment period (OEP) to allow issuers to focus their resources on enrollment and other OEP activities.

Response: HHS agrees that issuers should devote their resources to enrollment during the OEP and will take this request into consideration in scheduling the start of future audits. Because audits are an ongoing process and the timeline for completion is not always fixed, it may not be possible to

entirely avoid overlap between audit activities and OEP, but HHS will work with issuers to avoid situations where audit activities could undermine or otherwise negatively impact issuers' ability to focus on enrollment during the annual OEP. For example, we are finalizing the proposal to permit issuers to request an extension to certain audit deadlines at §§ 153.410(d)(2)(iv), 153.620(c)(2)(iv), and 156.480(c)(2)(iv), for audits of issuers of reinsuranceeligible plans, audits of issuers of risk adjustment covered plans, and audits of the APTC, CSR, and user fee programs, respectively. We clarify that an issuer who has made good faith efforts to otherwise comply with HHS audit requests could submit such an extension request if it needed more time with respect to completing its audit activities under 45 CFR 153.410(d)(2)(ii) or (iii) for reinsurance program audits, 45 CFR 153.620(c)(2)(ii) or (iii) for risk adjustment program audits, and 45 CFR 156.480(c)(2)(ii) or (iii) for APTC, CSR, and user fee audits, due to the overlap with the annual OEP.

Comment: Some commenters asked that HHS rely on existing audits rather than adding new audits and audit requirements.

Response: In response to these comments, we clarify that HHS is not adding new audit authority for reinsurance-eligible plans, risk adjustment covered plans, or APTC, CSRs, and user fees. Rather, we are expanding the existing authority to codify more details about audit activities to set clear expectations, facilitate compliance and enforcement, protect federal funds, and maintain program integrity. The standards being codified comprise best practices and procedures that HHS has established in audit entrance conferences and incorporates lessons learned from audits of the reinsurance and CSR programs for the 2014 benefit year, and audits of the APTC program for the 2014 through 2017 benefit years. HHS's audit regulations in these areas were finalized in earlier rulemakings.²⁷⁰ We are, however, finalizing new authority to permit HHS to conduct compliance reviews to ensure compliance with applicable reinsurance, risk adjustment, and federal APTC, CSR, and user fee standards. As explained elsewhere in this rule and in the proposed rule, we believe this additional authority related to compliance reviews is necessary and appropriate in order to provide HHS a mechanism to address situations in which a systematic error or issue is

identified during the random and targeted auditing of a sample of QHP issuers, and HHS suspects similarly situated issuers may have experienced the same systematic error or issue but were not selected for audit in the year in question.

Comment: A few commenters noted that the proposed compliance reviews would place an increased burden on states and issuers.

Response: We generally disagree that the proposed compliance review proposals would place an increased burned on states. Of particular note, these proposals, which we are finalizing in the introductory language to §§ 153.410(d), 153.620(c), and 156.480(c), involve situations where HHS—rather than the states—would conduct a review to confirm an issuer's compliance with the applicable federal program standards and requirements. While there may be some increased burden associated with coordination between HHS and the states, any such increased burden on states should be minimal. We further note that the purpose of the proposed HHS compliance reviews, as stated in the preamble section above and in the proposed rule, is to confirm QHP issuer compliance with the applicable federal reinsurance, risk adjustment, or APTC, CSR, and user fee standards. These compliance reviews are intended to be less burdensome than audits of compliance with requirements under the applicable programs, and may further be targeted at a specific potential error and conducted on an ad hoc basis. 271 For example, HHS may require an issuer to submit data pertaining to specific data submissions. We believe this flexibility is necessary and appropriate to provide HHS a mechanism to address situations in which a systematic error or issue is identified during the random and targeted auditing of a sample of QHP issuers, and HHS suspects similarly situated issuers may have experienced the same systematic error or issue but were not selected for audit in the year in question. HHS intends to conduct compliance reviews sparingly and will provide advance notice of a compliance review to the issuer being reviewed and the applicable state regulator(s), State Exchange, or SBE-FP. Therefore, while we acknowledge that there will be some burden on issuers associated with these compliance reviews, we believe the benefits for all stakeholders associated with finalizing this additional oversight tool outweighs such burdens as it allows for a more targeted approach to ensure

²⁶⁸ We also reiterate that an issuer, acting in good faith, can submit an extension request if it finds additional time is needed to respond to certain HHS requests stemming from these audits. See 45 CFR 153.410(d)(2)(iv), 156.620(c)(2)(iv) and 156.480(c)(2)(iv).

²⁶⁹ As proposed and finalized, issuers may request to extend the following timeframes: (1) For reinsurance program audits, the timeframes under 45 CFR 153.410(d)(2)(ii) or (iii); (2) for risk adjustment audits, the timeframes under 45 CFR 153.620(c)(2)(ii) or (iii); and (3) for APTC, CSR, and user fee audits, the timeframes under 45 CFR 156.480(c)(2)(ii) or (iii).

 $^{^{270}\,\}mathrm{See},$ for example, 78 FR at 65077–65078; 79 FR at 13770–13771 and 13781–13782.

²⁷¹ See 78 FR 65100.

compliance with applicable federal requirements.

Comment: One commenter asked that HHS only conduct CSR audits of issuers for the time during which HHS made advance CSR payments; that is, the 2014 benefit year through September of the 2017 benefit year.

Response: At this time, HHS is beginning audits of the 2015 and 2016 benefit year of CSR payments. HHS has not yet made a determination as to whether or not CSR audits will be conducted for the 2017 benefit year and hevond

Comment: One commenter supported HHS recouping up to 100 percent of applicable APTC or CSR payments. Another commenter stated that HHS should use the normal debt collection process of netting and then invoicing issuers to collect any remaining debt amount owed as a result of audit findings and that the proposed 100 percent recoupment of APTC, CSR, reinsurance, and risk adjustment payments was unreasonable.

Response: If an issuer is not able to adequately substantiate the APTC, CSR, reinsurance, or risk adjustment payments it received from HHS during the course of an audit, HHS has an obligation to recoup federal funds and protect the integrity of these programs. We further note that issuers have separate record retention requirements that must be met and the documents required to be maintained can be utilized to substantiate payment.272 Therefore, it is appropriate and necessary for HHS to recoup any APTC, CSR, reinsurance, or risk adjustment payments made to issuers that were not adequately substantiated by the issuer during the course of an audit. This may include up to 100 percent recoupment if the issuer is entirely unable to substantiate the payments it received that are the subject of the audit. However, we anticipate that this situation would be extremely rare, and HHS would work with the issuer to provide reasonable opportunities for the issuer to substantiate the payments it received under these programs. As with all debt collection for the ACA financial programs, HHS will follow the process set forth in § 156.1215 to collect any amounts owed as a result of an audit under 45 CFR 153.410(d), 153.620(c) and 156.480(c). We affirm that we therefore intend to leverage the existing netting and debt collection process to recoup monies owed due to a finding as the result of these audits. That is, to recoup an amount identified as owed as

²⁷² See §§ 153.410(c), 153.620(b), 156.480(a), and

Comment: A couple of commenters requested more information on the proposed updates to audits and compliance reviews of APTC, CSRs, and user fees under § 156.480(c) and, more specifically, the proposed inclusion of user fees as part of the audit framework in this regulation. One commenter wanted more information on the user fee audits referred to in this proposal. Another commenter wanted HHS to publish audit protocols with information on audit requirements, file layouts, submission requirements, and source documentation for the § 156.480(c) audits.

Response: As stated in the preamble section above, HHS currently reviews compliance with applicable federal user fee standards in 45 CFR 156.50 when conducting APTC audits, because the same data is used to audit both APTC and user fees. Audits of APTC and user fees are conducted simultaneously using the same data; as such, there is minimal increased burden as a result of the amendments being finalized in this rule to consolidate the user fee audit standards alongside the APTC and CSR audit standards in § 156.480(c).

We further note that HHS currently provides information on audit requirements, file layouts, submission requirements, and source documentation as part of the applicable audit entrance conference. Issuers selected for audit receive this information at the entrance conference, which they are required to attend, and also receive further details on these requirements from HHS via the audit contractor. Guidance documents related to APTC audit requirements are also available on REGTAP.273

After consideration of the comments on the audit proposals in §§ 153.410(d), 153.630(c), and 156.480(c), we are finalizing these provisions as proposed, with slight modifications to certain audit timelines in response to comments stating that issuers need more time during audits to provide complete and accurate data and to provide written corrective action plans. HHS will provide at least 30 calendar days advance notice of its intent to conduct a reinsurance, risk adjustment, APTC, CSR, or user fee audit, rather than the

proposed 15 calendar days. If an audit results in the inclusion of a finding in the final audit report, the issuer must provide a written corrective action plan to HHS for approval within 45 calendar days of the issuance of the final audit report, rather than the proposed 30 calendar days.

We also clarify that we will recoup monies owed due to a finding as the result of a reinsurance, risk adjustment, APTC, CSR, or user fee audit using the same method with which we collect all ACA financial program debts. That is, we will first net using the process set forth in 45 CFR 156.1215, and we will then invoice issuers for the remaining debt.

7. Subpart I—Enforcement Remedies in Federally-Facilitated Exchanges; Available Remedies; Scope. (§ 156.800)

We proposed to rename Subpart I to "Enforcement Remedies in the Exchanges," and to make other amendments to clarify that HHS has the ability to impose CMPs when it is enforcing the applicable federal requirements in part 156, subpart E and 45 CFR 156.50 for user fees, regardless of whether the Exchange is established and operated by a state (including a regional Exchange or subsidiary exchange) or by HHS.274 As explained in prior rulemaking, in states where there is a State Exchange, the State Exchange has primary enforcement authority over QHP issuers participating in the Exchange and ensuring compliance with the applicable federal APTC, CSR, and user fee standards. 275 However, consistent with the framework established in section 1321(c)(2) of the ACA, HHS has authority to step in to enforce requirements related to the operation of Exchanges and the offering of QHPs through Exchanges if a state fails to do so.²⁷⁶ ²⁷⁷ As such, in the case of a determination by the Secretary that a State Exchange or SBE-FP has failed to enforce or substantially enforce a federal requirement (or requirements) related to QHP issuer participation in the individual market Exchange, HHS has authority to step in and enforce

a result of an audit under 45 CFR 153.410(d), 156.620(c), and 156.480(c), we will first net using the process set forth in 45 CFR 156.1215, and will then invoice issuers for the remaining debt (if any is owed).

Advance Payments of the Premium Tax Credit,' April 1, 2019. Available at (login required): https:// www.regtap.info/uploads/library/CMS_PPFMG_EA_ CMSAPTCAudits_5CR_040119.pdf.

 $^{^{273}}$ See, for example, "CMS Issuer Audits of the

²⁷⁴ Exchange models include State Exchanges, SBE-FPs, and FFEs. HHS does not intend to use this authority to impose CMPs related to user fee standards applicable to QHP issuer participating in State Exchanges.

²⁷⁵ See the proposed Program Integrity Rule, 78 FR 37058. Also see 78 FR 65077 and 65078. 276 Ibid.

²⁷⁷ Section 1321(c)(2) of the ACA provides that the enforcement framework established in section 2736(b), which was renumbered 2723(b), of the PHS Act shall apply to the enforcement of requirements established in section 1321(a)(1).

QHP issuer compliance with the requirement(s).

Through its cross-reference to section 2723(b) of the PHS Act,278 section 1321(c)(2) of the ACA authorizes the Secretary to impose CMPs for noncompliance with applicable federal Exchange requirements. In the proposed rule, we proposed to codify HHS authority to impose CMPs for noncompliance by QHP issuers that participate or have participated in a State Exchange or SBE-FP in situations where HHS steps in to enforce certain requirements. Specifically, this proposal is focused on ensuring compliance with the standards for APTC, CSR payments, and user fees captured in part 156, subpart E and 45 CFR 156.50. Under this proposal, we would apply the bases and follow the processes for imposing CMPs as set forth in § 156.805, would send a notice of non-compliance as set forth in § 156.806, and would extend the administrative review and appeal process set forth in § 156.901, et seq. to provide a forum for QHP issuers in State Exchanges and SBE–FPs to appeal the imposition of CMPs by HHS. We did not propose to extend the authority to decertify a QHP under § 156.800(a)(2) for non-compliance by QHP issuers in State Exchanges or SBE-FPs; QHP decertification in State Exchanges or SBE-FPs would remain an available enforcement tool for the applicable Exchange. We explained that this proposal is not intended to duplicate state enforcement efforts, as HHS generally depends on State Exchanges and SBE-FPs to enforce federal requirements applicable to QHPs and QHP issuers participating in the state's individual market Exchange. The proposed amendments are instead intended to establish an enforcement framework to capture situations where HHS is responsible for enforcement if a State Exchange or SBE-FP fails to do so and is focused on the federal APTC, CSR, and user fee requirements in order to protect federal funds.

We also explained that we expected that states that established a State Exchange or SBE–FP will enforce all applicable federal requirements applicable to QHPs and QHP issuers participating in Exchanges, including the applicable APTC, CSR, and user fee standards captured in part 156, subpart E and 45 CFR 156.50. However, to address situations where a State Exchange or SBE–FP fails to enforce

these federal Exchange requirements, consistent with the framework established in section 2723(b) of the PHS Act, we proposed that if HHS determines that a State Exchange or SBE-FP lacks authority or has otherwise failed to substantially enforce the requirements captured in part 156, subpart E or 45 CFR 156.50, HHS would step in to enforce these requirements with respect to QHP issuers participating in the State Exchange or SBE-FP. Once this determination is made, HHS would become responsible for enforcement of these provisions and would take appropriate action to ensure QHP issuer compliance with the applicable requirement(s),279 and may impose CMPs, if appropriate. To more clearly capture HHS's authority to impose CMPs in these situations, we proposed to amend the introductory sentence to § 156.800(a) to replace the current references to the "Federallyfacilitated Exchange" with references to "an Exchange." We also proposed to amend § 156.800(b) to remove the word "only" from the sentence describing the scope of HHS sanctions with respect to QHP issuers participating in FFEs and to add a new second sentence that affirms HHS authority to impose CMPs for non-compliance with the applicable requirements in part 156, subpart E and 45 CFR 156.50 by QHP issuers participating in State Exchanges and SBE-FPs.

We also noted that we intend to continue our collaborative enforcement approach and would coordinate our actions with state efforts to avoid duplication and to streamline oversight of the administration of APTC, CSRs, and user fees. We solicited comments for how HHS can collaborate with State Exchanges and SBE-FPs to proactively address non-compliance with applicable federal requirements and share compliance tools regarding APTC, CSRs, and user fees. We are finalizing the proposals to (1) amend the introductory sentence to § 156.800(a) to replace the current references to the "Federallyfacilitated Exchange" with references to "an Exchange," and (2) amend § 156.800(b) to remove the word "only" from the sentence describing the scope of HHS sanctions with respect to QHP issuers participating in FFEs and to add a new sentence that affirms HHS

authority to impose CMPs for noncompliance with the applicable requirements in part 156, subpart E and 45 CFR 156.50 by QHP issuers participating in State Exchanges and SBE–FPs.

We received public comments on the proposed updates to Subpart I— Enforcement Remedies in Federally-Facilitated Exchanges; Available remedies; Scope (§ 156.800). The comments we received to this section were also made to the sections regarding the application of requirements to issuers in State Exchanges and SBE-FPs (§ 156.480), HHS enforcement of the applicable federal APTC, CSR, and user fee standards if a State Exchange or SBE-FP is not enforcing or fails to substantially enforce one or more of these requirements (§ 156.480(c)(6)), and the bases and process for imposing CMPs in the Exchanges (§ 156.805), and we responded to all of these parallel comments in the bases and process for imposing CMPs in the Exchanges (§ 156.805) preamble section below.

After consideration of the relevant comments, we are finalizing the amendments to § 156.800 as proposed. As detailed further in the below section on the bases and process for imposing CMPs in the FFEs, we also clarify that we intend to leverage this authority to pursue enforcement and the imposition of CMPs in State Exchange and SBE-FP states where HHS is responsible for enforcement in a targeted manner with a focus on egregious or repeated occurrences of QHP issuer noncompliance with the applicable APTC, CSR, and user fee standards that are discovered as the result of audits and the State Exchange or SBE-FP fails to substantially enforce the applicable standard(s). We further note that we did not propose and are not finalizing any substantive changes related to the enforcement framework applicable to QHP issuers participating in FFEs. The below section on bases and process for imposing CMPs in the Exchanges discusses this point in further detail.

8. Bases and Process for Imposing Civil Money Penalties in Federally-Facilitated Exchanges (§ 156.805)

We also proposed to amend § 156.805 to more clearly reflect HHS's authority to impose CMPs due to non-compliance with respect to the applicable federal APTC, CSR, and user fee standards against a QHP issuer participating in a State Exchange or SBE–FP. Under this proposal, we would use the same bases and process currently captured in § 156.805 for imposing CMPs on QHP issuers participating in an FFE. More specifically, in § 156.805, we proposed

²⁷⁸ While the text of section 1321(c)(2) of the ACA cites to section 2736(b) of the PHS Act, this PHS Act provision was renumbered a second time to section 2723(b) as part of the technical and conforming amendments in the ACA. See section 1562(c)(13)(C) of the ACA.

²⁷⁹ As detailed earlier, when HHS is responsible for enforcement of these Exchange requirements, we are finalizing the proposal to extend authority for HHS to pursue a compliance review under § 156.480(c), consistent with the framework establish in § 156.715, to confirm compliance with federal APTC, CSR, and user fee requirements by a QHP issuer participating in a State Exchange or SRE-FP

renaming this section to "Bases and process for imposing CMPs in the Exchanges," and also proposed to amend the introductory language in § 156.805(a) to use the words "an Exchange," instead of "Federallyfacilitated Exchange," to more clearly capture HHS's authority to impose CMPs on QHP issuers participating in State Exchanges and SBE-FPs who fail to comply with the applicable requirements in part 156, subpart E or § 156.50 in situations where HHS is responsible for enforcement. We similarly proposed to modify § 156.805(a)(5)(i) where the reference to 'HHS" currently appears to also incorporate a reference to "an Exchange" to clarify that all QHP issuers must avoid intentionally or recklessly misrepresenting or falsifying APTC, CSR, and user fee information to both HHS and Exchanges, regardless of whether HHS or a state operates the Exchange. We proposed this amendment to clarify that HHS has authority to impose CMPs against QHP issuers participating in State Exchanges and SBE-FPs who misrepresent or falsify APTC, CSR, and user fee information provided to HHS in situations where HHS is responsible for enforcement of the requirements in part 156, subpart E or § 156.50, including when HHS is performing an audit or compliance review under § 156.480(c). If HHS seeks to use this authority to impose CMPs against a QHP issuer participating in a State Exchange or SBE-FP, we proposed the issuer would have the opportunity to appeal the CMPs following the existing framework for administrative hearings in § 156.901, et seq.

Finally, we proposed to add a new paragraph (f) to § 156.805 to capture in this regulation details on the circumstances requiring HHS enforcement of the applicable requirements in part 156, subpart E and § 156.50. Consistent with the framework established in section 2723(b) of the PHS Act and section 1321(c) of the ACA, we propose in new $\S 156.805(f)(1)$ that HHS's authority to enforce in these situations would be limited to situations where the State Exchange or SBE-FP notifies HHS that it is not enforcing these requirements or if HHS makes a determination using the process set forth at 45 CFR 150.201, et seq. that a State Exchange or SBE-FP is failing to substantially enforce these requirements.280 In new proposed $\S 156.805(f)(2)$, we proposed to affirm that when HHS is responsible for enforcement in these circumstances,

HHS may impose CMPs on an issuer in the State Exchange or SBE–FP, in accordance with the bases and process set forth in this section. As noted in the proposed rule, this includes the ability for a QHP issuer in a State Exchange or SBE–FP to appeal the imposition of CMPs by HHS following the existing framework for administrative hearings in § 156.901, et seq.

We proposed that HHS would apply the same process HHS uses to determine when a state is failing to substantially enforce PHS Act requirements in determining whether a State Exchange or SBE-FP is substantially enforcing the applicable federal APTC, CSR, and user fee standards. More specifically, we proposed that if an audit of a QHP issuer in a State Exchange or SBE-FP demonstrates the State Exchange or SBE-FP's failure to enforce the applicable federal APTC, CSR, and user fee standards, HHS would investigate the State Exchange or SBE-FP's enforcement and follow the process set forth in 45 CFR 150.207 if necessary. We proposed that if HHS receives or obtains information (including information discovered through an audit) that a State Exchange or SBE-FP may not be enforcing the applicable requirements in part 156, subpart E, or 45 CFR 156.50, HHS may initiate the process described in 45 CFR 150.207 to determine whether the State Exchange or SBE-FP is failing to substantially enforce these requirements. Mirroring the process set forth in 45 CFR 150.207 for making determinations regarding substantial enforcement of PHS Act requirements, HHS would follow the procedures in §§ 150.209 through 150.219 to determine if a State Exchange or SBE-FP is failing to enforce one or more of the applicable requirements in part 156, subpart E or 45 CFR 156.50. If HHS believes there is a reasonable question whether there has been a failure to enforce one or more of the applicable requirements in part 156, subpart E or 45 CFR 156.50, HHS would send a notice, as described in 45 CFR 150.213, identifying the applicable requirement(s) that allegedly have not been substantially enforced to the proper State Exchange or SBE-FP officials using the process outlined in 45 CFR 150.211. We proposed that, following the process described in 45 CFR 150.215, HHS may extend, for good cause, the time the State Exchange or SBE-FP has for responding to the notice, such as if there is an agreement between HHS and the State Exchange or SBE-FP that there should be a public hearing on the State Exchange or SBE-FP's enforcement, or evidence that the

State Exchange or SBE-FP is undertaking expedited enforcement activities. Using the process described in 45 CFR 150.217, if at the end of the extension period HHS determines that the State Exchange or SBE-FP has not established to HHS's satisfaction that it is substantially enforcing the applicable requirements, we proposed that HHS would consult with the appropriate State Exchange or SBE-FP officials, notify the State Exchange or SBE-FP of its preliminary determination that the State Exchange or SBE-FP has failed to substantially enforce the requirements and that the failure is continuing, and permit the State Exchange or SBE-FP a reasonable opportunity to show evidence of substantial enforcement. If, after providing notice and a reasonable opportunity for the State Exchange or SBE-FP to show that it has corrected any failure to substantially enforce, HHS finds that the failure to substantially enforce has not been corrected, HHS would notify the State Exchange or SBE-FP of its final determination using the process described in 45 CFR 150.219. Therefore, we proposed that after a determination that a State Exchange or SBE-FP is not or cannot substantially enforce the applicable requirements in part 156, subpart E or § 156.50, HHS could impose CMPs on issuers in the State Exchange or SBE-FP if there is cause for such imposition. HHS would also provide a notice of non-compliance, consistent with § 156.806, to QHP issuers in State Exchanges or SBE-FPs prior to imposing CMPs.

We explained that we sought to work collaboratively with State Exchanges and SBE–FPs for any topics of mutual concern and oversight activities where possible. We also sought comment to this proposal, the proposed updates to § 156.805, and ways in which HHS and state authorities can efficiently and effectively enforce federal standards related to APTC, CSRs, and user fees.

We also proposed that if the changes to §§ 156.800 and 156.805 were finalized as proposed, we would also amend § 156.903 such that an administrative law judge's authority also extends to CMPs imposed against QHP issuers in State Exchanges and SBE-FPs under § 156.805. Specifically, we proposed to amend § 156.903(a) to extend the provision to also include State Exchanges and SBE-FPs so that the ALJ has the authority, including all the authority conferred by the Administrative Procedure Act, to adopt whatever procedures may be necessary or proper to carry out in an efficient and effective manner the ALJ's duty to provide a fair and impartial hearing on

²⁸⁰ See, for example, 45 CFR 150.203.

the record and to issue an initial decision concerning HHS's imposition of a CMP on a QHP offered in a FFE, State Exchange, or SBE–FP.

We received public comments on the proposed updates to bases and process for imposing civil money penalties in Federally-facilitated Exchanges (§ 156.805). The majority of the comments we received to this section were also made to the proposals regarding HHS enforcement of the applicable federal APTC, CSR, and user fee standards if a State Exchange or SBE-FP is not enforcing or fails to substantially enforce one or more of these requirements (§ 156.480(c)(6)), the application of requirements to issuers in State Exchanges and SBE-FPs (§ 156,480), and the enforcement remedies in the Exchanges, available remedies, and scope (§ 156.800). The following is a summary of these comments and our responses.

Comment: One commenter supported the proposed updates to the application of requirements to issuers in State Exchanges and SBE-FPs (§ 156.480(c)), the enforcement remedies in the Exchanges, available remedies, and scope (\S 156.800), and the bases and process for imposing CMPs in the Exchanges and the accompanying updates to § 156.805. Several commenters opposed the proposal and asked for more information on the process by which HHS would determine that a State Exchange or SBE–FP is failing to substantially enforce the applicable requirements. A few commenters asked for more information on the types of issues that would result in HHS commencing the process to determine whether a State Exchange or SBE–FP is failing to substantially enforce the applicable federal requirements.

Response: We anticipate that an imposition of a CMP by HHS on QHP issuers in State Exchanges and SBE-FPs through these proposed updates should be very rare, as we have not yet imposed a CMP on any QHP issuer in any of the APTC, CSR, user fee, reinsurance, or risk adjustment audits we have conducted to date. We also anticipate that it would be rare for an issuer to repeatedly fail to comply with the applicable federal APTC, CSR, and user fee standards, as well as for the State Exchange or SBE–FP to fail to substantially enforce these standards after being notified by HHS of such potential non-compliance as the result of an audit. We reiterate our commitment to working with issuers, State Exchanges, and SBE-FPs to evaluate issuer non-compliance with the applicable federal APTC, CSR, and user

fee standards and intend to resort to leveraging the authority for HHS to step in and take the appropriate enforcement action in State Exchange and SBE–FP states, including imposing CMPs, in very limited situations where we have evidence or information suggesting that the state is not enforcing and QHP issuers in that state are not complying with the applicable federal standard(s) for APTC, CSRs, and/or user fees. We did not propose and are not finalizing any substantive changes related to the enforcement framework applicable to QHP issuers participating in FFEs. The purpose of these proposals is to codify the authority for HHS to step in and enforce the applicable standards, including the ability to impose CMPs, if necessary should the situation arise. We emphasize that the amendments to §§ 156.800 and 156.805 are targeted to provide HHS authority to step in when there are egregious or repeated occurrences of OHP issuer noncompliance with the applicable APTC, CSR, and user fee standards that are discovered as the result of multiple audits and the State Exchange or SBE-FP is also failing to substantially enforce the applicable standard(s). We therefore anticipate such situations will be rare.

In response to comments, we offer the following example of a situation in which HHS could begin the process of making a determination that a State Exchange or SBE-FP is failing to substantially enforce the applicable APTC, CSR, and user fee requirements. If HHS discovers, as the result of an audit, that an issuer in a State Exchange or SBE-FP failed to comply with a federal APTC requirement, it would inform the State Exchange or SBE-FP and the issuer of this finding and set forth required corrective actions for the issuer to take. If HHS then discovers in the following year's audit of this same issuer that the issuer has not taken the corrective actions and is continuing to fail to comply with the requirement, HHS would again inform the State Exchange or SBE-FP and the issuer of this repeated finding, and ask the State Exchange or SBE-FP to take the appropriate enforcement action against the issuer for noncompliance. If the State Exchange or SBE-FP repeatedly fails to enforce the applicable requirement across multiple benefit years and the issuer continues to have an audit finding related to this noncompliance across multiple benefit years, HHS would begin the process of making a determination that the State Exchange or SBE-FP is failing to substantially enforce that requirement. We reiterate our commitment to

working with State Exchanges and SBE-FPs, and we confirm that this policy is narrowly targeted at egregious or repeated occurrences of QHP issuer non-compliance with the applicable APTC, CSR, and user fee standards evaluated through audits of these programs. We also reiterate that the above is an illustrative example. Consistent with the statutory framework outlined in section 1321(c) of the ACA, and as reflected in the amendments we are finalizing to §§ 156.800 and 156.805, HHS may step in to enforce applicable federal APTC, CSR, and user fee standards in other situations where there is evidence or information suggesting that the State Exchange or SBE-FP is failing to do so.²⁸¹ Once HHS makes a determination that a State Exchange or SBE-FP is failing to substantially enforce the applicable federal requirements, HHS may pursue CMPs against issuers for noncompliance under §§ 156.800 and 156.805 in appropriate situations.

The process by which HHS proposed and is finalizing to determine whether a State Exchange or SBE-FP is failing to substantially enforce the applicable APTC, CSR, and user fee requirements mirrors the process set forth in 45 CFR 150.207 for making determinations regarding a state's substantial enforcement of PHS Act requirements. As detailed above, the process involves HHS sending notice to the proper State Exchange or SBE-FP officials; permits extending the time the State Exchange or SBE-FP has for responding to the notice; requires consulting with the appropriate State Exchange or SBE-FP officials; and mandates that HHS notify the State Exchange or SBE-FP of HHS's preliminary determination that the State Exchange or SBE-FP has failed to substantially enforce the requirement(s) and that the failure is continuing. Only after HHS goes through the process and makes a determination that the State Exchange or SBE-FP is substantially non-enforcing applicable APTC, CSR, and user fee requirements, and the State Exchange or SBE-FP fails to address the identified concerns, would HHS have authority to begin the process to impose a CMP on a QHP issuer in a State Exchange or SBE-FP state pursuant to 45 CFR 156.805 for their noncompliance.

Comment: Numerous commenters stated that this proposal would improperly usurp the role of states in

²⁸¹Consistent with the statute, HHS may also leverage this authority in situations where there is evidence or information suggesting the State Exchange or SBE–FP is failing to substantially enforce other federal Exchange requirements.

enforcing these requirements in their own Exchanges.

Response: We disagree that this approach improperly usurps the role of states in enforcing requirements within their own Exchanges, as the process outlined above provides ample opportunity for State Exchanges and SBE-FPs to take action and demonstrate substantial enforcement at multiple points in the process before HHS assumes enforcement authority. Additionally, pursuant to section 1321(c) of the ACA, HHS has the statutory authority and responsibility to enforce federal requirements when the State Exchange or SBE-FP fails to do so and is instructed to follow the framework set forth in section 2723(b) of the PHS Act when doing so. This authority necessarily includes the ability to impose CMPs on issuers for non-compliance with APTC, CSR, or user fee requirements in states where HHS is responsible for enforcement. As explained above and in the proposed rule, our experience with APTC, CSR, and user fee audits led us to propose these amendments to ensure a framework is in place for HHS to address non-compliance and protect federal funds when a State Exchange or SBE-FP fails to substantially enforce federal standards and QHP issuers in those states are failing to comply with applicable federal APTC, CSR, and user fee requirements. We again reiterate our commitment to working with State Exchanges and SBE-FPs to address noncompliance by QHP issuers operating in their respective states with applicable federal APTC, CSR, and user fee standards. As noted earlier, the purpose of these proposals is to codify in regulation HHS's authority to step in and enforce federal requirements and protect federal funds when the applicable state authority fails to do so. Further, we also note that we intend to focus our enforcement efforts on egregious or repeated occurrences of OHP issuer non-compliance with the applicable APTC, CSR, and user fee standards evaluated through an audit of these programs.

Comment: Several commenters emphasized that HHS should work with State Exchanges and SBE–FPs to enforce the applicable federal requirements. One commenter requested that HHS monitor State Exchange and SBE–FP remediation efforts to address issuer non-compliance before imposing CMPs.

Response: HHS will work with State Exchanges and SBE-FPs to enforce the applicable requirements, as set forth above. We intend for audits, compliance reviews, and enforcement activities to be collaborative processes with states,

State Exchanges, and SBE-FPs, where possible. For instance, HHS will consider the recommendations for how to leverage existing audit activities that HHS requires State Exchanges to conduct under § 155.1200 to collaborate with State Exchanges on identifying instances of issuer non-compliance or monitoring State Exchange or issuer remediation activities. HHS will follow the process for determining that a State Exchange or SBE–FP is failing to enforce or failing to substantially enforce these requirements, consistent with the framework set forth in §§ 150.209 through 150.219. As described above, this process follows a collaborative approach and permits HHS to monitor State Exchange and SBE-FP remediation efforts as the Exchange works to address issues identified by HHS. It also provides ample opportunity for the State Exchange or SBE-FP to show that it has corrected (or is working to correct) any failure to substantially enforce before HHS makes a final determination about whether a State Exchange or SBE-FP is failing to enforce one or more of the applicable requirements in part 156, subpart E or 45 CFR 156.50. It is only after HHS goes through the process and makes a determination that the State Exchange or SBE-FP is substantially failing to enforce these requirements, and the State Exchange or SBE-FP fails to address the identified concerns, that HHS would have authority to begin the process to impose a CMP on a QHP issuer in a State Exchange or SBE-FP state pursuant to 45 CFR 156.805 for their non-compliance.²⁸² As detailed in the above illustrative example, we intend to work closely with the applicable state authorities and monitor state remediation efforts to address issuer non-compliance before HHS starts the process to step in to enforce the applicable federal requirements or impose CMPs.

Comment: One commenter requested that we link the proposed audit provisions for the APTC, CSR and user fee programs and HHS's authority to recoup payments to the regulations codified in 45 CFR part 150 to more directly link this recoupment authority to the PHS Act.

Response: Consistent with the authority in section 1321(c) of the ACA, HHS proposed and is finalizing the proposals to establish and clarify its authority to audit and conduct

compliance reviews of all QHP issuers who receive APTC or CSRs or pay user fees under § 156.480(c) regardless of Exchange type. We are also finalizing provisions that reference the process in 45 CFR 150.201, et seq., so HHS can leverage the existing, known process in situations where HHS has evidence or other information that the State Exchange or SBE-FP is failing to substantially enforce the applicable requirements found at 45 CFR 156, subpart E for APTC and CSRs and 45 CFR 156.50 for user fees. We believe this is an appropriate and adequate link of the audit requirements in § 156.480(c) to the regulations codified in 45 CFR part 150, which implement section 2723(b) of the PHS Act. 283 We confirm that our current intention is to apply this new framework to situations involving egregious or repeated occurrences of QHP issuer noncompliance with the applicable APTC, CSR, and user fee standards evaluated through the audits of these programs. However, consistent with the statutory framework outlined in section 1321(c) of the ACA, and as reflected in the amendments we are finalizing to §§ 156.800 and 156.805, HHS may step in to enforce applicable federal APTC, CSR, and user fee standards in situations where there is evidence or information suggesting that the State Exchange or SBE-FP is failing to do so.²⁸⁴ As detailed above, we believe it is appropriate and necessary for HHS to recoup amounts that were not adequately substantiated by the issuer during the course of an audit.²⁸⁵

After consideration of the comments received on these proposals, we are finalizing the proposed amendments to § 156.805 to describe the bases and process by which HHS may determine that a State Exchange or SBE–FP is failing to substantially enforce the applicable federal APTC, CSR, and user fee standards and subsequently impose CMPs on these State Exchange or SBE–FP issuers as proposed.

²⁸² If a State Exchange or SBE–FP notifies HHS that it has not enacted legislation to enforce or that it is not otherwise enforcing the applicable federal requirement(s), HHS may step in to enforce the requirement(s) in that state at that time. See 45 CFR 150 203(a)

²⁸³ While the APTC, CSR, and user fee statutory provisions are codified outside of the PHS Act, section 1321(c) of the ACA applies the PHS Act enforcement framework to the enforcement of the federal Exchange requirements.

²⁸⁴ Consistent with the statute, HHS may also leverage this authority in situations where there is evidence or information suggesting the State Exchange or SBE–FP is failing to substantially enforce other federal Exchange requirements.

²⁸⁵ Issuers have separate record retention requirements that must be met and the documents required to be maintained can be utilized to substantiate payment. See §§ 153.410(c), 153.620(b), 156.480(a), and 156.705.

9. Subpart J—Administrative Review of QHP Issuer Sanctions (§§ 156.901, 156.927, 156.931, 156.947)

We proposed to change the title to subpart J, removing the reference to "in Federally-Facilitated Exchanges" to make clear it applies to QHP issuers participating in any Exchange type to align with accompanying proposed changes outlined above to §§ 156.800 and 156.805. We also proposed several procedural changes to provisions in subpart J of part 156 related to administrative hearings consistent with the amendments discussed in the preamble to part 150. These proposed procedural changes are intended to align with the Departmental Appeals Board's current practices for administrative hearings to appeal CMPs. Specifically, we proposed changes that would remove requirements to file submissions in triplicate and instead require electronic filing. This change is reflected in the proposed amendments to the definition of "Filing date" in § 156.901, to the introductory text in § 156.927(a), and to the service of submission requirements captured in paragraph (b). We also proposed to allow for the option of video conferencing as a form of administrative hearing by amending the definition of "Hearing" in § 156.901 and to the requirements outlined in § 156.919(a) related to the forms for the hearing, § 156.941(e) related to prehearing conferences, and § 156.947(a) related to the record of the hearing. Finally, we proposed to update § 156.947 to allow the ALJ to communicate the next steps for a hearing in either the acknowledgement of a request for hearing or on a later date. We sought comment on these proposals.

We received the same public comments on the proposed updates to Subpart I—Administrative Review of QHP Issuer Sanctions (§§ 156.901, 156.927, 156.931, 156.947) and the parallel proposed updates to Part 150, Administrative Hearings, for the parallel amendments made to reflect the Departmental Appeals Board's current practices for administrative hearings to appeal CMPs. We summarized and responded to these comments in the above preamble section on Part 150 Administrative Hearings. We did not receive comments on the proposed change to the title to subpart J, removing the reference to "in Federally-Facilitated Exchanges". After consideration of the comments on the proposed amendments to §§ 156.901, 156.927, 156.931 and 156.947 and the title to subpart J, we are finalizing these amendments as proposed.

10. Quality Rating System (§ 156.1120) and Enrollee Satisfaction Survey System (§ 156.1125)

Section 1311(c)(3) of the ACA directs the Secretary of HHS to develop a quality rating for each QHP offered through an Exchange, based on quality and price. Section 1311(c)(4) of the ACA directs the Secretary to establish an enrollee satisfaction survey that will assess enrollee satisfaction with each QHP offered through the Exchanges with more than 500 enrollees in the prior year.

prior year. Based on this authority, HHS finalized rules in May 2014 to establish standards and requirements related to QHP issuer data collection and public reporting of quality rating information in every Exchange.²⁸⁶ To balance HHS's strategic goals of empowering consumers through data, minimizing cost and burden on QHP issuers, and supporting state flexibility, HHS developed a phased-in approach to establishing quality standards for Exchanges and QHP issuers, collecting and reporting quality measure data, and displaying quality rating information across the Exchanges. Since 2015, we have collected clinical quality measure data and enrollee experience survey measure data and generated quality ratings to provide reliable, meaningful information about QHP quality performance data across Exchanges. In addition, since 2016, select states 287 with FFEs and State Exchanges have displayed QHP quality rating information as a tool for consumer decision-making while shopping for health insurance coverage in an Exchange. Beginning with the open enrollment period for plan year 2020, we displayed the QHP quality rating information for all Exchanges that used the HealthCare.gov platform, including the FFEs and SBE-FPs. State Exchanges that operated their own eligibility and enrollment platform were similarly required to display QHP quality ratings beginning with the open enrollment period for plan year 2020, but had some flexibility to customize the display of the QHP quality rating information.²⁸⁸

Through valuable feedback from the

QRS and QHP Enrollee Survey Call

Letter process and continued

received many comments requesting that we remove levels of the QRS hierarchy to help streamline and improve consumer understanding of the quality rating information. While we did not propose amendments to the QRS or to the QHP Enrollee Survey as part of the proposed rule, we sought comment on the removal of one or more levels of the QRS hierarchy, which is a key element of the QRS framework that establishes how quality measures are organized for scoring, rating and reporting purposes. We previously described the general overall framework for the QRS, including details on the hierarchical structure of the measure set and the elements of the QRS rating methodology.²⁸⁹ Currently, the QRS measures are organized into composites, domains, and summary indicators that serve as a foundation for the rating methodology and scores are calculated at every level of the hierarchy using specific scoring and standardization rules, as described in the annual QRS and QHP Enrollee Survey Technical Guidance.²⁹⁰ We noted in the proposed rule that we believe that a simplified QRS hierarchy would support alignment with other CMS quality reporting programs and help the overall quality score be more reflective of the performance of individual survey and clinical quality measures within the QRS. For example, the Medicare Part C & D Star Ratings framework consists of measures, domains, summary ratings and an overall rating.²⁹¹ In addition, we

engagement with health plan issuer organizations, health care quality measurement experts, state representatives, consumer advocates and other stakeholders, we continued to learn about populations buying insurance coverage across the Exchanges and about areas of improvement for these programs. We also continued to assess potential refinements to the QRS rating methodology and the QHP Enrollee Survey to prioritize strategies to improve value for consumers and to reduce the burden of quality reporting. As part of the 2020 QRS and QHP Enrollee Survey Call Letter process, we

²⁸⁶ See 79 FR 30240 at 30352. Also see 45 CFR 155.1400, 155.1405, 156.1120 and 156.1125.

²⁸⁷ Prior to the PY2020 nationwide display of quality rating information, states that displayed QHP quality rating information included California, Colorado, Connecticut, Maryland, Michigan, Montana, New Hampshire, New York, Rhode Island. Virginia. Washington, and Wisconsin.

²⁸⁸ "CMS Bulletin on display of QRS star ratings and QHP Enrollee Survey results for QHPs offered through Exchanges (often called the Health Insurance Marketplace)," August 15, 2019. Available at https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Quality RatingInformationBulletinforPlanYear2020.pdf.

²⁸⁹ See, for example, 78 FR 69418.

²⁹⁰ "The Quality Rating System and Qualified Health Plan Enrollee Experience Survey: Technical Guidance for 2021," September 2020. Available at https://www.cms.gov/files/document/quality-ratingsystem-and-qualified-health-plan-enrollee-experience-survey-technical-guidance-2021.pdf.

²⁹¹ "Medicare 2019 Part C & D Star Rating Technical Notes," October 10, 2019. Available at Continued

noted that we believe a simplified hierarchy, in combination with additional methodology modifications we considered (for example, explicit weights at the measure level) will help stabilize ratings across years.²⁹² We sought comment specifically on which level or levels of the QRS hierarchy should be removed (for example, the composite level or the domain level).

In addition, to further support transparency of QHP quality data and to empower stakeholders including consumers, states, issuers and researchers with valuable information related to enrollee experience with OHPs, we proposed to make the full QHP Enrollee Survey results publicly available in an annual PUF. Currently, we post on *HealthCare.gov* some enrollee experience results in the form of a quality rating for Member Experience and Plan Administration that make up part of the overall rating for QHPs.²⁹³ The Member Experience rating is based on a select number of survey measures from the QHP Enrollee Survey. The Plan Administration rating is based on a select number of survey measures and clinical quality measures. To promote transparency of data to the public, we already post QRS PUFs every year for QHP issuers operating in all Exchange types that were eligible to receive quality ratings. As we stated in the Exchange and Insurance Market Standards for 2015 and Beyond Final Rule, we have been considering different ways to make QHP quality data, including QHP Enrollee Survey results, publicly available and accessible to researchers, consumer groups, states and other entities.294 Similar to the QRS PUFs, we proposed to post a QHP Enrollee Survey PUF annually, beginning with the 2021 QHP Enrollee Survey results and during the 2022 open enrollment period, that would include the score and proportion of responses (for example, the percentage of respondents answering 'Never' or "Sometimes") for every survey question and composite as well as demographic information such as employment status, race and ethnicity, and age at the reporting unit and national level to facilitate data transparency.

We solicited comment on this proposal to post a QHP Enrollee Survey

PUF annually and on potential changes to the QRS hierarchy.

The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the removal of levels of the QRS hierarchy to align with other CMS quality reporting programs and to increase the ability for the overall quality score to be more reflective of the performance of individual quality measures in the QRS. Several commenters specifically supported the removal of the composite and domain levels of the QRS hierarchy. Some commenters requested the timeframe of when modifications to the QRS hierarchy would take effect.

Response: We agree that with removal of levels of the QRS hierarchy, there will be closer alignment with other CMS quality reporting programs such as Medicare Part C & D Star Ratings. We also agree that by removing the composite level and domain level from the QRS hierarchy, we will be simplifying the hierarchy and the anticipated, improved understanding of the overall quality scores will be more reflective of the individual measures' performance that contributes to those scores. Thus, after consideration of the comments received, we are finalizing the removal of the composite level and domain level from the QRS hierarchy. We intend to clarify the timeframe for these modifications to the QRS hierarchy in the QRS and QHP Enrollee Survey Technical Guidance for 2022, which would affect the 2022 ratings vear for Plan Year 2023.

Comment: One commenter urged CMS to route any changes related to the QRS hierarchy through the QRS Technical Expert Panel (TEP), which is comprised of subject matter experts who will be able to give feedback on the proposed changes to the methodology and weigh proposed changes against any other QRS methodology changes that are being considered. Another commenter urged CMS to continue examining the QRS hierarchy to understand impact to weight redistribution before finalization of removal of a level of the QRS hierarchy (that is, with either the composite or domain level removed) and to identify evidence that the streamlined hierarchy is effective in mitigating data or calculation concerns encountered in other rating systems.

Response: We appreciate the commenters' suggestions and requests for clarification related to the removal of one or more levels of the QRS hierarchy. We confirm that we discussed the potential removal of levels of the QRS

hierarchy with the QRS TEP in 2017 and based on testing using previous years' data, CMS believes that the removal of the composite and domain levels and the explicit weights at the summary indicator will balance the weight of individual measures on the global score. In addition, removal of both the composite and domain levels of the QRS hierarchy will not result in issues with weight redistribution because we intend to retain the explicit weights at the summary indicator level to align with the amount of measures within each summary indicator. CMS intends to retain the summary indicators to remain in alignment with other CMS quality reporting programs (that is, Medicare Part C & D Star Ratings) and intends to continue to assign a weight of 2/3 (66.67%) to the Clinical Quality Management summary indicator, and a weight of ½ (16.67%) to the Enrollee Experience and Plan Efficiency, Affordability, & Management summary indicators. This weighting structure reflects the approximate percentage of measures in each summary indicator. CMS believes that the removal of both the composite and domain levels of the QRS hierarchy will mitigate stakeholders' main concern with data and calculations in the QRS (that is, the implicit weighting). We also clarify that we continue to explore the potential of introducing new methods of assessing performance at the measure level and have proposals available in the current Draft 2021 Call Letter.²⁹⁵

Comment: A few commenters requested further clarifications and considerations including urging CMS to grant additional flexibility to states in the display of the star ratings and noted that technical details around quality rating information display are provided to State Exchanges too late for states to update system requirements.

Response: We clarify that per the 2021 Payment Notice final rule, State Exchanges have increased flexibility and can make determinations about display of quality rating information to best meet the needs of their population. As part of the 2021 Payment Notice final rule, we codified in §§ 155.1400 and 155.1405 the option for State Exchanges that operate their own eligibility and enrollment platforms to customize the display of quality rating information provided by HHS or to display HHSprovided quality rating information with certain state-specific customizations for their QHPs to best

https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Star-Ratings-Technical-Notes-Oct-10-2019.pdf.

 $^{^{292}\,\}mathrm{CMS}$ anticipates continuing to propose methodology refinements to the QRS and QHP Enrollee Survey through the Call Letter process.

²⁹³ A rating for Medical Care is the other component of the overall rating.

²⁹⁴ 79 FR at 30311.

²⁹⁵ "Draft 2021 Call Letter for the Quality Rating System and QHP Enrollee Experience Survey," February 2021. Available at https://www.cms.gov/ files/document/draft-2021-call-letter-qrs-qhpenrollee-survey.pdf.

reflect local priorities or information.²⁹⁶ We also clarify that refinements to the QRS hierarchy do not change the display requirements for State Exchanges that operate their own eligibility and enrollment platforms. State Exchanges that operate their own eligibility and enrollment platforms continue to have the flexibility to make certain state-specific customizations related to the display of quality ratings or to maintain the display of the overall rating and three summary indicator ratings in alignment with HealthCare.gov. We understand that guidance posted by CMS related to the display of quality rating information on *HealthCare.gov* may be communicated too late for states to update their system requirements. Thus, CMS will continue to provide flexibility and technical assistance to State Exchanges as necessary and appropriate, and will continue to discuss timelines for implementation with any State Exchanges that are unable to meet applicable quality rating information display requirements.

Comment: A majority of commenters strongly agreed with the proposal to make QHP Enrollee Survey results publically available in an annual PUF to increase transparency and consumer satisfaction and to assist states in monitoring the quality of insurance coverage offered through the Exchanges. One commenter asked for clarification related to the reasons underlying CMS' proposal to make QHP Enrollee Survey results publically available.

Response: We agree that a PUF that includes results from the full QHP Enrollee Survey will improve transparency of enrollee experience information across Exchanges. We stated in the Exchange and Insurance Market Standards for 2015 and Beyond Final Rule that we have been considering different ways to make QHP quality data, including QHP Enrollee Survey results, publicly available and accessible to researchers, consumer groups, states and other entities.297 We believe that providing this QHP quality data aligns with other CMS quality reporting programs, including Medicare Advantage and Prescription Drug Plan (PDP) Consumer Assessment of Healthcare Providers and Systems (CAHPS) and CAHPS for the Meritbased Incentive Payment System (MIPS), that publically report survey scores and help beneficiaries, issuers, researchers and others better understand the experiences of the individuals and

families that are enrolled in different health plans and programs.

Comment: A few commenters who supported the proposal to make QHP Enrollee Survey results publicly available urged CMS to require additional information related to quality measure data submitted to an Exchange by survey vendors and issuers. One commenter requested that CMS permit states to collect a de-identified survey response file that includes demographic information needed to appropriately case-mix adjust the results to facilitate a better understanding of opportunities for improvement. Another commenter urged CMS to require stratification of at least some quality measures by race, ethnicity, primary language, and disability to address highly prevalent conditions in communities of color.

Response: We appreciate the requests for CMS to require that additional quality measure information to be submitted to an Exchange by survey vendors and issuers. CMS does permit HHS-approved survey vendors to share de-identified person-level data sets of QHP Enrollee Survey questions with States, but to protect enrollee confidentiality, survey vendors are prohibited from sharing person-level demographic data. CMS case-mix adjusts QHP Enrollee Survey response data using variables including the following: General health rating, mental health rating, chronic conditions/ medications, age, education, survey language, help with the survey, and survey mode. CMS intends to include case-mix adjusted scores for QHP Enrollee Survey questions and composites at the reporting unit level in the PUF. In general, CMS is supportive of stratification of at least some quality measures by areas such as race, ethnicity, primary language, disability, and potentially other social determinants of health. We intend to include demographic information such as age, education level, employment, race and ethnicity in the QHP Enrollee Survey PUF to facilitate transparency of this data at the reporting unit level. CMS is not requiring additional quality measure data at this time because we understand that stratification requires QHP issuers to have specific memberlevel data and anticipates that the incorporation of stratification for quality measures may take time. CMS is committed to advancing health equity and addressing health and health care disparities. As part of this objective, CMS is exploring the stratification of measures by sociodemographic factors including race and ethnicity. CMS will follow industry standards around the

type of data needed to report stratified measure rates.

Comment: A few commenters mentioned they do not support publishing QHP Enrollee Survey results at this time because of a lack of transparency of the information to be included in the PUF, explanatory materials, data definitions and communication strategy that would allow consumers to use this information appropriately in making decisions. One commenter noted that survey results are already displayed through star ratings and that additional results would not be meaningful without sufficient explanation, including cut points.

Response: We clarify that CMS will provide details and materials related to the QHP Enrollee Survey PUF in alignment with other Exchange PUFs and other quality data PUFs, including a data dictionary, an overview of the QHP Enrollee Survey, as well as the definitions of all survey questions and composites. We agree that there are already some survey results displayed on HealthCare.gov in the form of a quality rating for Member Experience, which makes up part of the Overall Rating for QHPs. The Member Experience rating is based on a select number of survey measures from the QHP Enrollee Survey. However, after 4 years of collecting survey measure data, we believe it is important to facilitate transparency of QHP enrollee experience results from the full survey. Similar to the QRS PUF, CMS intends to include responses at the reporting unit level for all survey questions in the annual QHP Enrollee Survey PUF, including those not included in the QRS. The QHP Enrollee Survey PUF will provide results of scoring the QHP Enrollee Survey questions and composites. CMS does not use cut points to calculate the QHP Enrollee Survey scores. We agree that including cut points may provide more meaning to the ORS results included in the ORS PUF and will consider adding the cut points to the QRS PUFs in the future.

Comment: One commenter noted that the QHP Enrollee Survey results are proprietary and cannot be shared publicly.

Response: We disagree with the assertion that QHP Enrollee Survey results are proprietary. In accordance with section 1311(c)(3) and (c)(4) of the ACA and 45 CFR 155.1400 and 155.1405, all Exchanges have the authority to publicly report QHP quality rating information, including survey results, on their websites to help consumers compare and shop for QHPs. QHP issuers are required to collect survey data and the data is used both by

²⁹⁶ 85 FR 29214 through 29216.

²⁹⁷ 79 FR 30311.

CMS and to inform issuers' internal quality improvement efforts. Similar to the QRS PUF and other Exchange PUFs, CMS will publish the QHP Enrollee Survey PUF on data.healthcare.gov.

Comment: One commenter expressed concerns regarding potential negative impacts on the QHP Enrollee Survey results due to the COVID–19 pandemic, including significant membership fluctuations and membership composition changes.

Response: We recognize the concern regarding negative impacts of the COVID-19 pandemic on the QHP Enrollee Survey results. We note that CMS proposed, in the Draft 2021 Call Letter, temporary QRS methodology changes to mitigate the impact of COVID-19 on QRS ratings. We also clarify that CMS will review all quality measure data that is submitted for 2021 QRS ratings, including survey measure data, and make determinations regarding display of quality rating information and release of quality data PUFs after the scoring and rating process and prior to the 2022 open enrollment period for the individual Exchange.

Comment: Some commenters noted general concerns about the QHP Enrollee Survey, including burdensome survey length and appropriate survey timing resulting in lower response rates and lower reliability on certain questions. Before publicly reporting full survey results, the commenter recommended that CMS consider removing questions that have reliability below 0.70, remove questions outside of the health plan's control, remove any survey questions with less than 100 responses in the denominator from reporting and remove the demographic items from the survey that duplicate information submitted at enrollment and rely on the 834 enrollment file instead.

Response: We understand the commenter's concerns and provide the following clarifications about the QHP Enrollee Survey. CMS aims for statistically high reliability (generally, 0.70 or above) for the survey questions and composites. In some cases, there are topic areas critical to inform consumer understanding and issuer quality improvement that may not consistently meet high reliability thresholds but remain important indicators of quality (for example, topics such as enrollee experience with their provider and health care). Given the importance of transparency around these topics, CMS anticipates including all survey questions within the PUF. CMS also anticipates monitoring reliability over time and will consider refinements to

this approach, if needed. CMS expects the PUF will include the number of responses to each question and the number of completed surveys to assist users with analyzing survey data. We also clarify that we continue to assess the length and timing of the QHP Enrollee Survey. We believe that currently, the QHP Enrollee Survey generally aligns with the length and timing of other CAHPS surveys (for example, Medicare Advantage PDP CAHPS survey, Medicare Advantage Only CAHPS) and similarly, posting of an annual QHP Enrollee Survey PUF would align with other quality reporting programs. In addition, we rely on QHP issuers to populate the sample frame files used to field the QHP Enrollee Survey. QHP issuers' access to demographic data collected in the 834 enrollment file can vary based on the type of Exchange in which the issuer operates (that is, State Exchanges or Federally-facilitated Exchanges). Furthermore, CMS collects demographic data through the QHP Enrollee Survey that may not be included in the 834 enrollment file.

After consideration of all public comments received, we are finalizing the proposal to make the full QHP Enrollee Survey results publicly available in an annual PUF, and the removal of the composite level and domain level from the QRS hierarchy. We intend to clarify the timeframe for the removal of the composite and domain levels of the QRS hierarchy in the QRS and QHP Enrollee Survey Technical Guidance for 2022, which would affect the 2022 ratings year for Plan Year 2023.

11. Dispute of HHS Payment and Collections Reports (§ 156.1210)

In the 2014 Payment Notice, we established provisions related to the confirmation and dispute of payment and collection reports. These policies were finalized under the assumption that all issuers that receive APTC would generally be able to provide these confirmations or disputes automatically to HHS. However, HHS has found that many issuers prefer to research payment errors and use enrollment reconciliation and disputes to update their enrollment and payment data, and may be unable to complete this research and provide confirmation or dispute of their payment and collection reports within 15 days, the timeline established by the 2014 Payment Notice.

In the 2021 Payment Notice, we amended § 156.1210(a) to lengthen the time to report payment inaccuracies from 15 days to 90 days to allow all issuers who receive APTC more time to

research, report, and correct inaccuracies through other channels. The longer timeframe also allows for the processing of reconciliation updates, which may resolve potential disputes. Additionally, at § 156.1210, we removed the requirement at paragraph (a) that issuers actively confirm payment accuracy to HHS each month, as well as the language in paragraph (b) regarding late filed inaccuracies. Instead, we amended paragraph (b) to require an annual confirmation from issuers that the amounts identified in the most recent payment and collections report for the coverage year accurately reflect applicable payments owed by the issuer to the federal government and the payments owed to the issuer by the federal government, or that the issuer has disputed any identified inaccuracies, after the end of each payment year, in a form and manner specified by HHS.

Since finalizing these changes, HHS's experience has shown that some data inaccuracies reasonably will be identified after the 90-day reporting window. For example, issuers might receive notification of an eligibility appeal adjudication after the 90-day submission window. Additionally, some issuers are directed to update their enrollment and payment data after an HHS data review or audit which may occur after this 90-day window. In such instances it is in the interest of HHS, states, issuers, and enrollees to accept the late reporting of data inaccuracies. As such, we proposed to amend § 156.1210 by redesignating current § 156.1210(b) to § 156.1210(d) and adding new § 156.1210(b) to establish a process for issuers to report enrollment or payment data changes in these situations.

We clarified that this proposed flexibility would not reduce an issuer's obligation to make a good faith effort to identify and promptly report discrepancies within the 90-day reporting window established under § 156.1210(a). We further explained that issuers could demonstrate good faith by sending regular and accurate enrollment reconciliation files and timely enrollment disputes throughout the applicable enrollment calendar year, making timely and regular changes to enrollment reconciliation and dispute files to correct past errors, and by reaching out to HHS and responding timely to HHS outreach to address any issues identified. With respect to inaccuracies identified after the end of the applicable 90-day period, we proposed to work with the issuer to resolve the inaccuracy if the issuer promptly notifies HHS, in a form and

manner specified by HHS, no later than 15 days after identifying the inaccuracy. The failure to identify the inaccuracy in a timely manner in these situations must not have been due to the issuer's misconduct or negligence. For example, issuers must regularly perform monthly enrollment reconciliation as required under § 156.265(f), and should regularly review monthly enrollment reconciliation files so that disputes are submitted in the 90-day reporting window. Disputes submitted after the expiration of the reporting window as a result of an issuer's failure to conduct these activities in a timely manner would not satisfy the good faith standard. We proposed to codify these criteria at new proposed § 156.1210(b)(1) and (2).

Additionally, we proposed to add paragraph (c) to allow the reporting of data inaccuracies after the 90-day period up to 3 years following the end of the plan year to which the inaccuracy relates or the date of the completion of the HHS audit process for such plan year, whichever is later. We believe this deadline will provide issuers with enough time to report any data inaccuracies discovered after the 90-day submission window, while providing a reasonable end date by which HHS, the State Exchange, issuer and other stakeholders can consider the records for a particular benefit year closed.

We noted that, under section 1313(a)(6) of the ACA, "payments made by, through, or in connection with an Exchange are subject to the False Claims Act (31 U.S.C. 3729, et seq.) if those payments include any Federal funds." As such if an issuer has an obligation to pay back APTC, the issuer could be liable under the False Claims Act for knowingly and improperly avoiding the obligation to pay. We proposed to codify in § 156.1210(c)(3), that, if a payment error is discovered after the 3-year or end of audit reporting deadline, the issuer is obligated to notify HHS and the State Exchange, as applicable and repay any overpayment. However, HHS will not pay the issuer after the 3-year or end of audit reporting deadline for any underpayments discovered.

We further clarified that the requirements of § 156.1210 apply to all issuers who receive APTC, including issuers in State Exchanges. We sought comment on all aspects of this proposal, including its impact on the State Exchanges' ability to resolve disputes and report payment adjustments to HHS in this timeframe. We are finalizing the amendments to §§ 156.1210(b) and (c), as proposed, to establish a framework to permit issuers to report data inaccuracies after the 90-day window

up to 3 years following the end of the plan year to which the inaccuracy relates or the date of the completion of the HHS audit process for such plan year, whichever is later. As detailed further below, we are also codifying the clarification we announced in the proposed rule by finalizing conforming amendments to section § 156.1210 to more clearly reflect that these requirements also apply to issuers in state Exchanges. We received public comments on the proposed updates to dispute of HHS payment and collections reports (§ 156.1210). The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the amendments to § 156.1210 which provide issuers the flexibility to identify inaccuracies after the 90-day reporting window within the 3-year or end of audit deadline for reporting identified inaccuracies window. Commenters, including those representing a State Exchange, appreciated HHS's interest in removing unnecessary reporting requirements to reduce administrative burden for issuers, and improving data accuracy, as well as HHS's expressed intention to work cooperatively with issuers that make a good faith effort to comply with these requirements. These commenters also supported the proposed change to reporting timeframes and appreciated the additional time to report payment inaccuracies, while highlighting the importance of maintaining compliance standards.

Response: We agree with commenters that finalizing these provisions will improve data accuracy and reduce administrative burden on issuers by allowing more time to address inaccuracies in enrollment and payment data, while maintaining compliance standards. We are committed to supporting State Exchanges in resolving disputes and reporting payment adjustments in an efficient and timely manner. We are finalizing the proposed amendments to § 156.1210, which will allow the identification of inaccuracies in the monthly payment and collections reports after the 90-day period if the late-identification was not due to the issuer's misconduct or negligence. We are also finalizing the provision that permits the reporting of these inaccuracies up to 3 years following the end of the plan year to which the inaccuracy relates or the date of the completion of the HHS audit process for such plan year after which point the issuer will not be paid for any underpayments that may be discovered. However, if any payment errors are discovered after the applicable deadline,

the issuer remains obligated to notify HHS and the State Exchange, or SBE-FP, as applicable, and will be responsible for repaying any identified overpayments. As detailed further below, we are also codifying the clarification we announced in the proposed rule by finalizing conforming amendments to section § 156.1210 to more clearly reflect that these requirements also apply to issuers in State Exchanges. We clarify that these conforming amendments are not intended to change existing requirements or processes for State Exchanges or their respective issuers. If State Exchange issuers currently work with the State Exchange to review the amounts identified in the payment and collection reports and resolve inaccuracies, they should continue to do so with any identified overpayments being repaid to HHS within the applicable timeframe set forth in § 156.1210. State Exchange issuers who currently work with HHS to review these reports and resolve any inaccuracies under § 156.1210, along with issuers in FFE states, should continue to work with HHS on these matters and should also repay any identified overpayments to HHS within the applicable timeframe(s) set forth in § 156.1210.

Comment: One commenter suggested that HHS make payments to issuers for underpayments discovered after the 3year or end of audit deadline proposed in § 156.1210(c). Another commenter opposed the 3-year deadline and noted it would prolong the dispute resolution process and the time and work that goes into addressing disputes. This commenter suggested that HHS shorten the timeframe for identifying inaccuracies from 3 years following the end of a plan year to 1 year following the end of a plan year.

Response: The 3-year following the end of the plan year to which the inaccuracy relates or end of HHS audit process for such plan year deadline is intended to provide issuers the flexibility to resolve data inaccuracies encountered after the initial 90-day reporting window, while still encouraging the timely review of enrollment and payment data by providing a date certain for the deadline for identification of such inaccuracies. Based on our experience operating the FFE, we believe shortening this timeframe to one year following the end of a plan year would be insufficient to support the resolution process both for issuers, States, and HHS. For example, the one year timeframe would not align with the submission window for an issuer in a State Exchange time to

complete the retroactive State Based Marketplace Inbound (SBMI) payment files, which are submitted up to 3 years after the relevant benefit year. Further, our changes align with the 3-year timeframe established by the IRS. More specifically, 26 U.S.C. 6501 and 26 U.S.C. 6511 state that the amount of any tax imposed shall be assessed within 3 years after the return was filed. For example, in both the FFE and State Exchanges, a consumer may dispute or amend their insurance coverage by submitting a 1095A update which allows them to amend their taxes up to 3 years. We further note that the 3-year following the end of the plan year to which the inaccuracy relates or end of the HHS audit process for such plan year deadline finalized in this rule does not reduce the issuer's obligation to make a good faith effort to promptly report discrepancies within the 90-day reporting window. In order to encourage all issuers to complete review within the applicable timeframes, HHS reaffirms that it will not make additional payments to issuers for identified underpayments after 3 years following the end of the plan year to which the inaccuracy relates or the date of the completion of the HHS audit process for such plan year, whichever is

After consideration of the comments on these proposals, we are finalizing amendments to § 156.1210 which will allow issuers the flexibility to identify data inaccuracies after the 90-day period and report inaccuracies up to 3 years following the end of the plan year to which the inaccuracy relates or the date of the completion of the HHS audit process for such plan year. We are finalizing these amendments as proposed and are codifying the clarification we announced in the proposed rule by finalizing conforming amendments to more clearly reflect that the requirements of § 156.1210 apply to all issuers who receive APTCs, including issuers in State Exchanges by adding a reference to "or the State Exchange (as applicable)" to paragraph (a), the introductory sentence to paragraph (b), paragraphs (b)(1) and (b)(2), as well as paragraph (c)(3).

12. Payment and Collection Processes (§ 156.1215)

In the 2015 Payment Notice, HHS established a monthly payment and collections cycle for insurance affordability programs, user fees, and premium stabilization programs. As discussed elsewhere in this rule, we proposed to eliminate state user fee collection flexibility that HHS had previously offered to states as part of the

2017 Payment Notice,²⁹⁸ and proposed conforming amendments to remove the reference to "State" governments from paragraph (b). We sought comment on these proposed amendments.

We received public comments on the proposed updates to dispute of HHS payment and collections processes (§ 156.1215). The following is a summary of the comments we received and our responses.

Comment: The comments received on the proposed updates to payment and collection processes (§ 156.1215) supported the elimination of the state user fee collection flexibility that HHS had previously offered to states in the 2017 Payment Notice, and the conforming amendments to remove the reference to "State" governments from § 156.1215(b).

Response: We believe that updating the payment and collection processes in § 156.1215 to align with the elimination of the unutilized state user fee collection flexibility by striking the reference to "State" will clarify the policy and is an appropriate amendment to make at this time. We appreciate the supportive comments on this proposal.

After consideration of comments received on this proposal, we are finalizing the amendment to § 156.1215(b) as proposed.

13. Administrative Appeals (§ 156.1220)

As detailed earlier in this preamble, we previously established a three-level administrative appeals process for issuers to seek reconsideration of amounts under certain ACA programs, including the calculation of risk adjustment charges, payments and user fees. This process also applies to issuer disputes of the findings of a second validation audit (if applicable) as a result of HHS-RADV for the 2016 benefit year and beyond.²⁹⁹ As explained in the 2020 Payment Notice, only those issuers who have insufficient pairwise agreement between the initial validation audit and second validation audit will receive a Second Validation Audit Findings Report and therefore have the right to appeal the second validation audit findings. In this rule, we proposed to amend § 156.1220(a)(1)(vii) to add "if applicable" when discussing an issuer's ability to appeal the findings of the second validation audit to more clearly capture this limitation as part of the regulation, consistent with the existing language at § 153.630(d)(2) and the previously finalized policy. We

proposed a similar amendment in this rule to $\S 153.630(d)(3)$.

We also proposed amendments to § 156.1220(a)(3) to clarify that the 30calendar day timeframe to file a request for reconsideration of second validation audit findings (if applicable) or the risk score error rate calculation would be 30 calendar days from the applicable benefit year's Summary Report of Benefit Year Risk Adjustment Data Validation Adjustments to Risk Adjustment Transfers. To capture this clarification, we proposed to create a new proposed § 156.1220(a)(3)(ii) to specify the timeframe for filing a request for reconsideration for a risk adjustment payment or charge, including an assessment of risk adjustment user fees. This new proposed regulatory provision maintains the language that establishes a 30 calendar day window for these appeals that begin on the date of notification under § 153.310(e). We also proposed to create a new proposed § 156.1220(a)(3)(iii) to separately address the timeframe for filing a request for reconsideration of second validation audit findings or the risk score error rate calculation and to add the phrase "if applicable" to more clearly capture the limitation on the ability to appeal second validation audit findings. To accommodate these two new proposed paragraphs, we also proposed to amend § 156.1220 to redesignate paragraphs (a)(3)(iii) through (vi) as (a)(3)(iv) through (vii), respectively. We sought comment on these proposals.

The only comment received on the proposed updates to the administrative appeals regulations (§ 156.1220) noted general support of the proposed amendments and accompanying clarifications.

After consideration of comments received on these proposals, we are finalizing the amendments to § 156.1220 as proposed.

F. Part 158—Issuer Use of Premium Revenue: Reporting and Rebate Requirements

1. Definitions (§ 158.103)

We proposed to amend § 158.103 to establish the definition of prescription drug rebates and other price concessions that are deducted from incurred claims for MLR reporting and rebate calculation purposes.

In the preamble to the proposed rule, we discussed that HHS received numerous comments during the regulatory process of finalizing amendments to § 158.140(b)(1)(i) in the 2021 Payment Notice final rule with respect to reporting prescription drug

²⁹⁸ See 81 FR at 12317-12318.

²⁹⁹ See 45 CFR 156.1220(a)(1)(vii).

rebates and other price concessions.300 The commenters requested HHS to codify and align the definition of prescription drug rebates and other price concessions that are reported by issuers for MLR purposes with the definition in section 1150A of the Act, as added by the ACA,301 which requires QHP issuers and PBMs to report certain prescription drug benefit information to HHS. The reference to rebates, discounts, and price concessions in section 1150A(b)(2) of the Act excludes bona fide service fees paid to PBMs by drug manufacturers or issuers. Under section 1150A of the Act, bona fide service fees are fees negotiated by PBMs that include but are not limited to "distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs)." Section 156.295, implementing section 1150A of the Act, defines bona fide services fees as "fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.'

In light of the comments that we previously received during the process of amending § 158.140(b)(1)(i), we proposed to further amend the MLR rules to add the definition for prescription drug rebates and other price concessions to § 158.103 and to clarify that this term excludes bona fide service fees, consistent with how such fees are described in § 156.295. We proposed that this provision become applicable beginning with the 2022 MLR reporting year (MLR reports filed in 2023), which aligns with the applicability date of the amendment to § 158.140(b)(1)(i) and should provide issuers with adequate time to adjust contracts with entities providing pharmacy benefit management services to provide transparency regarding prescription drug rebates and other price concessions they receive from drug manufacturers. We solicited comment on this proposal.

We received public comments on the proposed amendment of § 158.103 to

establish the definition of prescription drug rebates and other price concessions that are deducted from incurred claims for MLR reporting and rebate calculation purposes. The following is a summary of the comments we received and our responses.

Comment: All of the commenters generally supported the proposal to define prescription drug rebates and other price concessions that issuers must deduct from incurred claims because they agreed it would provide clarity, consistency, transparency, and accuracy for reporting incurred claims in the MLR calculation. A few commenters expressed concern that excluding bona fide service fees from the definition of prescription drug rebates and other price concessions could facilitate evasion and abuse, and incentivize greater use of service feegenerating activities focused on impeding or denying care. These commenters urged HHS to ensure that amounts that are treated as bona fide service fees are in fact bona fide service fees and that this category is not inappropriately exploited to obscure the true cost of prescription drugs.

Response: We agree that including a definition of prescription drug rebates and other price concessions will promote transparency and higherquality reporting of incurred claims. We also share commenters' concerns that the regulated entities may restructure their contracts in ways that could circumvent the rules regarding the exclusion of bona fide service fees and emphasize that we will only permit as an exclusion from prescription drug rebates and other price concessions bona fide service fees that meet the definition at § 158.103. We intend to continue monitoring developments in the prescription benefit markets in order to ensure that the MLR rules continue to appropriately reflect the prevailing market practices.

Comment: Several commenters requested that HHS clarify that the definition of prescription drug rebates and other price concessions at § 158.103 excludes prescription drug coupons and similar items that benefit enrollees directly at the point of sale, since these items do not reduce issuers' drug costs and may not be known to issuers.

Response: We agree with the commenters and clarify that it was never our intent to include prescription drug coupons and similar items that benefit enrollees directly at the point of sale in the definition of prescription drug rebates and other price concessions at § 158.103. Accordingly, we are modifying the proposed definition of prescription drug rebates and other

price concessions in this final rule to clarify that this term excludes any remuneration, coupons, or price concessions for which the full value is passed on to the enrollee, such that no other entity receives any portion of the coupon payment, remuneration, or price concession.

Comment: Several commenters recommended that HHS exclude from the definition of prescription drug rebates and other price concessions at § 158.103 payments for services related to quality improvement activities (QIA).

Response: We disagree with this recommendation. The purpose of the requirement at § 158.140(b)(1)(i)(B) that prescription drug rebates and other price concessions must be subtracted from an issuer's incurred claims for MLR purposes is to accurately capture issuers' true expenditures on enrollees' prescription drugs. Separately, section 158.150 requires reporting of QIA expenditures. Excluding amounts attributable to QIA from the definition of prescription drug rebates and other prices concessions that must be subtracted from incurred claims would improperly inflate incurred claims, preventing an accurate accounting of prescription drug costs. Thus, any portion of prescription drug rebates and other price concessions that represents compensation for QIA services should be reported as QIA for MLR purposes.

Comment: Several commenters recommended that HHS remove the term "direct and indirect remuneration" (DIR) from the definition of prescription drug rebates and other price concessions at § 158.103. These commenters stated that this term originated within the Medicare Part D program and would be confusing for issuers and PBMs.

Response: We note that in the preambles to both the 2021 Payment Notice proposed rule and the 2021 Payment Notice final rule, we explained that the prescription drug price concessions that must be subtracted from an issuer's incurred claims are intended to capture "any time an issuer or an entity that provides pharmacy benefit management services to the issuer receives something of value related to the provision of a covered prescription drug (for example, manufacturer rebate, incentive payment, direct or indirect remuneration, etc.)." 302 At that time, we did not receive any comments expressing concern with inclusion of DIR in the term price concessions. In addition, we are not persuaded that the DIR definitions used in the Medicare Part D program are inapplicable or

³⁰⁰ See 85 FR at 29240-29241.

³⁰¹ The requirements of section 1150A with respect to QHP issuers are codified at § 156.295. In the proposed rule, we proposed to amend that regulation and to codify the requirements with respect to PBMs at a new 45 CFR part 184.

^{302 85} FR 7139 and 85 FR 29240.

inappropriate in the non-Medicare markets, as it includes the same direct and indirect remuneration that is relevant in the commercial markets, such as PBM-retained rebates, PBM rebate guarantee amounts, PBM penalty payments, dispensing incentive payments, risk-sharing amounts, and remuneration from pharmaceutical manufacturers in the form of rebates, grants, reduced price administrative services, legal settlement amounts, and prompt pay discounts from pharmacies that are not included in the negotiated price. However, in response to comments and in order to avoid any confusion between the Medicare and non-Medicare markets, we are making a technical edit to remove the reference to DIR from the definition of prescription drug rebates and other price concessions at § 158.103. Nonetheless, we note that in the definition of prescription drug rebates and price concessions at § 158.103, we continue to intend to require issuers to treat both direct and indirect items of value related to the provision of a covered prescription drug, including compensation collected by an issuer or PBM after the point of sale, as prescription drug rebates and other price concessions that must be subtracted from an issuer's incurred claims. Further, HHS intends to continue to review issues surrounding the MLR definition and treatment of prescription drug rebates and other price concessions, and as more information and data become available, HHS may propose revisions in the future as may be necessary or appropriate to ensure that consumers receive value for their premium dollars pursuant to section 2718 of the PHS Act.

Comment: Several commenters recommended that HHS remove the term "receivable" from the definition of prescription drug rebates and other price concessions at § 158.103.

Response: In response to these comments and to preserve consistency with the language used throughout § 158.140, we are making a technical edit to remove the term "receivable" from the definition of prescription drug rebates and other price concessions at § 158.103. However, we note that, similar to other components of incurred claims, prescription drug rebates and other price concessions attributable to enrollees' drug utilization during the MLR reporting year are not always settled and received by the time issuers submit MLR reports to the Secretary. Consequently, while § 158.140 commonly refers to "payments" and "receipts" as well as amounts "paid" and "received," the MLR Annual Reporting Form Filing Instructions

provide more detailed guidance specifying where these terms include amounts that are payable or receivable. Currently, for MLR purposes, issuers report the prescription drug rebate amounts they expect to receive with respect to the reporting year, and QHP issuers and PBMs similarly report such expected amounts for purposes of the reporting required under section 1150A of the Act. Therefore, we intend to clarify in the MLR Annual Reporting Form Filing Instructions that the prescription drug rebates and other price concessions that issuers must subtract from incurred claims (which for the 2022 and later MLR reporting years will include amounts received and retained by PBMs) include the receivable amounts.

After consideration of all the comments received and for the reasons stated in our responses, we are finalizing the definition of prescription drug rebates and price concessions at § 158.103 as proposed, with a modification to clarify that the definition excludes any remuneration, coupons, or price concessions for which the full value is passed on to the enrollee, and technical edits to replace the phrase "direct and indirect remuneration" with "remuneration," and remove the term "receivable."

2. Premium Revenue (§ 158.130)

We proposed to clarify the MLR premium reporting requirements under § 158.130 for issuers that choose to offer temporary premium credits during a public health emergency (PHE) declared by the Secretary of HHS (declared PHE) in the 2021 benefit year and beyond, when such credits are permitted by HHS. In the August 4, 2020 guidance, Temporary Policy on 2020 Premium Credits Associated with the COVID-19 PHE, CMS adopted a temporary policy of relaxed enforcement to allow issuers in the individual and small group markets the flexibility, when consistent with state law, to temporarily offer premium credits for 2020 coverage to support continuity of coverage for individuals, families and small employers who may struggle to pay premiums because of illness or loss of incomes or revenue resulting from the COVID-19 PHE. 303 On September 2, 2020, HHS issued an interim final rule on COVID-19 wherein we set forth MLR data reporting and rebate requirements for issuers offering temporary premium

credits for 2020 coverage. 304 For the 2021 MLR reporting year 305 and beyond, we proposed to adopt these MLR data reporting and rebate requirements for all health insurance issuers in the individual and small group markets 306 who elect to offer temporary premium credits during a declared PHE in situations in which HHS issues guidance announcing its adoption of a similar temporary policy of relaxed enforcement to allow such issuers to offer temporary premium credits during the declared PHE. 307

We proposed that for purposes of § 158.130, issuers must account for temporary premium credits provided to enrollees during a declared PHE as reductions in earned premium for the applicable MLR reporting years, consistent with any technical guidance set forth in the applicable year's MLR Annual Reporting Form Instructions,³⁰⁸ when such credits are permitted by HHS. Specifically, as clarified in the interim final rule on COVID-19, we proposed that the amount of temporary premium credits 309 will constitute neither collected premium nor due and unpaid premium described in the MLR Annual Reporting Form Instructions for purposes of reporting written premium (which is a component of earned premium). Consequently, issuers that offer temporary premium credits during a declared PHE will report as earned premium for MLR and rebate

^{303 &}quot;Temporary Policy on 2020 Premium Credits Associated with the COVID—19 Public Health Emergency," August 4, 2020. Available at https:// www.cms.gov/CCIIO/Programs-and-Initiatives/ Health-Insurance-Marketplaces/Downloads/ Premium-Credit-Guidance.pdf.

^{304 85} FR 54820 (Sept. 2, 2020).

³⁰⁵ The MLR reporting year means a calendar year during which group or individual health insurance coverage is provided by an issuer. See 45 CFR 158.103. The 2021 MLR reporting year refers to the MLR reports that issuers must submit for the 2021 benefit year by July 31, 2022. See 45 CFR 158.110(b).

³⁰⁶ While this final rule, the interim final rule on COVID—19, and the August 4, 2020 guidance focus on the individual and small group markets, to remove the barriers in support of issuers offering these premium credits to enrollees impacted by a PHE declared by the Secretary of HHS, we note that issuers in the large group market may also, when consistent with state law, offer temporary premium credits and should similarly report the lower, adjusted amount that accounts for the premium credits for MLR purposes.

³⁰⁷ The Secretary of HHS may, under section 319 of the PHS Act, determine that: (a) A disease or disorder presents a public health emergency; or (b) that a public health emergency, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists.

³⁰⁸ Available at https://www.cms.gov/cciio/ Resources/Forms-Reports-and-OtherResources/ index#Medical_Loss_Ratio.

³⁰⁹ MLR rebates provided in the form of premium credits are different than the temporary premium credits such as those outlined in the August 4, 2020 guidance issued by CMS. When MLR rebates are provided in the form of premium credits, issuers must continue to report the full amount of earned premium and may not reduce it by the amount of MLR rebates provided in form of premium credits, as required by § 158.130(b)(3).

calculation purposes the actual, reduced premium paid when such credits are permitted by HHS.

We solicited comment on this proposal.

We received public comments on the proposal to require issuers for purposes of § 158.130 to account for temporary premium credits provided to enrollees during a declared PHE as reductions in earned premium for the applicable MLR reporting years, consistent with any technical guidance set forth in the applicable year's MLR Annual Reporting Form Instructions, when such credits are permitted by HHS. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal to adopt the MLR data reporting and rebate requirements for issuers who elect to offer temporary premium credits during a declared PHE in future MLR reporting years. Specifically, these commenters noted that the proposal ensures accuracy and consistency in the MLR reporting and rebate calculation process.

Response: We agree that this proposal provides accuracy and consistency in MLR reporting and rebate calculations and appreciate the comments.

Comment: A few commenters appeared to assume that this proposal sought to permanently codify CMS' temporary policy of relaxed enforcement that allowed issuers in the individual and small group markets the flexibility, when consistent with state law, to temporarily offer premium credits for 2020 coverage to support continuity of coverage for individuals, families and small employers who may struggle to pay premiums because of illness or loss of incomes or revenue resulting from the COVID-19 PHE and to extend this policy of relaxed enforcement to future years. Some commenters cautioned HHS to ensure that any such premium credits be aligned with state regulations and legislation or be subject to state regulatory approval.

Response: We note that this proposal did not seek to extend CMS' temporary policy of relaxed enforcement or expand issuers' ability to offer temporary premium credits in future years. Rather, we proposed that if HHS were to allow issuers to offer temporary premium credits during a declared PHE in future years, then issuers would account for such temporary premium credits as reductions in earned premium for the applicable MLR reporting years. We continue to be cognizant that state regulators may have additional considerations with respect to any temporary premium credits provided by

issuers, and note that both the interim final rule on COVID–19 and the August 4, 2020 guidance required issuers to receive the applicable insurance regulator's permission in advance of providing temporary premium credits for 2020 coverage.

After consideration of all of the comments received and for the reasons stated in our responses, we are finalizing as proposed the clarification that issuers must account for temporary premium credits provided to enrollees during a declared PHE as reductions in earned premium for the applicable MLR reporting years, when such credits are permitted by HHS.

3. Formula for Calculating an Issuer's Medical Loss Ratio (§ 158.221)

As noted in section IV of the preamble, on March 4, 2021, the United States District Court for the District of Maryland decided City of Columbus, et al. v. Cochran, No. 18-2364, 2021 WL 825973 (D. Md. Mar. 4, 2021), vacating 45 CFR 158.221(b)(8), which provided that beginning with the 2017 MLR reporting year, an issuer had the option of reporting an amount equal to 0.8 percent of earned premium in the relevant State and market in lieu of reporting the issuer's actual expenditures for activities that improve health care quality, as defined in §§ 158.150 and 158.151. Pursuant to this provision, issuers who chose this method of reporting were required to apply it for a minimum of 3 consecutive MLR reporting years and for all of their individual, small group, and large group markets; and all affiliated issuers were required to choose the same reporting method. As a result of the Court's decision, we are finalizing the deletion of § 158.221(b)(8).310

With the deletion of $\S 158.221(b)(8)$, our regulations will no longer provide issuers the option of reporting an amount equal to 0.8 percent of earned premium in the relevant State and market in lieu of reporting the issuers' actual expenditures for activities that improve health care quality. As discussed in section IV of the preamble and consistent with the court's decision, we are reverting to requiring issuers to itemize QIA expenditures, on a prospective basis, beginning with the 2020 MLR reporting year (MLR reports due by July 31, 2021). However, we are not requiring issuers to incur the burden or expense of revising MLR Annual Reporting Forms from prior years or otherwise updating QIA expenditure

amounts reported for prior years. In addition, because MLR calculations are based on a three-year average, ³¹¹ there will be a transition period during which these averages will continue to reflect the standardized QIA expenditure amounts for those issuers that reported such amounts in the 2017–2019 MLR reporting years. ³¹²

4. Rebating Premium if the Applicable Medical Loss Ratio Standard Is Not Met (§ 158.240)

In order to allow enrollees to benefit from the ability to receive estimated rebates earlier and to provide MLR reporting flexibilities to issuers that may owe rebates, we proposed to amend § 158.240 by adding paragraph (g) to explicitly allow issuers to prepay a portion or all of their estimated rebates to enrollees for any MLR reporting year. We also proposed to require that issuers that choose to prepay a portion or all of their estimated rebates do so for all eligible enrollees in a given state and market in a non-discriminatory manner.

In the preamble to the proposed rule, we noted that an issuer that prepays a portion or all of its estimated rebate and subsequently determines that such prepayment is less than the total rebate owed to an enrollee would have to incur the costs of disbursing rebates twice: First to disburse the prepaid rebate amount, and again to disburse the remaining rebate amount by the deadlines set forth in §§ 158.240(e) and 158.241(a)(2). Therefore, in order to reduce the regulatory burden on issuers and incentivize issuers to deliver rebates to enrollees sooner, we proposed to add to the new § 158.240(g) a safe harbor under which an issuer that prepays at least 95 percent of the total rebate owed to enrollees in a given state and market for a given MLR reporting year by the MLR rebate payment deadlines set forth in §§ 158.240(e) and 158.241(a)(2) may, without penalty or late payment interest under § 158.240(f), defer the payment of any remaining rebate owed to enrollees in that state and market until the MLR rebate payment deadlines set forth in §§ 158.240(e) and 158.241(a)(2) for the following MLR reporting year. This would enable such an issuer to maintain a single rebate disbursement cycle per year, while ensuring that enrollees continue to receive most of the rebate within the regular timeframe. To further ensure that enrollees do not regularly receive reduced rebates as a result of

 $^{^{310}\!}$ Consistent with the removal of § 158.221(b)(8), existing paragraph (b)(9) is redesignated as paragraph (b)(8).

³¹¹ See 42 U.S.C. 300gg–18(b)(1)(B)(ii) and 45 CFR 158.220(b).

³¹² For example, calculations for the 2020 MLR Reporting Year are based on 2018, 2019 and 2020 data

prepayments, we also proposed that under this safe harbor, the rebate amount remaining after prepayment would not be treated as *de minimis*, regardless of how small the remaining amount is. That is, the *de minimis* provisions in § 158.243 would continue to apply only if the total rebate (the sum of the prepaid amount and any amount remaining after prepayment) owed to an enrollee for a given MLR reporting year is below the applicable threshold.

We noted that § 158.250 requires issuers to provide a notice of rebates at the time any rebate is provided, which includes both rebate prepayments and payments of rebates remaining after prepayment. We also noted that we intend to modify the ICRs approved under OMB Control Number 0938-1164 to add modified standard notices that can be used by issuers that elect to prepay rebates under the proposed new § 158.240(g). In addition, we noted that we intend to revise the MLR Annual Reporting Form Instructions to clarify that an issuer that prepays a portion or all of its estimated rebate and subsequently determines that the amount of such prepayment is more than the total rebate owed to an enrollee for that MLR reporting year and that does not recoup the overpayment from the enrollee, may include the overpayment in its rebate payments reported for purposes of calculating the optional limit on the payable rebates under § 158.240(d). We also noted that we intend to revise the MLR Annual Reporting Form Instructions to clarify how issuers that prepay estimated rebates must report such prepayments.

We proposed that the amendment to create new § 158.240(g) would be applicable beginning with the 2020 MLR reporting year (MLR reports filed in 2021). We solicited comment on this proposal, including the proposed applicability date.

We received public comments on the proposed amendments to § 158.240. The following is a summary of the comments we received and our responses.

Comment: Most commenters supported the proposal, stating that it will benefit consumers, provide flexibility and relief for enrollees in future crises, and help consumers maintain comprehensive health coverage. Some commenters recommended that HHS clarify that rebate prepayment is only permitted if consistent with state law and provided statewide in a nondiscriminatory manner; one commenter requested that rebate prepayment be subject to state regulatory approval and only with the 95 percent safe harbor guardrail. Several commenters opposed the proposal,

expressing concern with the operational and administrative burden for State Exchanges and group health plan rebate recipients, consumers favoring issuers that provide prepayments, and the deferred rebates being less likely to reach consumers.

Response: We appreciate the comments in support of this proposal and generally believe that any potential disadvantages of rebate prepayment are outweighed by the benefit of consumers receiving rebates earlier in the year. While we recognize that issuers' ability to reach the original enrollees to provide them with any deferred rebates may diminish as time passes, we believe that the potential harm to consumers that are unable to receive the residual amount remaining after rebate prepayment is mitigated by the 95 percent safe harbor threshold and outweighed by the benefits associated with enrollees' ability to receive rebates earlier than September 30, when they are generally disbursed. We also note that payment of remaining rebate amounts after prepayment may only be deferred until the MLR rebate payment deadlines set forth in §§ 158.240(e) and 158.241(a)(2) for the following MLR reporting year. We further believe that issuers do not gain a significant advantage by prepaying rebates other than delivering a benefit to their enrollees, and we expect that issuers will consider whether in the group markets that benefit exceeds any complexities that it may create for group policyholders or any administrative burden or operational challenges for the issuer, their enrollees, or the Exchanges. Because a consumer is unlikely to know whether an issuer intends to prepay MLR rebates in any given year prior to purchasing a policy, and since an issuer that pre-paid rebates in a previous year may decide not to pre-pay them in a future year, we do not believe that consumers will be more likely to purchase a policy or enroll in health insurance coverage from any given issuer based on the issuer's prepayment of MLR rebates. And if consumers are able to take rebate prepayment into account when selecting an issuer, we do not see why they should be prevented from doing so and selecting an issuer that they believe provides a valuable service. We acknowledge the commenters' concerns regarding the potential interaction of rebate prepayment and state rules or State Exchange operations, and are modifying the proposal to clarify that issuers that choose to prepay a portion or all of their estimated rebates must do so to the extent consistent with state law or other

applicable state authority. This would include receiving state approval, if required under state law. Further, we note that the regulatory text does provide that any issuer that chooses to prepay a portion or all of their estimated rebates must provide the prepayment to all of the enrollees in that state and market in a non-discriminatory manner.

Comment: One commenter requested that the safe harbor threshold either be lowered to 85 percent or be based on the estimated MLR falling within 0.5 percent of actual MLR, to make the safe harbor more attainable for issuers that owe small rebate amounts and consequently may estimate rebates more accurately in dollar terms.

Response: We have considered this option but concluded that 95 percent is an appropriate safe harbor threshold. Reducing the threshold would expand the safe harbor for all issuers, rather than only issuers that owe relatively small rebates per enrollee, which would result in overall larger rebate amounts being eligible to be deferred for a year. Further, we trust that issuers will evaluate the relative value of prepaying very small per-enrollee rebate amounts early versus the associated administrative costs and the deferral of a fraction of those small per-enrollee rebates.

Comment: One commenter suggested that enrollees should have the option to choose whether an issuer that chooses to prepay a portion or all of their estimated rebates must pay any remaining rebate amounts in full during the current year or may defer the payment of any remaining rebate amounts until the following year under the proposed new § 158.240(g) safe harbor.

Response: We appreciate the commenter's suggestion, but believe that the burden of collecting and implementing each enrollee's election with respect to rebates remaining after prepayment would be a significant disincentive for issuers to offer rebate prepayment, and as stated above, we generally believe that any potential disadvantages of rebate prepayment are outweighed by the benefit of consumers receiving rebates earlier in the year.

After consideration of all the comments received and for the reasons stated in our responses, we are finalizing the amendments to § 158.240 as proposed, with an additional clarification that issuers that choose to prepay a portion or all of their estimated rebates must do so to the extent consistent with state law or other applicable state authority.

5. Form of Rebate (§ 158.241)

We proposed to amend § 158.241(a)(2) to allow issuers to provide rebates in the form of a premium credit prior to the date that the rules previously provided.

As discussed in the proposed rule, under § 158.240(e), issuers that choose to provide a rebate via a lump-sum check or lump-sum reimbursement to the account used to pay the premium must issue the rebate no later than September 30 following the end of the MLR reporting year. In contrast, § 158.241(a)(2) previously provided that issuers that elect to provide rebates in the form of a premium credit must apply the rebate to the first month's premium that is due on or after September 30 following the MLR reporting year, and that when the rebate is provided in the form of a premium credit and the total amount of the rebate owed exceeds the premium due in October, any excess rebate amount must be applied to succeeding premium payments until the full amount of the rebate has been credited.

Given the proposed addition of § 158.240(g) discussed in the prior section, the fact that an issuer may wish to provide rebates in the form of a premium credit earlier than October, and the desire to reduce the regulatory burden and enable enrollees to receive the benefit of rebates sooner, we proposed to amend § 158.241(a)(2) to allow issuers to provide rebates in the form of a premium credit prior to September 30. Specifically, we proposed to amend § 158.241(a)(2) to specify that when provided in the form of premium credits, rebates must be applied to premium that is due no later than October 30 following the MLR reporting year. We proposed that this amendment would be applicable beginning with the 2020 MLR reporting year (rebates due in 2021). We solicited comment on this proposal, including on the proposed applicability date.

We received public comments on the proposal to amend § 158.241(a)(2) to allow issuers to provide rebates in the form of a premium credit prior to the date that the rules previously provided. The following is a summary of the comments we received and our responses.

Comment: All of the commenters supported the proposal to allow issuers to provide rebates in the form of a premium credit before (rather than only after) September 30 because it would allow consumers to receive the benefit of rebates sooner. One commenter recommended making the amendment effective beginning with the 2021 MLR reporting year in order to enable issuers

to continue relying on the related guidance issued by HHS in 2020.

Response: We agree with the commenters that this amendment will benefit consumers. While we do not believe that the proposed applicability date overlaps with previous guidance regarding the timing of rebates provided in the form of premium credits, as that guidance applied to the 2019 MLR reporting year (rebates paid in 2020),³¹³ we agree that there is a potential for confusion, and therefore we are adding a clarification that this amendment will be applicable beginning with rebates due for the 2020 MLR reporting year.

After consideration of all the comments received and for the reasons stated in our responses, we are finalizing the amendment to § 158.241 as proposed, with a clarification that the amendment will be applicable beginning with rebates due for the 2020 MLR reporting year.

- G. Part 184—Pharmacy Benefit Manager Standards Under the Affordable Care Act
- 1. Prescription Drug Distribution and Cost Reporting by Pharmacy Benefit Managers (§§ 184.10 and 184.50)

PBMs are third-party administrators that manage the prescription drug benefit for a contracted entity. ³¹⁴ This administration typically involves processing claims, maintaining drug formularies, contracting with pharmacies for reimbursement for drugs dispensed, and negotiating prices with drug manufacturers. ³¹⁵

The role of PBMs in the prescription drug landscape, including any impact on the rising cost of prescription drugs, is not well understood.³¹⁶ For example, PBMs generate revenue, in part, by retaining the difference between the amount paid by the health plan for prescription drugs and the amount the

PBM reimburses pharmacies, a practice commonly referred to as "spread pricing." While estimates report the increasing prevalence of spread pricing in private health insurance plans,³¹⁷ detailed data on the practice has generally not been collected by plans or by any state or federal regulatory body.

We proposed to add part 184 to 45 CFR subchapter E to codify in regulation the statutory requirement that PBMs under contract with QHP issuers report the data described at section 1150A(b) of the Act to the Secretary and to each QHP for which the PBM administers the

prescription drug benefit.

At proposed § 184.10(a)(1), we explained that new part 184 is based on section 1150A of the Act. At proposed § 184.10(b), we proposed that the scope of new part 184 establishes standards for PBMs that administer prescription drug benefits for health insurance issuers which offer QHPs with respect to the offering of such plans. We also proposed definitions for part 184 at new § 184.20. Except for the definition of pharmacy benefit manager, these proposed definitions would codify terms already in use in parts 144 and 155 of subchapter B of subtitle A of title 45 of the Code of Federal Regulations.

As part of the ACA, Congress passed section 6005, which added section 1150A to the Act, requiring a PBM under a contract with a QHP offered through an Exchange established by a state under section 1311 of the ACA 318 to provide certain prescription drug information to the QHP and to Secretary at such times, and in such form and manner, as the Secretary shall specify. Section 1150A(b) of the Act addresses the information that a QHP issuer and their PBM must report. Section 1150A(c) of the Act requires the Secretary to keep the information reported confidential and specifies that the information may not be disclosed by the Secretary or by a plan receiving the information, except that the Secretary may disclose the information in a form which does not disclose the identity of a specific PBM, plan, or prices charged for drugs for certain purposes.319

^{313 &}quot;Temporary Period of Relaxed Enforcement for Submitting the 2019 MLR Annual Reporting Form and Issuing MLR Rebates in Response to the Coronavirus Disease 2019 (COVID–19) Public Health Emergency," June 12, 2020. Available at https://www.cms.gov/files/document/Issuing-2019-MLR-Rebates-in-Response-to-COVID-19.pdf.

³¹⁴PBMs contract with a variety of health plans, including, but not limited to, individual and small group health plans, large group and self-insured plans, and Medicare Part D drug plans. In this section, we only reference PBMs that contract with a health insurance company to administer the prescription drug benefit for QHPs.

³¹⁵ "Pharmacy Benefit Managers," Health Affairs Health Policy Brief, September 14, 2017.

Available at https://www.healthaffairs.org/do/10.1377/hpb20171409.000178/full/.

³¹⁶ Elizabeth Seeley and Aaron S. Kesselheim. "Pharmacy Benefit Managers: Practices, Controversies, and What Lies Ahead," Commonwealth Fund, March 2019. Available at https://doi.org/10.26099/n60j-0886.

³¹⁷ See "The Prescription Drug Landscape, Explored." Available at https://www.pewtrusts.org/ -/media/assets/2019/03/the_prescription_drug_ landscape-explored.pdf.

³¹⁸ This includes an FFE, as a Federal Exchange may be considered an Exchange established under section 1311 of the ACA. *King* v. *Burwell*, 576 U.S. 988 (2015).

³¹⁹ As noted earlier in this preamble, the purposes are: As the Secretary determines to be necessary to carry out Section 1150A or part D of title XVIII; to permit the Comptroller General to review the information provided; to permit the Director of the Congressional Budget Office to review the

In the 2012 Exchange Final Rule, we codified the requirements of section 1150A of the Act, as it applies to QHPs, at § 156.295.320 On January 1, 2020 321 and on September 11, 2020,322 we published Federal Register notices and solicited public comment on collection of information requirements detailing the proposed collection envisioned by section 1150A of the Act, as referenced earlier. As noted earlier in this preamble, we proposed to revise § 156.295 to state that where a QHP issuer does not contract with a PBM to administer the prescription drug benefit for QHPs, the QHP issuer will report the data required by section 1150A of the Act to HHS.

We proposed to add § 184.50(a) to state that where a PBM contracts with an issuer of OHPs to administer the prescription drug benefit for their QHPs, the PBM is required to report the data required by section 1150Å(b) of the Act to the QHP and to the Secretary, at such times, and in such form and manner, as the Secretary shall specify. While we acknowledge that this section applies to both the QHP issuer and their PBMs to report this data, we proposed to implement section 1150A to require PBMs to report this data directly to the Secretary, and only to require the QHP issuer to report the data only when the QHP issuer does not contract with a PBM to administer the prescription drug benefit for their OHPs, as further discussed in the preamble to § 156.295 in this final rule.

We proposed to add § 184.50(a)(1) through (3) to require these PBMs to report the data described at section 1150A(b) of the Act to the Secretary. The data proposed to be collected, as required by section 1150A, are: The percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed (generic dispensing rate), that is paid by the health benefits plan or PBM under the contract; 323 the

information provided; and, to States to carry out section 1311 of the ACA.

aggregate amount, and the type of rebates, discounts, or price concessions (excluding bona fide service fees, which include but are not limited to distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs 324) that the PBM negotiates that are attributable to patient utilization under the plan, and the aggregate amount of the rebates, discounts, or price concessions that are passed through to the plan sponsor, and the total number of prescriptions that were dispensed; and the aggregate amount of the difference between the amount the health benefits plan pays the PBM and the amount that the PBM pays retail pharmacies (spread pricing), and mail order pharmacies, and the total number of prescriptions that were dispensed.

At new § 184.50(b) and (c), we also proposed to codify the confidentiality and penalty provisions that appear at § 1150A(c) and (d) to PBMs which administer the prescription drug benefits for QHP issuers.

We sought comment on these

proposals.

We received public comments on the proposed updates to prescription drug distribution and cost reporting by pharmacy benefit managers (§§ 184.10 and 184.50). We have consolidated the description of the public comments received in response to this proposal at Part 184 as part of the discussion in the preamble above for § 156.295. Please refer to that section for our responses to those comments received.

After consideration of all the comments received and for the reasons stated in our responses, we are finalizing this policy as proposed.

IV. Implementation of the Decision in City of Columbus, et al. v. Cochran

On March 4, 2021, the United States District Court for the District of Maryland decided *City of Columbus, et*

are not finalizing collecting data by pharmacy type at this time. We intend to collect this information at a time when the imposition of such a requirement would pose reasonable burden. We seek comment on ways that we may impose the collection of data by pharmacy type in the future without imposing unreasonable burden on the industry.

324 This definition of bona fide service fees was finalized at § 156.295 in the 2012 Exchange Final Rule at 77 FR 18432. There, we finalized this definition to align with the definition of bona fide service fees finalized in the Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes final rule. See 77 FR 22072 at 22093.

al. v. Cochran, No. 18–2364, 2021 WL 825973 (D. Md. Mar. 4, 2021). The court reviewed nine separate policies we had promulgated in the "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2019" (83 FR 16930) published in the Federal Register on April 17, 2018 (the 2019 Payment Notice). The court upheld five of the challenged policies but vacated four others. Specifically, the court vacated the following portions of the 2019 Payment Notice:

1. The 2019 Payment Notice's extension of the elimination of federal reviews of network adequacy of qualified health plans offered through the FFEs in certain circumstances by incorporating the results of the states' reviews, first finalized in rulemaking in the Market Stabilization final rule ³²⁵ (83 FR 17024 through 17026).

2. The 2019 Payment Notice's cessation of the practice of designating some plans in the FFEs as "standardized options" in an effort to encourage innovation in the individual market (83

FR 16974 through 16975).

3. The 2019 Payment Notice's modification of Exchange income verification requirements for resolving data matching issues related to eligibility for advance payments of premium tax credits to require an individual who attests to a household income within 100 percent to 400 percent of the federal poverty level (FPL), but whose income according to trusted electronic data sources is below 100 percent FPL, to submit additional documentation supporting the attested to household income (83 FR 16985 through 16987).

4. The 2019 Payment Notice's amendment of medical loss ratio requirements to allow issuers to submit either a detailed, itemized report of quality improvement activity (QIA) expenditures or to report a single, fixed QIA amount (83 FR 17032 through 17036).

We intend to implement the court's decision as soon as possible. However, we will not be able to fully implement those aspects of the court's decision regarding network adequacy review and standardized options in time for issuers to design plans and for Exchanges to be prepared to certify such plans as QHPs for the 2022 plan year, and therefore, intend instead to address these issues in time for plan design and certification for plan year 2023. Specifically, in order to implement the court's ruling on the network adequacy provision, HHS will need to set up a new network adequacy review process, and issuers will need

³²⁰ Section 1150A(a)(1) also authorizes the collection of data from PBMs that manage prescription drug coverage under contract with a Prescription Drug Plan sponsor of a prescription drug plan or a Medicare Advantage organization offering a Medicare Advantage prescription drug plan.

³²¹ 85 FR 4993 through 4994.

^{322 85} FR 56227 through 56229.

³²³ As stated above in the preamble for § 156.295, section 1150A(b)(1) requires the Secretary to collect data by pharmacy type. However, we are aware that it is not currently possible to report such data by pharmacy type because pharmacy type is a not standard classification currently captured in industry databases or files. To reduce burden, we

^{325 82} FR 18346, 18371-18372 (April 18, 2017).

sufficient time before the applicable plan year to assess that their networks meet the new regulatory standard, submit network information, and have the information reviewed by applicable regulatory authorities in order for their plans to be certified as QHPs. Issuers might also have to contract with other providers in order to meet the standard. This is not feasible for the QHP certification cycle for the 2022 plan year, since the annual QHP certification cycle generally begins in late April of each year. CMS' planning for the 2022 plan year had already taken into account the provisions that the court vacated before the court issued its decision, and it is too late now to revisit those factors if the process is to go forward in time for plans to be certified by open enrollment later this year. We plan to propose specific steps to address implementation of this aspect of the court's decision in future rulemaking. At that time, we might also address other aspects of the court's decision, including potentially some provisions that the court upheld.

The same is true for the court's decision regarding standardized options. With the rule removing standardized options vacated, we need to design and propose new standardized options that otherwise meet current market reform requirements, and we must also alter the Federal Exchange eligibility and enrollment platform system build (HealthCare.gov) to provide differential display of such plans. Web-brokers that are direct enrollment partners in FFE and SBE-FP states will also need time to adjust their respective systems to provide differential display of such plans on their non-Exchange websites.326 We will need to design, propose and finalize such plans in time for issuers to design their own standardized options in accord with HHS's parameters and submit those plans for approval by applicable regulatory authorities and for certification by Exchanges as qualified health plans. Again, this is not feasible for the QHP certification cycle for the 2022 plan year, since the annual QHP certification cycle generally begins in late April of each year. CMS' planning for the 2022 plan year had already taken into account the provisions that the court vacated before the court issued its decision, and it is too late now to revisit those factors if the process is to go forward in time for plans to be developed, reviewed and certified by open enrollment later this year.

been required in the past, we will not

Although standardized options have

be able to simply reinstate the same standardized option plans that previously existed. Specifically, in the last iteration of standardized options we finalized in the 2018 Payment Notice, we created three sets of standardized options based on FFE and SBE-FP enrollment data and state cost-sharing laws. The basis on which we created these three sets of options as well as a number of other factors in the individual market) have changed considerably since the last iteration of standardized options in 2018. Several such changes include modifications in the most popular plans' cost-sharing structures, shifting enrollment trends, the introduction of new state cost sharing laws that affect standardized option plan designs, and states with FFEs or SBE-FPs transitioning to SBEs (which affects the number of sets of options). As a result of these changes, the sets of standardized options and the design of the options themselves must be adjusted accordingly. Further, we do not have sufficient time prior to the 2022 plan year to conduct a full analysis of the changes that have occurred in the last several years in order to design and propose adequate standardized options suitable for the current environment. Additionally, in prior years, we proposed and finalized standardized option plan designs prior to the start of the QHP certification cycle for the following plan year such that issuers had sufficient time to assess these standardized options in order to determine if they wanted to offer them and take the steps necessary to do so. Even if we were able to design standardized option plans prior to the 2022 plan year, issuers would not have a sufficient amount of time to meaningfully assess any standardized options we might propose and decide whether or not to offer them.

For these reasons, we intend to resume the designation of standardized options and propose specific designs in more complete detail in the 2023 Payment Notice. As such, we will seek comment during the corresponding comment period. In the interim, we encourage states with FFEs or SBE-FPs and unique cost-sharing laws that could affect standardized plan design to contact us to discuss their circumstances.

We can take more immediate steps to begin to implement the court's holdings regarding income verification and QIA reporting. First, as discussed more fully later in this section, we are exercising flexibilities under the Administrative Procedure Act (APA) to rescind or replace in this final rule relevant parts of the income verification and MLR

regulations the court invalidated. Second, we plan to implement accompanying operational policies to begin implementation of the court's order with respect to the impacted income verification regulation.

Specific to income verification, we are deleting the invalidated provision requiring certain consumers to provide information for income verification purposes. We note that HHS's systems automatically generate requests for income verification information for those with income data matching issues, and it will take some time for us to redesign this function. Until that redesign is complete, however, HHS will be able to identify consumers who receive requests for verification information and we have established a manual process to notify those recipients that they need not provide the requested information.

As to QIA reporting, we are deleting the invalidated provision to remove the option to report the fixed standardized amount of QIA. The regulation will thus revert to requiring issuers to itemize QIA expenditures on a prospective basis beginning with the 2020 MLR reporting year (MLR reports due by July 31, 2021).327 However, we are not requiring issuers to incur the burden or expense of revising MLR Annual Reporting Forms from prior years or otherwise updating QIA expenditure amounts reported for prior years. In addition, because MLR calculations are based on a 3-year average,328 there will be a transition period during which these averages will continue to reflect in part the standardized QIA expenditure amounts for those issuers that reported such amounts in the 2017-2019 MLR reporting years.329

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 30-day notice in the Federal Register and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. This final rule contains information collection requirements (ICRs) that are subject to review by OMB. A description of these provisions is given in the following

 $^{^{327}\,\}mbox{With the removal of}\ \S\,158.221(b)(8),\mbox{CMS}$ regulations require issuers to separately track and itemize QIA expenditures. See 45 CFR 158.150, 158.151 and 158.221.

³²⁸ See 42 U.S.C. 300gg-18(b)(1)(B)(ii) and 45 CFR 158.220(b).

 $^{^{329}}$ For example, calculations for the 2020 MLR Reporting Year are based on 2018, 2019 and 2020

paragraphs with an estimate of the annual burden, summarized in Table 12. To fairly evaluate whether an information collection 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 solicited public comment on each of the required issues under section 3506(c)(2)(A) of the PRA for the following ICRs.

A. Wage Estimates

To derive wage estimates, we generally used data from the Bureau of Labor Statistics to derive average labor costs (including a 100 percent increase for fringe benefits and overhead) for estimating the burden associated with the ICRs.³³⁰ Table 11 in this final rule presents the mean hourly wage, the cost

of fringe benefits and overhead, and the adjusted hourly wage.

As indicated, employee hourly wage estimates have been adjusted by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly across employers, and because methods of estimating these costs vary widely across studies. Nonetheless, there is no practical alternative, and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

TABLE 11: Adjusted Hourly Wages Used in Burden Estimates

Occupation Title	Occupational Code	Mean Hourly Wage (\$/hr.)	Fringe Benefits and Overhead (\$/hr.)	Adjusted Hourly Wage (\$/hr.)
Compliance Officer	13-1041	\$35.03	\$35.03	\$70.06
Pharmacy Technician	29-2052	\$16.95	\$16.95	\$33.90
Secretaries and Administrative Assistants	43-6014	\$18.84	\$18.84	\$37.68
Billing and Posting Clerks	43-3021	\$19.53	\$19.53	\$39.06
Chief Executives	11-1011	\$93.20	\$93.20	\$186.40
Business Operations Specialist	13-1198	\$38.57	\$38.57	\$77.14
Computer System Analyst	15-1121	\$46.23	\$46.23	\$92.46
Computer Programmer	15-1251	\$44.53	\$44.53	\$89.06
Computer and Information Systems Manager	11-3021	\$75.19	\$75.19	\$150.38
General and Operations Manager	11-1021	\$59.15	\$59.15	\$118.30
Auditor	13-2011	\$38.23	\$38.23	\$76.46
All Occupations	00-0000	\$25.72	\$25.72	\$51.44

B. ICRs Regarding Submission of Adjusted Premium Amounts for Risk Adjustment

45 CFR 153.610 and 153.710 provide that issuers of a risk adjustment covered plan must provide HHS with access to risk adjustment data through a dedicated distributed data environment (EDGE server), in a manner and timeframe specified by HHS. We clarify that, for purposes of risk adjustment data submissions in the 2021 benefit year and beyond when a declared PHE is in effect and HHS permits temporary premium credits, issuers that choose to provide temporary premium credits must submit the adjusted (that is, lower) plan premiums for those months, instead of the unadjusted plan premiums. HHS is finalizing the proposal to require issuers to submit adjusted plan premiums to their EDGE servers for all enrollees whom the issuer has actually provided temporary

premium credits as a reduction to the corresponding benefit year premiums. We do not believe that issuers who elect to provide these temporary premium credits during a declared PHE will incur additional operational burden associated with EDGE server data submissions as a result of these requirements because we expect issuers' premium reporting systems will already be configured to enable issuers to upload the billable premiums actually charged to enrollees for the applicable benefit year to the EDGE server. Additionally, the current EDGE server operational guidance for the risk adjustment program allows issuers to submit billable premium changes so there will be no changes to the data submission rules. The burden related to this information collection is currently approved under OMB control number 0938-1155 (Standards Related to Reinsurance, Risk Corridors, Risk Adjustment, and Payment Appeals). The information collection request expires on February 23, 2021.

C. ICRs Regarding Direct Enrollment (§§ 155.220 and 155.221)

At $\S 155.220(c)(6)$, we are finalizing the proposal that a web-broker must demonstrate operational readiness and compliance with applicable requirements prior to the web-broker's non-Exchange website being used to complete an Exchange eligibility application or a QHP selection, which may include submission of a number of artifacts of documentation or completion of certain testing processes. The required documentation may include operational data including licensure information, points of contact, and third-party relationships; security and privacy assessment documentation, including penetration testing results, security and privacy assessment reports, vulnerability scan results, plans of action and milestones, and system

³³⁰ See May 2019 Bureau of Labor Statistics, Occupational Employment Statistics, National

Occupational Employment and Wage Estimates.

Available at $https://www.bls.gov/oes/2019/may/oes_nat.htm#00-0000.$

security and privacy plans; and an agreement between the web-broker and HHS documenting the requirements for participating in the applicable direct enrollment program. We estimate that it will take up to 2 hours for a Business Operations Specialist (at an hourly cost of \$77.14) to complete and submit the required operational data and webbroker agreement to HHS each year. We estimate that it will take up to 17 hours for a Business Operations Specialist (at an hourly cost of \$77.14) to complete and submit the required security and privacy assessment documentation to HHS. The total burden for each webbroker would be approximately 19 hours, with an equivalent cost of approximately \$1,466. Based on current web-broker participation and potential market size, we estimate that 30 webbrokers will participate. We estimate that these data collections will have an annual burden of 570 hours with a cost of approximately \$43,970.

We are finalizing the proposal to add additional detail to the operational readiness requirement in § 155.221(b)(4) for direct enrollment entities. In § 155.221(b)(4), we require that a direct enrollment entity must demonstrate operational readiness and compliance with applicable requirements prior to the direct enrollment entity's website being used to complete an Exchange eligibility application or a QHP selection, which may include submission of a number of artifacts of documentation or completion of various testing or training processes. The required documentation may include business audit documentation including: Notices of intent to participate including auditor information; documentation packages including privacy questionnaires, privacy policy statements, and terms of service; and business audit reports including testing results. The required documentation may also include security and privacy audit documentation including: Interconnection security agreements; security and privacy controls assessment test plans; security and privacy assessment reports; plans of action and milestones; privacy impact assessments; system security and privacy plans; incident response plans; vulnerability scan results; and an agreement between the direct enrollment entity and HHS documenting the requirements for participating in the applicable direct enrollment program. We estimate that for each direct enrollment entity it will take up to 9 hours for a Business Operations Specialist (at an hourly cost

of \$77.14) to complete and submit a typical documentation package and related information to HHS each year. Based on current EDE participation and potential market size, we estimate that 77 EDE entities will participate in a manner such that they will be required to submit this type of information, and therefore, this data collection will have an annual burden of 693 hours with an annual cost of approximately \$53,458.

In addition, we estimate that it will take up to 72 hours for an Auditor (at an hourly cost of \$76.46) to complete and submit a business requirements audit package for a direct enrollment entity, including audit report and testing results, to HHS. Based on current EDE participation and potential market size, we estimate that 4 EDE entities will participate, and therefore this data collection would have an annual burden of 288 hours with a cost of approximately \$22,020.

We also estimate that it will take up to 122 hours for an Auditor (at an hourly cost of \$76.46) to complete and submit a security and privacy audit package for a direct enrollment entity to HHS each year. Based on current EDE participation and potential market size, we estimate that 14 EDE entities will participate, and therefore this data collection will have an annual burden of 1,708 hours with a cost of approximately \$130,594.

We are finalizing these burden estimates as proposed.

D. ICRs Regarding Income Inconsistencies (\S 155.320(c))

We anticipate that removing the income verification requirements for resolving data matching issues will reduce burden on those consumers who are identified and notified as having this income inconsistency, saving them approximately 45 minutes since they will not be required to complete associated questions in the application or submit supporting documentation. Based on historical data from the FFE, HHS estimates that approximately 295,000 inconsistencies are generated at the household level. Therefore, eliminating these inconsistencies will reduce burden by approximately 221,250 hours. Using the average hourly wage for all occupations (at an hourly cost \$51.44 per hour), we estimate that the annual reduction in cost for each consumer will be approximately \$39, and the annual cost reduction for all consumers who would have generated this income inconsistency will be approximately \$11,381,100.

The burden related to this information collection is approved under OMB control number 0938-1191 (Data

Collection to Support Eligibility **Determinations for Insurance** Affordability Programs and Enrollment through Health Insurance Marketplaces, Medicaid and Children's Health Insurance Program Agencies), which will be revised to account for this reduced burden. The approval for this information collection expires on September 30, 2022.

E. ICRs Regarding Prescription Drug Distribution and Cost Reporting by QHP Issuers (§ 156.295) and PBMs (§ 184.50)

We are finalizing the proposal to revise § 156.295 and add § 184.50 to require QHP issuers or PBMs that contract with QHP issuers to report the data envisioned by section 1150A. We have not previously collected this data; therefore, the burden associated with these proposals will reflect the imposition of the burden for a new collection, and not merely the burden created by changes to existing regulatory text. On January 1, 2020 331 and on September 11, 2020,332 we published notices in the Federal Register and solicited public comment on the burden related to these ICRs. Here, we replicated the discussion regarding burden from the information collection published in September 2020 and solicited a third round of public comment on the burden associated with this collection.

The burden associated with this collection is attributed to QHP issuers and PBMs, and the burden estimates were developed based on our previous experience with QHP information reporting activities. We stated that we were unaware of any QHP issuer that does not contract with a PBM to administer their prescription drug benefit. While we invited comment on whether any QHP issuer does not use a PBM, we did not estimate any burden for a QHP issuer to submit data directly. The following burden estimate reflects our expectation that all data will be

submitted by PBMs.

Across all 50 states and the District of Columbia, we estimate approximately 40 PBMs will be subject to the reporting requirement. We further estimate that these PBMs, taken as a whole, annually contract with approximately 275 QHP issuers to administer the prescription drug benefit for their QHPs. We estimate that the 275 OHP issuers offer 7,000 total QHPs annually or 25.4 QHPs per QHP issuer. Thus, we estimate that each of the 40 PBMs will report data for 175 QHPs on average each year. We understand that some of these PBMs

^{331 85} FR 4993 through 4994.

^{332 85} FR 56227 through 56229.

will contract with more QHP issuers than others, and as such, the reporting requirement will vary per PBM.

Each PBM that administers pharmacy benefits for a QHP issuer will be required to complete a web form and a data collection instrument. The web form will collect data aggregated at the QHP issuer level for all plans and products offered by the QHP issuer combined. The web form will also require the reporting of an allocation methodology that is selected by the PBM to allocate data, where necessary. We expect submitters to maintain internal documentation of the allocation methodologies chosen, as we may need to follow-up with the submitter to better understand the methodology.

PBMs will prepare and submit one data collection instrument per QHP issuer by Health Insurance Oversight System (HIOS) ID. Each data collection instrument will contain information regarding each plan the issuer offers. We estimated that an average PBM will report information for 5,200 NDCs for each QHP. The reports must include the data for all of the plans that the QHP issuer offered in their QHPs in the applicable plan year, even if they have no data to report for that plan year.

Each submitter will also be required to complete an attestation which confirms the data submitted is accurate,

complete, and truthful.

We estimate that 40 PBMs will submit data for this reporting requirement, each submitting data for 175 QHPs on average. For each PBM, we estimate that it will take compliance officers approximately 570 hours (for an annual cost of approximately \$39,934 at a rate of \$70.06 per hour), pharmacy technician 350 hours (for an annual cost of \$11,865 at a rate of \$33.90 per hour), secretaries and administrative assistants 175 hours (for an annual cost of \$6,594 at a rate of \$37.68 per hour), and billing and posting clerks 175 hours (for an annual cost of approximately \$6,836 at a rate of \$39.06 per hour) to prepare and submit the information and 8 hours for a chief executive (for an annual cost of approximately \$1,491.20 at a rate of \$186.40 per hour) to review the information and complete the attestation. In total, we estimate it will take a PBM approximately 1,278 hours to respond to this reporting requirement each year on average, for a total annual cost of approximately \$66,719 per PBM to report data. This estimate will vary by PBM, since each PBM will report for a different number of plans, depending on the number of QHPs offered by a particular QHP issuer. Thus, we estimate the total annual burden for all 40 PBMs combined to be approximately 51,120 hours or \$2,668,796.

We estimate that PBMs will incur burden to complete a one-time technical build to implement the changes necessary for this collection, which will involve activities such as planning, assessment, budgeting, contracting, and reconfiguring systems to generate data extracts that conform to this collection's requirements. We expect that this onetime burden will be incurred primarily in 2021. We estimate that, for each PBM, on average, it will take project management specialists and business operations specialists 500 hours (at \$77.51 per hour), computer system analysts 1,300 hours (at \$92.46 per hour), computer programmers 2,080 hours (at \$89.06 per hour), computer and information systems managers 40 hours (at \$150.38 per hour) and general and operations managers 50 hours (at \$118.30 per hour) to complete this task. The total one-time burden for a PBM would be approximately 3,970 hours on average, with an equivalent cost of approximately \$356,128. For all 40 PBMs, the total one-time burden will be 158,800 hours for a total cost of approximately \$14.2 million. For all 40 PBMs, the average annual burden in 2021–2023 incurred for implementation and reporting will be approximately 87,000 hours with an average annual cost of approximately \$6.5 million.

We estimate that 275 QHP issuers will need to identify for the PBMs each year which plans are QHPs. For each QHP issuer, we estimate that it will take secretaries and administrative assistants 7 hours (for an annual burden of \$263.76 at a rate of \$37.68 per hour) to identify, on average, approximately 25 QHPs offered by a QHP issuer. This estimate will vary by QHP issuer, since each QHP issuer would identify a different number of QHPs, depending on the number of QHPs offered by a particular QHP issuer. Thus, we estimate the total annual burden for all 275 QHP issuers combined to be 1,925 hours or approximately \$72,534.

Comment: We received one comment that inquired whether QHPs that are part of integrated systems comprised of health plans that operate their own pharmacy network are subject to this reporting requirement, and if so, whether such a system would qualify as a PBM or QHP issuer under this burden estimate.

Response: While there is nothing in the statute that would allow exemption from this reporting requirement based on the business structure of reporting entities, we acknowledge that some entities may have initial difficulty complying with the instructions and reporting mechanisms described in the ICR. We intend to provide robust technical assistance to all reporting entities to minimize the upfront burden created by this collection. For purposes of this estimate, we consider such a system a PBM that will report this data.

We are finalizing as proposed.

F. ICRs Regarding Medical Loss Ratio (§§ 158.103, 158.130, 158.240, 158.241)

We are finalizing our proposal to amend § 158.103 to establish the definition of prescription drug rebates and other price concessions that issuers must deduct from incurred claims for MLR reporting and rebate calculation purposes under § 158.140(b)(1)(i). We are also finalizing the proposal to add a new § 158.240(g) to explicitly allow issuers to prepay a portion or all of their estimated MLR rebates to enrollees for a given MLR reporting year, and to establish a safe harbor allowing such issuers, under certain conditions, to defer the payment of rebates remaining after prepayment until the following MLR reporting year. In addition, we are finalizing the proposal to amend § 158.241(a)(2) to allow issuers to provide MLR rebates in the form of a premium credit prior to the date that the rules currently provide. Finally, are finalizing the proposal to clarify MLR reporting and rebate requirements for issuers that choose to offer temporary premium credits during a PHE declared by the Secretary of HHS in the 2021 benefit year and beyond when such credits are permitted by HHS. We anticipate that implementing these provisions will require minor changes to the MLR Annual Reporting Form, but will not significantly increase the associated burden. The burden related to this information collection was approved under OMB control number 0938–1164 (Medical Loss Ratio Annual Reports, MLR Notices, and Recordkeeping Requirements (CMS-10418)). The control number expired on October 31, 2020. A revised collection of information seeking OMB approval for an additional 3 years is currently under review by OMB.

G. Summary of Annual Burden Estimates for Requirements **TABLE 12: Annual Recordkeeping and Reporting Requirements**

Regulation Section(s)	OMB control number	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting (\$)	Total Cost (\$)
§ 155.220(c)(6)	0938-NEW	30	30	19	570	\$43,970	\$43,970
§ 155.221(b)(4)	0938-NEW	77	77	9	693	\$53,458	\$53,458
§ 155.221(b)(4) - Business	0938-NEW	4	4	72	288	\$22,020	\$22,020
Requirements Audit							
§ 155.221(b)(4) - Security and Privacy Audit	0938-NEW	14	14	122	1,708	\$130,594	\$130,594
156.295 & 184.50 (PBM Burden)	0938-NEW	40	40	2,175	87,000	\$6,527,571	\$6,527,571
156.295 & 184.50 (QHP Issuer Burden)	0938-NEW	275	275	7	1,925	\$72,534	\$72,534
Total		440	440		92,184	\$6,850,147	\$6,850,147

Note: There are no capital/maintenance costs associated with the ICRs contained in this rule; therefore, we have removed the associated column from Table 12.

H. Submission of PRA-Related Comments

We have submitted a copy of this final 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 collections discussed in this rule (CMS–9914–F2), please visit the CMS website at www.cms.hhs.gov/

PaperworkReductionActof1995, or call the Reports Clearance Office at 410– 786–1326.

VI. Waiver of Proposed Rulemaking and Delay in Effective Date

We ordinarily publish a notice of proposed rulemaking in the Federal Register and invite public comment on the proposed rule before the provisions of the rule are finalized, either as proposed or as amended, in response to public comments and take effect, in accordance with the APA (Pub. L. 79-404), 5 U.S.C. 553 and, where applicable, section 1871 of the Act. Specifically, 5 U.S.C. 553 requires the agency to publish a notice of proposed rulemaking in the Federal Register that includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. Section 553(c) of the APA further requires the agency to give interested parties the opportunity to participate in the rulemaking through public comment before the provisions of the rule take effect. Section 553(b)(B) of the APA authorize the agency to waive these

procedures, however, if the agency finds good cause that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

Section 553(d) of the APA ordinarily requires a 30-day delay in the effective date of a final rule from the date of its publication in the Federal Register. This 30-day delay in effective date can be waived, however, if an agency finds good cause to support an earlier effective date. Finally, the Congressional Review Act (CRA) (Pub. L. 104–121, Title II) requires a 60-day delay in the effective date for major rules unless an agency finds good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, in which case the rule shall take effect at such time as the agency determines 5 U.S.C. 801(a)(3) and 808(2).

In City of Columbus, as explained earlier in the preamble, the district court vacated four provisions of the 2019 Payment Notice. Implementing the court's order as to two of those provisions, regarding income verification and QIA expenditure reporting, can be accomplished immediately. We find that it is necessary and in the public interest to implement these two provisions quickly to provide immediate notice to the regulated community on what standards will apply and to prevent injury to the public. A delay in implementing the court's decision regarding these two provisions would cause unnecessary harm. HHS needs to move quickly on

these two provisions to fill the regulatory void caused by the court's vacatur. Without immediate action, there will be confusion among issuers and consumers regarding what is expected, which we find to be contrary to the public interest. We find it impractical to wait months to clarify what standards apply after the vacatur of the two policies. In this rule we have explained the impact of the court's decision.

With regard to MLR QIA expenditures, we need to clarify that CMS will implement the court's decision going forward, that is, as CMS explained above, issuers will have to report actual data and cannot report standardized QIA expenditure amounts for 2020 and future MLR reporting years, but issuers will not be required to go back and correct their MLR Annual Reporting Forms for 2017-2019. We find it necessary to immediately clarify issuer reporting obligations to avoid issuer confusion regarding how to report QIA on the 2020 MLR Annual Reporting Forms (due by July 31, 2021) and to mitigate the potential of any delay or inaccuracy in providing consumers rebates that may be owed for the 2020 MLR reporting year. In vacating the QIA provision of the 2019 Payment Notice, the court found that the statute requires the itemization of QIA expenditures and does not permit a reporting of such expenses as a standard percentage of earned premium. In light of the court's decision, additional public comments could not meaningfully impact whether CMS is authorized to allow the standardized reporting of QIA expenses. For this additional reason, we find good

cause to dispense with any delay in implementing the court's decision on this issue to allow for a comment period, because such a delay would be unnecessary.

With regard to income verification requirements, in which the court vacated the requirement imposed on consumers to provide verification if certain sources of information indicated a variance from a consumer's reported income, we find it necessary and in the public interest to immediately suspend enforcement of these provisions to ensure that consumers are not improperly denied advance payments of premium tax credits. Any delay in clarifying what is required after the court's decision will create confusion and interfere with consumers' access to health coverage. We have concerns that any delay in implementing clarification of this rule could lead eligible consumers to improperly losing coverage if they are unable to produce documentation compliant with the income verification requirements. Without immediate changes, the public, and particularly consumers who are eligible for advance payments of the premium tax credits, may be deterred in accessing advance payments of the premium tax credits that allow them to afford coverage.

For these reasons, we find it necessary and in the public interest to move quickly and without the delay that would accompany a period for notice and comment to address the court's decision regarding the QIA provisions and income verification requirements. We find good cause for waiving noticeand-comment rulemaking and the delay in effective date given the decision of the district court and the public interest in expeditious implementation of the district court's ruling. Immediately taking the steps described in section IV. of this final rule to implement the court's decision regarding income verification and QIA reporting, including removing the regulation text at §§ 155.320(c) and 158.221(b)(8) directly in this final rule rather than through the normal notice-and-comment rulemaking cycle and waiving delay of the effective date, will ensure an expeditious implementation of those aspects of the court's decision and remove any doubt about what standards apply after that decision. We believe rulemaking without notice and comment for these limited purposes is a reasonable response to the court's order that will minimize confusion over the current status of our rules in those two areas. Therefore, we find good cause to waive notice-and-comment rulemaking for the provisions in section

IV. of this final rule, waive delay of the effective date, and to issue these changes as part of this final rule.

VII. Regulatory Impact Analysis

A. Statement of Need

This final rule includes standards related to the risk adjustment program and cost sharing parameters for the 2022 benefit year and beyond. It also includes changes related to special enrollment periods; direct enrollment entities; the administrative appeals process with respect to health insurance issuers and non-federal governmental group health plans; and the medical loss ratio program. In addition, it includes changes to the regulation to require the reporting of certain prescription drug information for QHPs or their PBM.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects (\$100 million or more in any one year).

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 \$100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as "economically significant"); (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 novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. An RIA must be prepared for major rules with economically significant effects (\$100 million or more in any one year), and a "significant" regulatory action is subject to review by OMB. HHS has concluded that this rule is likely to have economic impacts of \$100 million or more in at least one year, and therefore, meets the definition of "significant rule" under Executive Order 12866. Therefore, HHS has provided an assessment of the potential costs, benefits, and transfers associated with this rule. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by OMB.

The provisions in this final rule aim to ensure that consumers continue to have access to affordable coverage and health care, and that states have flexibility and control over their insurance markets. They will reduce regulatory burden, reduce administrative costs for states, ensure greater market stability, increase transparency and availability of QHP survey data, and increase transparency on the impact of PBMs on the cost of prescription drugs for QHPs. Through the reduction in financial uncertainty for issuers and increased affordability for consumers, these provisions are expected to increase access to affordable health coverage.

Affected entities, such as Exchanges, issuers and FFE Classic DE and EDE partners, will incur costs to implement new special enrollment period requirements. Issuers will incur costs to comply with audits and compliance reviews of risk adjustment covered plans, reinsurance-eligible plans, and APTC, CSRs, and user fees requirements. Web-brokers and direct enrollment entities will incur costs to comply with operational readiness demonstration requirements. QHP issuers and PBMs will incur costs to implement and operationalize drug data reporting. In accordance with Executive Order 12866, HHS believes that the benefits of this regulatory action justify

Comment: A few commenters stated that the RIA in the proposed rule was inadequate.

Response: As explained in the proposed rule, we are unable to quantify all the effects of the provisions of this rule. Therefore, we have included

qualitative discussions of costs and benefits related to the provisions in this final rule.

C. Impact Estimates of the Payment Notice Provisions and Accounting Table

In accordance with OMB Circular A–4, Table 13 depicts an accounting statement summarizing HHS's assessment of the benefits, costs, and transfers associated with this regulatory action.

This final rule implements standards for programs that will have numerous effects, including allowing consumers to have continued access to coverage and health care, and stabilizing premiums in the individual and small group health insurance markets and in an Exchange. We are unable to quantify all benefits and costs of this final rule. The effects in Table 13 reflect non-quantified impacts and estimated direct monetary costs and transfers resulting from the provisions of this final rule for health insurance issuers and consumers.

We are finalizing the risk adjustment user fee of \$0.25 PMPM for the 2022 benefit year to operate the risk adjustment program on behalf of states, ³³³ which we estimate to cost approximately \$60 million in benefit year 2022. We expect risk adjustment user fee transfers from issuers to the federal government to remain steady at \$60 million, the same as those estimated for the 2021 benefit year.

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³³³ As noted earlier in this rule, no state has elected to operate the risk adjustment program for the 2022 benefit year; therefore, HHS will operate the program for all 50 states and the District of Columbia

TABLE 13: Accounting Statement

Benefits:

Oualitative:

- Continued access to coverage and health care due to new special enrollment periods, and due to change in measure of premium growth to calculate the premium adjustment percentage index.
- Increased probability that consumers are able to maintain continuous coverage as a result of receiving MLR rebates somer
- Increased transparency on the impact of PBMs on the cost of prescription drugs for QHPs.

Costs:	Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized (\$/year)	- \$ 31.57 million	2020	7 percent	2021-2025
	- \$ 30.99 million	2020	3 percent	2021-2025

Quantitative:

- Costs incurred by web-brokers and direct enrollment entities to comply with requirements related to demonstration of operational readiness and compliance with applicable requirements.
- Costs incurred by issuers and PBMs to implement and operationalize drug data reporting, estimated to be approximately \$14.2 million in 2021 and approximately \$2.7 million in 2022 onwards.
- Reduction in costs to consumers, since certain consumers will no longer be required to provide information for income verification purposes, estimated to be approximately \$11.38 million annually starting in 2021.
- Costs incurred by State Exchanges to complete the necessary system changes to remove functionality for processing data matching issues, estimated to be approximately \$3.15 million in 2021.
- Reduction in operational costs to FFEs and State Exchanges due to the rescission of the requirement to process data matching issues, estimated to be approximately \$4.57 million annually starting in 2021.
- Costs incurred by issuers for audits and compliance reviews of risk adjustment covered plans, audits and compliance reviews of reinsurance-eligible plans, and audits and compliance reviews of APTC, CSR, and user fee programs, estimated to be approximately \$2.1 million on average annually in 2021-2025.
- Reduction in potential costs to Exchanges since they would not be required to conduct random sampling as a verification process for enrollment in or eligibility for employer-based insurance when the Exchange reasonably expects that it will not obtain sufficient verification data, estimated to be savings of \$113 million in 2022.
- Regulatory familiarization costs of approximately \$83,000 in 2021.

Qualitative:

• Increased costs due to increases in providing medical services (if health insurance enrollment increases).

Transfers:	Estimate	Year Dollar	Discount Rate	Period Covered
Federal Annualized Monetized	\$266.1 million	2020	7 percent	2021-2025
(\$/year)	\$277.3 million	2020	3 percent	2021-2025
Other Annualized Monetized	\$23 million	2020	7 percent	2021-2025
(\$/year)	\$23 million	2020	3 percent	2021-2025

Quantitative:

- Federal Transfers: Increase in premium tax credit payments estimated to be approximately \$460 million in 2023, \$480 million in 2024, and \$490 million in 2025, due to the change in measure of premium growth to calculate the premium adjustment percentage index.
- Other Transfers: Increase in rebate payments from issuers to consumers due to the removal of the option to report a single QIA activity expense amount equal to 0.8 percent of earned premium, estimated to be \$23 million annually beginning with the 2020 MLR reporting year (rebates payable in 2021).

This RIA expands upon the impact analyses of previous rules and utilizes the Congressional Budget Office's (CBO) analysis of the ACA's impact on federal spending, revenue collection, and insurance enrollment. The ACA ends the transitional reinsurance program and temporary risk corridors program

after the benefit year 2016. Therefore, the costs associated with those programs are not included in Table 13 or 14. Table 14 summarizes the effects of the risk adjustment program on the federal budget from fiscal years 2022 through 2026, with the additional, societal effects of this final rule discussed in this

RIA. We do not expect the provisions of this final rule to significantly alter CBO's estimates of the budget impact of the premium stabilization programs that are described in Table 14.

In addition to utilizing CBO projections, HHS conducted an internal analysis of the effects of its regulations

on enrollment and premiums. Based on these internal analyses, we anticipate that the quantitative effects of the provisions in this rule are consistent with our previous estimates in the 2021 Payment Notice for the impacts associated with the APTC and the premium stabilization programs.

TABLE 14: Estimated Federal Government Outlays and Receipts for the Risk Adjustment and Reinsurance Programs from Fiscal Year 2022-2026, in billions of dollars³³⁴

Year	2022	2023	2024	2025	2026	2022-2026
Risk Adjustment and Reinsurance Program Payments	6	6	7	7	8	34
Risk Adjustment and Reinsurance Program Collections	6	6	7	7	8	34

Note: Risk adjustment program payments and receipts lag by one quarter. Receipt will fully offset payments over time.

Source: Congressional Budget Office. *Net Federal Subsidies Associated With Health Insurance Coverage, 2020 to 2030.* March 6, 2020. Available at https://www.cbo.gov/system/files/2020-03/51298-2020-03-healthinsurance.pdf.

BILLING CODE 4150-28-C

1. Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets (§ 147.104)

The revision to § 147.104(b)(4)(ii) will allow an individual or dependent who did not receive timely notice of a triggering event and otherwise was reasonably unaware that a triggering event occurred to use the date the individual knew, or reasonably should have known, of the occurrence of the triggering event as the date of the triggering event for a special enrollment period to enroll in individual market coverage through or outside of an Exchange. This will enable consumers to maintain continued access to coverage and health care.

2. CMS Enforcement in Group and Individual Markets (Part 150) and Administrative Review of QHP Issuer Sanctions (Part 156, Subpart J)

We are removing the requirement to file submissions to the Departmental Appeals Board in triplicate and instead require electronic filing. Based on our experience, such filings are infrequent, and this proposed change will not have a significant impact. An entity filing a submission will experience a small reduction in costs related to printing and mailing the submission.

3. Risk Adjustment (Part 153)

The risk adjustment program is a permanent program created by section 1343 of the ACA that collects charges from issuers with lower-than-average

risk populations and uses those funds to make payments to issuers with higherthan-average risk populations in the individual, small group, and merged markets (as applicable), inside and outside the Exchanges. We established standards for the administration of the risk adjustment program in subparts A, B, D, G, and H of part 153. If a state is not approved to operate, or chooses to forgo operating its own risk adjustment program, HHS will operate risk adjustment on its behalf. For the 2022 benefit year, HHS will operate a risk adjustment program in every state and the District of Columbia. As described in the 2014 Payment Notice, HHS's operation of risk adjustment on behalf of states is funded through a risk adjustment user fee. For the 2022 benefit year, we used the same methodology that we finalized in the 2020 Payment Notice to estimate our administrative expenses to operate the program. Risk adjustment user fee costs for the 2022 benefit year are expected to remain steady from the prior 2021 benefit year estimates of approximately \$60 million. We estimate that the total cost for HHS to operate the risk adjustment program on behalf of all 50 states and the District of Columbia for 2022 will be approximately \$60 million, and the risk adjustment user fee will be \$0.25 PMPM. Because of the constant costs estimated for the 2022 benefit year, we expect the final risk adjustment user fee for the 2022 benefit year to have no additional financial impact on issuers of risk adjustment covered plans or the federal government.

Additionally, for the risk adjustment factors, we are finalizing an approach to recalibrate the HHS risk adjustment models for the 2022 benefit year by using the 2016, 2017 and 2018 enrolleelevel EDGE data, the same data years

used for the 2021 benefit year.335 We are adopting an approach of using the 3 most recent consecutive years of available enrollee-level EDGE data that are available in time for incorporating the data in the draft recalibrated coefficients published in the proposed rule for recalibration of the risk adjustment models for the 2022 benefit year and beyond. We believe that the approach of blending (or averaging) 3 years of separately solved coefficients will provide stability within the risk adjustment program and minimize volatility in changes to risk scores from the 2021 benefit year to the 2022 benefit year. We are also finalizing the continuation of a pricing adjustment for Hepatitis C drugs for all three models (adult, child and infant). Overall, these changes make limited changes to the number and type of risk adjustment model factors; therefore, we do not expect these changes to impact issuer burden beyond the current burden for the risk adjustment program.

We are finalizing the requirement that issuers that choose to offer premium credits to consumers during a declared PHE, when HHS permits such credits, must report the adjusted plan premium amount, taking into account the credits provided to consumers as a reduction to premiums for the applicable months for risk adjustment data submissions for the 2021 benefit year and beyond. We do not believe that the clarifications regarding risk adjustment reporting in this provision will impose additional administrative burden on health insurance issuers beyond the effort already required to submit data to HHS for the purposes of operating risk adjustment, as previously estimated in

³³⁴ Reinsurance collections ended in FY 2018 and outlays in subsequent years reflect remaining payments to Treasury under section 1341(b)(3)(B)(iv) of the ACA and to CMS for administrative expenses under section 1341(b)(3)(B)(ii) of the ACA, refunds, and allowable activities

³³⁵ As discussed earlier, the one exception relates to RXC 09, which involved the use of only 2016 and 2017 enrollee-level data to develop the applicable 2022 benefit year coefficients and interaction terms.

the interim final rule on COVID-19 (85 FR 54820).

In the 2021 Payment Notice, HHS finalized the risk adjustment state payment transfer formula under the HHS risk adjustment methodology for the 2021 benefit year, and reaffirmed that HHS will continue to operate the risk adjustment program in a budget neutral manner. As finalized in this rule, we will maintain the same methodology for the 2022 benefit year and beyond, unless changed through notice-and-comment rulemaking.336 Therefore, there is no net aggregate financial impact on health insurance issuers or the federal government as a result of the risk adjustment provisions with respect to the finalized proposals regarding the methodology, as well as the premium credit related provisions. However, while risk adjustment transfers are net neutral in aggregate, we recognize that individual issuers may be financially impacted by reduced transfers (either lower risk adjustment payments or lower risk adjustment charges) if any issuer in the issuer's state market risk pool provides premium credits to enrollees in future benefit years during a declared PHE when HHS permits such credits. The extent of this impact will vary based on the number of issuers in a state market risk pool that elect to provide the temporary premium credits during a declared PHE, the amount of these premium credits provided, as well as the market share of the issuers that provide these premium credits.

We do not believe that the impact of this provision will vary from what was previously estimated in the interim final rule on COVID-19 (85 FR 54820). Similar to our analysis of regulatory impacts in the interim final rule on COVID-19, we recognize the potential for financial impacts for individual issuers as a result of these clarifications. We believe that if HHS permitted issuers that provided premium credits when permitted by HHS during a declared PHE to submit unadjusted premiums for the purposes of calculating risk adjustment, distortions could occur which could also financially impact individual issuers. For example, absent the requirement that issuers that offer premium credits report the adjusted, lower premium amount for risk adjustment purposes, an issuer with a large market share with

higher-than-average risk enrollees that provides temporary premium credits would inflate the statewide average premium by submitting the higher, unadjusted premium amount, thereby increasing its risk adjustment payment. In such a scenario, a smaller issuer in the same state market risk pool that owes a risk adjustment charge, and also provides premium credits to enrollees, would pay a risk adjustment charge that is relatively higher than it would have been if it were calculated based on a statewide average that reflected the actual, reduced premium charged to enrollees by issuers in the state market risk pool.

For all of these reasons, we believe that requiring issuers that offer temporary premium credits when permitted by HHS for 2021 and future benefit years' coverage to accurately report to the EDGE server the adjusted, lower premium amounts actually charged to enrollees is most consistent with existing risk adjustment program requirements. We also believe this requirement will mitigate the distortions that would occur if issuers that offer these temporary premium credits did not report the actual amounts charged to enrollees, while avoiding additional financial burden on issuers, as compared to an approach that would permit issuers to report unadjusted premium amounts.

We also are providing more clarity regarding audits and establishing authority to conduct compliance reviews of issuers of risk adjustment covered plans by finalizing amendments to § 153.620(c), with slight modifications to certain audit timeframes in response to comments requesting issuers be provided more time to provide the initial audit data submissions and written corrective action plans. Issuers being audited under the risk adjustment program will be required to comply with audit requirements including participating in entrance and exit conferences, submitting complete and accurate data to HHS in a timely manner, and providing responses to additional requests for information from HHS and to preliminary audit reports in a timely manner. If an audit results in a finding, issuers must also provide written corrective plans in the time and manner set forth by HHS. We are also codifying our authority to recoup risk adjustment (including high-cost risk pool) payments if they are not adequately substantiated by the data and information submitted by issuers during the course of the audit.

We anticipate that compliance with risk adjustment program (including

high-cost risk pool) audits will take 120 hours by a business operations specialist (at a rate of \$77.14 per hour), 40 hours by a computer systems analyst (at a rate of \$92.46 per hour), and 20 hours by a compliance officer (at a rate of \$70.06 per hour) per issuer per benefit year. The cost per issuer will be approximately \$14,356. While the number of issuers participating in the risk adjustment program varies per benefit year, (for example, there were 751 issuers participating in the risk adjustment program for the 2016 benefit year), HHS only intends to audit a small percentage of these issuers, roughly 30-60 issuers per benefit year, and intends to focus these audits on payments under the high-cost risk pool.³³⁷ Depending on the number of issuers audited each year, the total cost to issuers being audited will be between \$430,692 and \$861,384, with an average annual cost of approximately \$646,038.

We anticipate that compliance with risk adjustment program (including high-cost risk pool) compliance reviews will take 30 hours by a business operations specialist (at a rate of \$77.14 per hour), 10 hours by a computer systems analyst (at a rate of \$92.46 per hour), and 5 hours by a compliance officer (at a rate of \$70.06 per hour) per issuer per benefit year. The cost per issuer will be approximately \$3,589. While the number of issuers participating in the risk adjustment program varies per benefit year, (for example, there were 751 issuers participating in the risk adjustment program for the 2016 benefit year), HHS only intends to conduct compliance reviews for no more than 15 issuers per benefit year and intends to focus these reviews on payments under the highcost risk pool. 338 The total annual cost to issuers undergoing compliance reviews will be approximately \$53,836.

We are increasing the materiality threshold for EDGE discrepancies, beginning in the 2020 benefit year of HHS-operated risk adjustment, so that HHS may only take action if the amount in dispute is equal to or exceeds \$100,000 or one percent of the total estimated transfer amount in the applicable state market risk pool, whichever is less. As a result of this change, some discrepant issuers will no

³³⁶ As finalized in the 2020 Payment Notice, we intend to also maintain the high-cost risk pool parameters with a threshold of \$1 million and a coinsurance rate of 60 percent for the 2020 benefit year and beyond unless amended through notice with comment rulemaking. See 84 FR at 17480 through 17484.

³³⁷ Currently, HHS uses HHS–RADV to audit the actuarial risk reported by issuers to their EDGE servers that is used for performing calculations under the state payment transfer formula. See 45 CFR 153.350 and 153.630.

³³⁸ Currently, HHS uses HHS–RADV to audit the actuarial risk reported by issuers to their EDGE servers that is used for performing calculations under the state payment transfer formula. See 45 CFR 153.350 and 153.630.

longer be charged for their EDGE data error. In addition, issuers in the same state market risk pool as the discrepant issuer will not receive positive adjustments to their risk adjustment transfers. This is because HHS's process for addressing material EDGE data discrepancies is to recalculate the dollar value of any difference in risk adjustment transfers, charge the discrepant issuer for the difference, and distribute the amount collected from the discrepant issuer to the issuers in the same state market risk pool who were harmed. Based on analysis of discrepancies from prior years' data, payments to these issuers who were harmed by the discrepant issuer's error are occasionally as low as \$1.00 and typically represent a fraction of one percent of the issuer's overall transfers in the state market risk pool for the applicable benefit year. We anticipate that this change will have a minimal impact on regulatory burden. There might be a slight reduction in administrative burden to some issuers who currently report, and receive adjustments for, EDGE discrepancies that are less than a fraction of total state market risk pool transfers.

4. Audits of Reinsurance-Eligible Plans (§ 153.410(d))

We are finalizing the amendments to § 153.410(d) providing more clarity regarding audits and establishing authority to conduct compliance reviews of reinsurance-eligible plans, with slight modifications to certain audit timeframes in response to comments requesting issuers be provided more time to provide the initial audit data submissions and written corrective action plans. Issuers of reinsurance-eligible plans being audited will be required to comply with audit requirements including participating in entrance and exit conferences, submitting complete and accurate data to HHS in a timely manner, and providing responses to additional requests for information from HHS and to preliminary audit reports in a timely manner. If an audit results in a finding, issuers must also provide written corrective plans in the time and manner set forth by HHS. We are also codifying our authority to recoup reinsurance payments if they are not adequately substantiated by the data and information submitted by issuers during the course of the audit.

We anticipate that compliance with reinsurance program audits will take 120 hours by a business operations specialist (at a rate of \$77.14 per hour), 40 hours by a computer systems analyst (at a rate of \$92.46 per hour), and 20

hours by a compliance officer (at a rate of \$70.06 per hour) per issuer per benefit year. The cost per issuer will be approximately \$14,356. There were 557 issuers participating in the reinsurance program for the 2015 benefit year and 496 issuers participating in the reinsurance program for the 2016 benefit year; however, HHS will only audit a small percentage of these issuers, roughly 30-60 issuers per benefit year. As noted above, we also intend to combine the 2015 and 2016 benefit year reinsurance audits to reduce the burden on issuers subject to such audits. Depending on the number of issuers audited for each benefit year, the total cost to issuers being audited will be between \$430,692 and \$861,384, with an average annual cost of approximately \$646,038.

We anticipate that compliance with reinsurance program compliance reviews will take 30 hours by a business operations specialist (at a rate of \$77.14 per hour), 10 hours by a computer systems analyst (at a rate of \$92.46 per hour), and 5 hours by a compliance officer (at a rate of \$70.06 per hour) per issuer per benefit year. The cost per issuer will be approximately \$3,589. There were 557 issuers participating in the reinsurance program for the 2015 benefit year and 496 issuers participating in the reinsurance program for the 2016 benefit year; however, HHS only intends to conduct compliance reviews for no more than 15 issuers per benefit year and intends to focus these reviews on payments received by reinsurance-eligible plans under the program. The total annual cost to issuers undergoing compliance reviews will be approximately \$53,836.

5. HHS Risk Adjustment Data Validation (§ 153.630(g))

We are codifying two previouslyestablished exemptions from HHS-RADV under § 153.630(g). These exemptions apply when the issuer only has small group carryover coverage for the applicable benefit year or when an issuer is the sole issuer in the state market risk pool for the applicable benefit year (and did not participate in another risk pool with other issuers for that benefit year). We further note that these new regulatory provisions are not establishing new exemptions; instead, the amendments to § 153.630(g) merely codify existing policies and previously established exemptions from HHS-RADV for these subsets of issuers. The impact of the exemption for sole issuers was addressed in the 2019 Payment Notice and the discussion of exempting small group carryover coverage issuers was set forth in the 2020 Payment

Notice.³³⁹ Under these exemptions, these issuers are not be required to complete HHS-RADV for the given benefit year, and therefore, they will have a decreased administrative burden. However, given that these exemptions are limited to issuers only offering small group carry-over coverage and issuers who are sole issuers in all markets in a state, we estimate that approximately 13 issuers will be exempt from HHS-RADV for a given benefit year under these exemptions.

We are also changing the HHS–RADV collections timeline from the timeline finalized in the 2020 Payment Notice in response to stakeholder feedback. Under the revised timeline, we will implement the collection of HHS-RADV charges and disbursement of payments in the calendar year in which HHS-RADV results are released. We do not believe this will change the administrative burden previously estimated in the 2020 Payment Notice 340 as we understand that the majority of states and issuers follow a timeline that aligns more closely with the one in this rulemaking and few pursued the flexibility provided under the timeline finalized in the 2020 Payment Notice.

- 6. Direct Enrollment (§§ 155.220 and 155.221)
- a. QHP Information Display on Web-**Broker Websites**

After consideration of comments received, we are not finalizing the proposal to provide flexibility to webbrokers regarding the information they are required to display on their non-Exchange websites for QHPs in certain circumstances. As explained above, we intend to further consider these issues and clarify the display requirements for web-broker non-Exchange websites in future rulemaking. Until addressed in future rulemaking, beginning at the start of the open enrollment period for plan year 2022, web-broker non-Exchange websites will be required to display all QHP information received from the Exchange or directly from QHP issuers, consistent with the requirements of § 155.205(b)(1) and (c) for all available QHPs with the exception of medical loss ratio information and transparency of coverage measures under § 155.205(b)(1)(vi) and (vii). This interim approach does not establish new requirements and instead represents a change in the exercise of enforcement discretion regarding the standardized comparative information web-brokers are required to display under existing

³³⁹ 83 FR 17047 and 83 FR 17504.

³⁴⁰ See 84 FR 1507.

regulations following our consideration of comments on the proposed changes to the web-broker QHP display requirements.³⁴¹ We previously estimated the administrative burden related to the display of QHP information on web-broker websites in the 2013 Program Integrity final rule.³⁴²

 b. Web-Broker and Direct Enrollment Entity Operational Readiness Review Requirements

At $\S 155.220(c)(6)$, we are finalizing that a web-broker must demonstrate operational readiness and compliance with applicable requirements prior to the web-broker's non-Exchange website being used to complete an Exchange eligibility application or a QHP selection. As reflected in § 155.220(c)(6)(i) through (iv), HHS may request a web-broker submit a number of artifacts or documents or complete certain testing processes to demonstrate the operational readiness of its non-Exchange website. The required documentation may include operational data including licensure information, points of contact, and third-party relationships; security and privacy assessment documentation, including penetration testing results, security and privacy assessment reports, vulnerability scan results, plans of action and milestones, and system security and privacy plans; and an agreement between the web-broker and HHS documenting the requirements for participating in the applicable direct enrollment program. The required testing processes may include enrollment testing, prior to approval or at the time of renewal, and website reviews performed by HHS to evaluate prospective web-brokers' compliance with applicable website display requirements prior to approval. To facilitate testing, prospective and approved web-brokers will have to maintain and provide access to testing environments that reflect their prospective or actual production environments. These amendments codify in regulation existing program requirements that apply to web-brokers that participate in the FFE direct enrollment program and are captured in the agreements executed with participating web-broker direct enrollment entities and related technical guidance.343 Some of these

requirements, such as the collection of operational data, have effectively existed for many years, and so they will impose little to no new burden. The collection of security and privacy assessment documentation is a new requirement, although historically the web-broker agreement has required webbrokers to attest to the implementation and assessment of privacy and security controls. As a result, web-brokers should have historically completed any technical implementation of the controls and should be familiar with assessment of those controls. Completion of enrollment testing is also a new requirement, but use of the direct enrollment pathways inherently requires a web-broker's platform to be capable of processing enrollments. Therefore, the burden of testing that functionality will be very limited. Website reviews have been conducted historically and are performed by HHS, so there will be no burden to webbrokers associated with the completion of those reviews. The burden related to these requirements is discussed in the Collection of Information Requirements section in this rule.

We are revising $\S 155.221(b)(4)$ to add additional detail on the operational readiness requirements for direct enrollment entities. Similar to the proposed web-broker operational readiness requirement at new $\S 155.220(c)(6)$, these amendments codify in § 155.221(b)(4) additional details about the existing program requirements that apply to direct enrollment entities and are captured in the agreements executed with participating web-broker and QHP issuer direct enrollment entities. We note that these requirements are in addition to the operational readiness requirements at new § 155.220(c)(6) for web-brokers, although web-brokers may not be required to submit the documentation required under this proposal to revise § 155.221(b)(4) or they may be permitted to use the same documentation to satisfy the requirements of both operational readiness reviews depending on the specific circumstances of their participation in direct enrollment programs and the source and type of documentation.

In paragraph (b)(4), we require a direct enrollment entity to demonstrate operational readiness and compliance with applicable requirements prior to the direct enrollment entity's website being used to complete an Exchange eligibility application or a QHP selection. We add new paragraphs (b)(4)(i) through (v) to reflect that direct enrollment entities may need to submit

or complete, in the form and manner specified by HHS, a number of artifacts of documentation or various testing or training processes. The documentation may include business audit documentation including: Notices of intent to participate including auditor information; documentation packages including privacy questionnaires, privacy policy statements, and terms of service; and business audit reports including testing results. The required documentation may also include security and privacy audit documentation including: Interconnection security agreements; security and privacy controls assessment test plans; security and privacy assessment reports; plans of action and milestones; privacy impact assessments; system security and privacy plans; incident response plans; and vulnerability scan results. Submission of agreements between the direct enrollment entity and HHS documenting the requirements for participating in the applicable direct enrollment program may also be required. Required testing may include eligibility application audits performed by HHS. The direct enrollment entity may also be required to complete online training modules developed by HHS related to the requirements to participate in direct enrollment programs. We expect minimal new burden associated with this policy as these requirements have historically been established through agreements EDE entities have executed with HHS, and therefore entities have completed these tasks in the past to be able to use the EDE pathway. The burden related to these requirements is discussed in the Collection of Information Requirements section in this final rule.

c. Direct Enrollment Entity Plan Display Requirements

We are revising § 155.221(b)(1) to require that direct enrollment entities display and market QHPs offered through the Exchange, individual health insurance coverage as defined in § 144.103 offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits), and all other products, such as excepted benefits, on at least three separate website pages, with certain exceptions. This change is a revision of a policy adopted in 2019. We anticipate this policy will provide increased flexibility and believe many direct enrollment entity websites are already designed in a manner largely consistent with this proposal, and therefore the burden associated with it is minimal.

³⁴¹ See 45 CFR 155.220(c)(3)(i)(A) and (D).

³⁴² See 78 FR 54128.

³⁴³ See, for example, "Updated Web-broker Direct Enrollment Program Participation Minimum Requirements," May 21, 2020. Available at https:// www.cms.gov/CCIIO/Programs-and-Initiatives/ Health-Insurance-Marketplaces/Downloads/2020-WB-Program-Guidance-052120-Final.pdf.

- 7. Verification Process Related to Eligibility for Insurance Affordability Programs (§ 155.320)
- a. Income Inconsistencies (§ 155.320(c))

In the 2019 Payment Notice we estimated a one-time burden on Exchanges for necessary system changes to meet the requirement related to data matching issues. The 2019 Payment Notice estimate did not take into account the ongoing operational cost for processing data matching issues from this requirement, because ongoing operational costs are dependent on the Exchange's number of applicants with income inconsistencies and the threshold for setting a data matching issue which was unknown at the time.

Now that we are changing this requirement, we expect a cost saving and burden reduction. We estimate the amendments to § 155.320(c) will create a one-time cost for an Exchange of approximately \$450,000 to complete the necessary system changes to remove functionality for this policy. We estimate that approximately half of the State Exchanges implemented verification functionality in 2019 or 2020. Therefore, for 7 State Exchanges, the estimated total cost will be \$3.15 million.

Based on plan year 2019 and 2020 data of the volume of income inconsistencies generated in the FFEs, we estimate that approximately 295,000 fewer inconsistencies will be generated annually by FFEs by removing this requirement and will result in annual savings of approximately \$3,560,650 for FFEs. We anticipate additional ongoing annual savings for FFEs estimated at \$242,550 due to the reduction of approximately 385,000 mailed consumer notices (approximately \$0.63) per notice). We estimate that approximately 57,361 fewer inconsistencies will be generated annually by State Exchanges by removing this requirement and will result in annual savings of approximately \$692,349 annually for State Exchanges. Likewise, we anticipate additional ongoing annual savings for State Exchanges estimated at \$74,861 due to the reduction of approximately 10,694 mailed consumer notices. Total annual savings for FFEs and State Exchanges is estimated to be approximately \$4,570,410. We note that there could also be additional savings in appeals costs.

b. Employer Sponsored Coverage (155.320(d))

As discussed previously in the preamble, as for benefit years 2020 and 2021, we will not take enforcement

action against Exchanges that do not perform random sampling as required by § 155.320(d)(4) for benefit year 2022. HHS's experience conducting random sampling revealed that employer response rates to HHS's request for information were low. The manual verification process described in paragraph (d)(4)(i) requires significant resources and government funds, and the value of the results ultimately does not appear to outweigh the costs of conducting the work because only a small percentage of sample enrollees have been determined by HHS to have received APTC/CSRs inappropriately. We estimate the annual costs to conduct sampling on a statistically significant sample size of approximately 1 million cases to be approximately \$6 million to \$8 million for the Exchanges on the Federal platform and State Exchanges that operate their own eligibility and enrollment platforms. This estimate includes operational activities such as noticing, inbound and outbound calls to the Marketplace call center, and adjudicating consumer appeals. We estimate that the total annual cost for the Exchanges on the Federal platform and the 15 State Exchanges operating their own eligibility and enrollment platform in 2022 would have been approximately \$113 million. Relieving Exchanges of the requirement to conduct sampling for benefit year 2022 will therefore result in total savings of approximately \$113 million. We sought comment on this estimate.

Comment: While we did not receive specific comments on this estimate, one commenter did note that they supported the proposal but encouraged HHS to consider the costs and benefits of any new evidence-based alternative approach for employer-sponsored coverage verification and to assess whether any benefits would be significant enough to warrant future regulatory action on this issue.

Response: Given HHS's own findings that the manual verification process described in paragraph (d)(4)(i) requires significant resources and government funds to fully operationalize, we agree with the commenter that HHS should consider all costs and benefits of any future proposed verification process that is evidence-based as we do not wish to increase administrative burden on states, employers, consumers, and taxpayers. We will continue to explore the best approach for employer sponsored coverage verification, while taking into consideration the cost and benefits of such an approach in future rulemaking.

- 8. Special Enrollment Periods (§ 155.420)
- a. Exchange Enrollees Newly Ineligible for APTC

We are adding a new paragraph at § 155.420(a)(4)(ii)(C) to require Exchanges, no later than January 1, 2024, to allow enrollees and their dependents who qualify for a special enrollment period because they become newly ineligible for APTC in accordance with paragraph (d)(6)(i) or (ii) of this section to enroll in a QHP of any metal level. We anticipate that this change will help reduce Exchanges' implementation burden by simplifying the policy and providing additional time to operationalize it, which some Exchanges may need in light of competing priorities such as the need to implement changes to calculate financial assistance established in the American Rescue Plan Act of 2021. We also expect that this policy will help impacted enrollees' ability to maintain continuous coverage for themselves and for their dependents in spite of losing a potentially significant amount of financial assistance to help them purchase coverage. For example, an enrollee impacted by an increase to his or her monthly premium payment may change to a bronze-level plan, or to catastrophic coverage if they are otherwise eligible. Relatedly, this proposal may benefit the individual market risk pool by encouraging healthy individuals to maintain continuous coverage. Previously, an enrollee who lost APTC eligibility had only two choices: Paying the full premium or terminating his or her coverage. Healthy individuals who lose APTC may be more likely to terminate coverage due to increased premium liability, while enrollees who have one or more medical conditions will be incentivized to maintain coverage in spite of the additional expense. This provision will serve to facilitate continuous coverage of healthy individuals by giving them the ability to enroll in a new plan with a lower premium, thereby supporting a healthier risk pool. Finally, the American Rescue Plan Act of 2021 will prevent some individuals from losing a significant amount of APTC based on a relatively small change in household income, because it allows individuals whose household income exceeds 400 percent FPL to qualify for a premium tax credit if they are otherwise eligible. However, we believe that some consumers will still benefit from this flexibility to plan category limitations, in part because, as described in preamble, there are scenarios other than a household income increase that may

cause consumers to become ineligible for APTC.

As discussed in the proposed rule, we did not believe that this change would have a negative impact on the individual market risk pool, because most applicable enrollees would be seeking to change coverage based on financial rather than health needs. However, we sought comment on concerns about adverse selection risk with permitting newly unsubsidized enrollees to change to any plan of a lower metal level to help them maintain coverage (for example, permitting an individual to change from a gold plan to a bronze plan), or whether this risk would be significantly lower if we only permitted an enrollee to change to a plan one metal level lower than their current OHP. We also requested comment from issuers on whether there were concerns about impacts such as experiencing a decrease in premium receipts from enrollees who opted to change to a lower-cost plan, or whether they view adverse selection as a possibility.

Additionally, we solicited comments on the extent to which Exchanges would experience burden due to the proposed change, and on whether we should exempt the special enrollment periods at § 155.420(d)(6)(i) and (ii) due to becoming newly ineligible for APTC from plan category limitations altogether to help to mitigate this burden, or whether such a change would significantly increase risk for adverse selection.

Finally, we solicited comment on whether this change to current system logic would impose burden on FFE Direct Enrollment and Enhanced Direct Enrollment partners, as well as more generally, on the impact of this proposal.

We received public comments on the potential risk related to the proposed updates to add new flexibility to allow current Exchange enrollees and their dependents to enroll in a new QHP of a lower metal level if they qualify for a special enrollment period due to becoming newly ineligible for APTC. The following is a summary of the comments we received and our responses.

Comment: Almost all comments on this proposal were supportive of this change, for the same reasons that HHS proposed the policy: Allowing enrollees the flexibility to change to a plan of a lower metal level based on a loss of APTC will likely allow more individuals to maintain continuous coverage. No commenters raised concerns that this policy would increase the risk of adverse selection. One

commenter encouraged us to bear in mind the risks of adverse selection in general, but did not oppose this proposal and noted that it would help consumers. Some commenters also noted that this proposal could improve the individual market risk pool by increasing the likelihood that Exchange enrollees would maintain coverage in spite of losing financial assistance. No commenters raised concerns about receiving lower premium payments from enrollees who opted to change to a plan of a lower metal level. Many commenters supported allowing individuals who qualify for a special enrollment period based on a loss of APTC eligibility to change to a plan of any metal level, either to provide enrollees with flexibility to change to the best plan for themselves and their families, to make implementation easier for State Exchanges, or both. One of these commenters requested that instead of applying plan category limitations, HHS require Exchange enrollees to provide documents to confirm their SEP eligibility. Some commenters supported allowing individuals who lose APTC eligibility to change to a plan of a higher or lower metal level rather than just to a plan of a lower metal level. No commenters raised concerns about this proposal's implementation burden on direct enrollment or enhanced direct enrollment partners. Finally, many commenters disagreed with the need to require plan category limitations in general, and requested that HHS provide Exchanges with flexibility in terms of when or whether to implement plan category limitations at all based on considerations related to their specific State Exchange's market.

Response: We agree with commenters that allowing enrollees to access a plan at any metal level through this existing special enrollment period, rather than only allowing them to change to a plan of a lower metal level, will significantly decrease Exchange implementation complexity and cost. As discussed earlier in the preamble, we also agree with commenters who suggested that providing more flexibility for Exchange enrollees in this situation will help them to stay enrolled in coverage by switching to a new QHP that better suits their changed financial situation. We also agree with commenters that this specific policy does not pose adverse selection risk because enrollees are likely to access it based on a financial change as opposed to a change in their health care needs. Therefore, we are finalizing a modified version of this policy to permit Exchange enrollees who lose APTC eligibility to change to

a new plan at any metal level, and to require that Exchanges implement this change no later than January 1, 2024 to provide them with potentially necessary time to account for this change in their operational planning. While some Exchanges may be able to implement this new flexibility sooner than January 1, 2024, in light of competing priorities such as the need to implement changes to calculate financial assistance established in the American Rescue Plan Act of 2021, we believe that substantial flexibility for Exchanges is appropriate.

We also clarify that this policy does not create a new special enrollment period qualifying event, but rather is a change to limitations on plan selection that apply to an already-existing special enrollment period for Exchange enrollees who become newly ineligible for APTC per 45 CFR 155.420(d)(6)(i) and (ii).

We did not propose removing plan category limitations. We will continue to study potential policies to promote continuous coverage and provide consumers with flexibility. Finally, we acknowledge the potential benefit of requiring Exchanges to implement this change quickly, but we believe that providing Exchanges with flexibility to implement it no later than January 1, 2024 strikes an appropriate balance between allowing early implementation if possible and providing Exchanges with necessary flexibility to plan related system updates based on Exchangespecific competing priorities and resources, such as implementation of changes to eligibility for advance payments of the premium tax credit established by the American Rescue Plan Act of 2021.

b. Special Enrollment Periods— Untimely Notice of Triggering Event

We anticipate that the amendments related to qualified individuals who do not receive timely notice of a triggering event and otherwise are reasonably unaware that a triggering event occurred will provide certain consumers a pathway to maintain continuous coverage, which will have an overall positive impact on the risk pool and will benefit consumers. Consumers will benefit from being able to maintain continued access to coverage and health care. We recognize the possibility of some minor adverse selection risk given that consumers with known health issues may be more likely to request a retroactive effective date than healthy consumers. However, we expect this risk to be very limited as the proposal only permits individuals to request a retroactive effective date if they did not

receive timely notice of a triggering event, and we do not expect this to

happen very often.

We expect that Exchanges and direct enrollment partners might incur minor costs to update consumer messaging and processes to administer this proposal. State Exchanges that currently do not have this policy and issuers offering off-Exchange plans would incur minor costs to implement this proposal.

We received public comments on the proposed updates to Special Enrollment Periods—Untimely Notice of Triggering Event. See the preamble to this provision for a summary of the comments we received and our responses.

c. Cessation of Employer Contributions and Government Subsidies to COBRA as Special Enrollment Period Trigger

We anticipate that the amendments regarding special enrollment period eligibility for qualified individuals whose employers completely cease payment of their portion of COBRA continuation coverage premiums will provide clarity regarding a policy that has been operationalized on HealthCare.gov. In addition, we believe that specifying that cessation of government subsidies to COBRA is also a special enrollment period triggering event will help make stakeholders aware of the options consumers have for enrolling through a special enrollment period. We also believe that these amendments will benefit direct enrollment partners and employers by providing clarity regarding special enrollment period eligibility. In addition, consumers who would have otherwise lost coverage due to an increase in the cost of their COBRA continuation coverage will benefit from continuity of coverage and access to health care.

Although this special enrollment period has already been available to individuals enrolling in a qualified health plan on Exchanges on the Federal Platform, because cessation of government subsidies to COBRA has not previously been considered a triggering event, we do anticipate that the Exchanges on the Federal platform, direct enrollment partners, State Exchanges that do not have this policy, and issuers who operate off-Exchange plans will incur some costs to implement this policy, especially in light of the projected increase in COBRA enrollments as a result of the subsidies provided for in the American Rescue Plan Act of 2021.³⁴⁴ However, due to

the similarity between cessation of employer contributions to COBRA, which has already been a special enrollment period trigger on Exchanges on the Federal platform, and government subsidies, we do not believe these amendments will have a negative impact on the risk pool for Federally-facilitated Exchanges. However, we do anticipate that there may be some negative impact to the risk pool in State Exchanges and in the off-Exchange individual market where this special enrollment period has not previously been available.

We received public comments on the proposed updates to cessation of employer contributions to COBRA as special enrollment period trigger. The following is a summary of the comment we received and our response.

Comment: One commenter, while not opposing the proposal, expressed concern regarding the potential impact on adverse selection and premium costs of providing a pathway for those who were enrolled in COBRA continuation coverage to enroll in individual market coverage, given the likelihood of this population having increased claims. In addition, this commenter expressed concern that the requirements of this proposal would be burdensome for employers, as they would need to make changes to current COBRA administration procedures in order to be able to verify eligibility for this special enrollment period. They also noted that the existence of this special enrollment period could reduce the number of employers willing to provide COBRA subsidies as part of a severance package. Another commenter expressed support for the proposal, and stated that because the special enrollment period is based on reduced affordability of coverage rather than a health condition, it avoids concerns regarding adverse selection, and in fact will likely benefit the risk pool overall by encouraging younger individuals to enroll. A State Exchange noted that, because loss of COBRA coverage is used infrequently as a triggering event on its State Exchange, this policy would be unlikely to impact premium costs or the risk pool.

Response: We note that enrollments through this special enrollment period based on cessation of employer contributions to COBRA has already been available on Exchanges on the Federal platform, and thus this policy is

projections from the CBO reference an earlier version of the legislation in which enrollees would have been required to pay 15 percent of the COBRA premium, whereas the final version that was passed subsidizes COBRA premiums at 100 percent. Thus these projections may underestimate the increase in enrollments in COBRA as a result of the subsidies.

unlikely to result in changes for issuers on such Exchanges as a result of adverse selection or for consumers in the form of premium increases. In addition, for State Exchanges and off-Exchange issuers who have not treated cessation of employer contributions to COBRA continuation coverage as a special enrollment period triggering event, we expect, based on a recent CBO analysis projecting low overall enrollment in COBRA among the eligible population,345 as well as the comment on this provision from a State Exchange noting that loss of COBRA coverage is used infrequently as a triggering event on its Exchange, that the volume of enrollments through this special enrollment period based on cessation of employer contributions will be low. However, the inclusion of government subsidies to COBRA coverage as a special enrollment period trigger may lead to an increase in uptake of COBRA coverage among the eligible population, and a corresponding increase in enrollments through this special enrollment period for Exchanges using the Federal platform, State Exchanges, and off-Exchange issuers, and thereby have a negative impact on these risk pools and on premiums.

The aforementioned CBO analysis notes however that many of the enrollees who are projected to enroll in COBRA as a result of the federal subsidies would have otherwise enrolled in individual market coverage,³⁴⁶ thus limiting the potential negative impact. Additionally, because this provision does not impose any new requirements on employers or increase the opportunity to enroll in employersponsored coverage, it is unlikely that it will discourage them from providing COBRA subsidies as part of a severance package, nor is it likely to provide additional administrative burden. Because this special enrollment period provides a pathway to individual health insurance coverage for individuals whose employer ceases contributions to their COBRA coverage, this provision may, in fact, increase the number of employers willing to provide contributions to former employees'

9. Provisions Related to Cost Sharing (§ 156.130)

COBRA coverage.

As described earlier in the preamble, we are finalizing a premium adjustment percentage of 1.3760126457 for the 2022 benefit year. The annual premium

³⁴⁴ https://www.cbo.gov/system/files/2021-02/ hEdandLaborreconciliationestimate.pdf. These

³⁴⁵ https://www.cbo.gov/system/files/2021-02/ hEdandLaborreconciliationestimate.pdf.

³⁴⁶ https://www.cbo.gov/system/files/2021-02/ hEdandLaborreconciliationestimate.pdf.

adjustment percentage is used to set the rate of increase for several parameters detailed in the ACA, including: The annual limitation on cost sharing (defined at § 156.130(a)), the required contribution percentage used to determine eligibility for certain exemptions under section 5000A of the Code (defined at § 155.605(d)(2)), and the employer shared responsibility payments under sections 4980H(a) and 4980H(b) of the Code. Additionally, we

finalized other cost-sharing parameters using an index based on the final premium adjustment percentage for the 2022 benefit year.

In accordance with § 155.605(d)(2), we are finalizing a required contribution of 8.09 percent for the 2022 benefit year, which reflects the premium adjustment percentage calculation for the 2022 benefit year detailed in preamble. In accordance with § 156.130(a)(2), we are finalizing a maximum annual limitation

on cost sharing of \$8,700 for self-only coverage and \$17,400 for other than self-only for the 2022 benefit year. The CMS Office of the Actuary estimates that the change in measure of premium growth from using private health insurance (excluding Medigap, and property and casualty insurance) to ESI to calculate the premium adjustment percentage may have the following impacts between 2022 and 2026.³⁴⁷

TABLE 15: Impacts of Modifications to the 2022 Benefit Year Premium Adjustment Percentage

Calendar Year	2022 ³⁴⁸	2023	2024	2025	2026
Exchange Enrollment Impact (enrollees, thousands)	0	20	20	20	20
Premium Impacts					
Gross Premium Impact (change from 2018 %)	0%	0%	0%	0%	0%
Net Premium Impact (change from 2018, %)	0%	0%	-1%	-1%	-1%
Federal Impacts (dollars, millions)					
Premium Tax Credits (million, \$)*	0	460	480	490	510

^{*}Note: The federal impact figures are positive to indicate an increase in spending for the federal government.

As noted in Table 15, we expect that the change in measure of premium growth used to calculate the premium adjustment percentage index for the 2022 benefit year and beyond will likely result in:

- Net premium decreases of approximately \$181 million per year, which is approximately one percent of 2018 benefit year net premiums, for the 2024 benefit year through the 2026 benefit year.
- An increase in federal premium tax credit spending of \$460 million to \$510 million between 2023 and 2026, due to the decrease in the applicable percentage table, based on an assumption that the Department of the Treasury and the IRS will adopt the use of the NHEA ESI premium measure finalized for the calculation of the premium adjustment percentage in this rule for the purposes of calculating the indexing of the premium tax credit applicable percentage and required contribution percentage under section 36B of the Code.

We are also finalizing the proposed rates of reductions to the maximum annual limitation on cost sharing of 2/3 for enrollees with a household income between 100 and 200 percent of FPL, 1/5 for enrollees with a household income between 200 and 250 percent of FPL, and no reduction for individuals with household incomes of 250 to 400 percent of FPL for the 2022 benefit year and beyond. We are finalizing the proposed methodology to ensure that these reductions do not result in unacceptably high AVs. We do not anticipate that the rates of reduction and the methodology will result in significant economic impact because these rates of reduction and the AVimpact testing methodology have remained consistent since the 2014 Payment Notice.

We are also finalizing that beginning with the 2023 benefit year, we will publish the premium adjustment percentage, maximum annual limitation on cost sharing, reduced maximum annual limitations on cost sharing, and required contribution percentage in

guidance in January of the calendar year preceding the benefit year to which the parameters are applicable, unless HHS is changing the methodology, in which case we will do so through the applicable HHS notice of benefit and payment parameters. This policy change affects only the timing and method by which these parameters are released and will provide issuers with additional time for plan design and rate setting.

10. Prescription Drug Distribution and Cost Reporting by QHP Issuers (§ 156.295) and PBMs (§ 184.50)

As part of the ACA, Congress passed section 6005, which added section 1150A to the Act, requiring a PBM under a contract with a QHP offered through an Exchange established by a state under section 1311 of the ACA ³⁴⁹ to provide certain prescription drug information to the QHP and to Secretary at such times, and in such form and manner, as the Secretary shall specify. Section 1150A(b) of the Act addresses the information that a QHP issuer and their PBM must report. Section

³⁴⁷ CMS Office of the Actuary's estimates are based on their health reform model, which is an amalgam of various estimation approaches involving federal programs, employer-sponsored insurance, and individual insurance choice models that ensure consistent estimates of coverage and spending in considering legislative changes to current law.

supplant the economic impacts of finalizing the premium adjustment percentage and cost-sharing parameters using the NHEA ESI premium measure for the 2022 benefit year.

³⁴⁹ This includes an FFE, as a Federal Exchange may be considered an Exchange established under section 1311 of the ACA. *King* v. *Burwell*, 576 U.S. 988 (2015).

1150A(c) of the Act requires the Secretary to keep the information reported confidential and specifies that the information may not be disclosed by the Secretary or by a plan receiving the information, except that the Secretary may disclose the information in a form which does not disclose the identity of a specific PBM, plan, or prices charged for drugs for certain purposes.³⁵⁰

On January 1, 2020 ³⁵¹ and on September 11, 2020, ³⁵² we published notices in the **Federal Register** and solicited public comment on the burden related to the collection of information required by section 1150A of the Act. In those information collections and in this final rule, we fulfill this statutory requirement with the goal of imposing the least amount of burden possible while collecting data that would be usable to ensure increased transparency on prescription drug coverage in QHPs.

For example, to reduce overall burden, we will collect data directly from PBMs that contract with QHPs directly, rather than require QHP issuers to serve as a go-between their PBM and CMS.³⁵³ This approach will reduce overall burden on QHP issuers and will place the onus to report data on those entities that QHP issuers have already entrusted to oversee and manage their prescription drug line of business.

These information collections also explained how we utilize the reporting paradigm currently used by CMS' DIR reporting requirement which collects, in part, the data required by section 1150A(a)(1) of the Act from Prescription Drug Plan sponsors of a prescription drug plan and Medicare Advantage organizations offering a Medicare Advantage Prescription Drug Plan under part D of title XVII. We noted our intention to utilize the DIR reporting mechanisms only to the extent authorized solely by section 1150A(a)(2), explaining our understanding that DIR reporting is not authorized by section 1150A alone.354 Usage of these existing CMS reporting paradigms ensures minimal impact of a new data collection on QHP issuers and

PBMs, given the longstanding industry use of the DIR reporting mechanism. The payer community is familiar with fulfilling the DIR reporting requirement. Therefore, we believe replicating that collection to the greatest degree will enable respondents to implement this data collection with minimal relative burden.

11. Audits of APTC, CSRs, and User Fees (§ 156.480(c))

We are providing more clarity around the APTC, CSR, and user fee program audits and establishing authority for HHS to conduct compliance reviews to assess compliance with federal APTC, CSR, and user fee standards by finalizing amendments to § 156.480(c), with slight modifications to certain audit timeframes in response to comments requesting issuers be provided more time to provide the initial audit data submissions and written corrective action plans. QHP issuers being audited for compliance with federal APTC, CSR, and user fee standards will be required to comply with audit requirements including participating in entrance and exit conferences, submitting complete and accurate data to HHS in a timely manner, and providing responses to additional requests for information from HHS and to preliminary audit reports in a timely manner. If an audit results in a finding, issuers must also provide written corrective plans in the time and manner set forth by HHS. We are also codifying our authority to recoup APTC and CSR payments if they are not adequately substantiated by the data and information submitted by issuers during the course of the audit.

We anticipate that compliance with APTC, CSR, and user fee program audits will take 120 hours by a business operations specialist (at a rate of \$77.14 per hour), 40 hours by a computer systems analyst (at a rate of \$92.46 per hour), and 20 hours by a compliance officer (at a rate of \$70.06 per hour) per issuer per benefit year. The cost per issuer will be approximately \$14,356. While the number of QHP issuers participating in the APTC, CSR, and user fee programs varies per benefit year (for example, there were 561 QHP issuers participating in the programs for the 2019 benefit year), HHS only intends to audit a small percentage of these issuers, roughly 30-60 issuers per benefit year. Depending on the number of issuers audited each year, the total cost to issuers being audited will be between \$430,692 and \$861,384, with an average annual cost of approximately \$646,038.

We anticipate that APTC, CSR, and user fee program compliance reviews will take 30 hours by a business operations specialist (at a rate of \$77.14 per hour), 10 hours by a computer systems analyst (at a rate of \$92.46 per hour), and 5 hours by a compliance officer (at a rate of \$70.06 per hour) per issuer per benefit year. The cost per issuer will be approximately \$3,589. While the number of QHP issuers participating in the APTC, CSR, and user fee programs varies per benefit year, (for example, there were 561 QHP issuers participating in the programs for the 2019 benefit year), HHS only intends to conduct compliance reviews for no more than 15 issuers per benefit year. The total annual cost to issuers undergoing compliance reviews will be approximately \$53,836.

12. Quality Rating System (§ 156.1120) and Enrollee Satisfaction Survey System (§ 156.1125)

We are finalizing removal of the composite level and domain level of the QRS hierarchy, which is a key element of the QRS framework that establishes how quality measures are organized for scoring, rating and reporting purposes. We will also make the full QHP Enrollee Survey results publicly available in an annual PUF. We anticipate that these changes will benefit consumers and QHP issuers by increasing transparency and availability of QHP survey data through publication of a nationwide PUF, and simplifying the QRS scoring hierarchy to improve understanding of QRS quality rating information and alignment with other CMS quality reporting programs. Neither refinement will alter the data collection and reporting requirements for the QRS and QHP Enrollee Survey because QHP issuers are already required to report all data needed to support a QHP Enrollee Survey PUF and simplified QRS hierarchy. Therefore, these refinements will create no additional cost or burden for QHP issuers.

13. Medical Loss Ratio (§§ 158.103, 158.130, 158.240, and 158.241)

We are finalizing the proposal to amend § 158.103 to establish the definition of prescription drug rebates and other price concessions that issuers must deduct from incurred claims for MLR reporting and rebate calculation purposes pursuant to § 158.140(b)(1)(i). We do not expect this to change the result of the regulatory impact analysis previously conducted for the 2021 Payment Notice with respect to the requirement that issuers deduct from MLR incurred claims not only prescription drug rebates received by

as The purposes are: As the Secretary determines to be necessary to carry out section 1150A or part D of title XVIII; to permit the Comptroller General to review the information provided; to permit the Director of the Congressional Budget Office to review the information provided; and, to States to carry out section 1311 of the ACA.

^{351 85} FR 4993 through 4994.

^{352 85} FR 56227 through 56229.

³⁵³ Under this interpretation, QHP issuers will be required to report data directly to CMS only when the QHP issuer does not contract with a PBM to administer their drug benefit.

³⁵⁴ Except for PBM spread amount aggregated to the plan benefit package level, section 1150A imposes no additional reporting requirements for entities subject to DIR reporting. See 77 FR 22094.

the issuer, but also any price concessions received and retained by the issuer and any prescription drug rebates and other price concessions received and retained by a PBM or other entity providing pharmacy benefit management services to the issuer.

We are also finalizing the proposal that issuers that choose to provide temporary premium credits to consumers during a declared PHE in 2021 and beyond when permitted by HHS must account for these credits as reductions to premium for the applicable months when reporting earned premium for the applicable MLR reporting year. Although we do not know how many states will permit issuers to provide temporary credits to reduce premiums or how many issuers will elect to do so, for purposes of this analysis, we previously estimated in the interim final rule on COVID–19 (85 FR 54820) that approximately 40 percent of issuers offering individual, small group or merged market health insurance coverage will provide these premium credits to reduce the premiums charged to enrollees to support continuity of coverage during the PHE for COVID-19. We do not estimate a change to the cost or burden previously estimated in that final rule, and anticipate that that regulatory impact estimate would extend to 2021 and beyond. Although we do not know the number of issuers that will provide these temporary premium credits or the amount of premium credits that issuers may elect to provide, for purposes of this estimate we assume that such premium credits will on average constitute approximately 8 percent of total annual premium (equivalent to one month of premium), as previously estimated in that final rule. Because the MLR calculation uses three consecutive years of data, there may be additional rebate decreases in subsequent years, although the impact on rebates might be smaller as issuers will likely account for the premium relief provided to enrollees through these temporary premiums credits at the time they develop premium rates for the 2022 benefit year and future benefit years.

As noted in section IV of this final rule, on March 4, 2021, the U.S. District Court for the District of Maryland, in *City of Columbus, et al.* v. *Cochran,* vacated 45 CFR 158.221(b)(8). As a result, we are finalizing the deletion of § 158.221(b)(8) and removing the option that issuers had for the 2017–2019 MLR reporting years to report a single standardized QIA expense amount equal to 0.8 percent of earned premium in lieu of reporting the issuers' actual expenditures for activities that improve

health care quality. The 0.8 percent QIA option was added to 45 CFR part 158 in the 2019 Payment Notice final rule in order to reduce the burden on issuers required to accurately identify, track, and report QIA expenses. In that final rule, based on MLR data for the 2015 MLR reporting year, HHS estimated that the amendment would decrease rebate payments from issuers to consumers by approximately \$23 million.

Accordingly, we estimate that finalizing the deletion of § 158.221(b)(8) in this final rule will increase rebate payments from issuers to consumers by approximately \$23 million annually.

We are also finalizing the proposal to add a new § 158.240(g) to explicitly allow issuers to prepay a portion or all of their estimated MLR rebates to enrollees for a given MLR reporting year, and to establish a safe harbor allowing such issuers, under certain conditions, to defer the payment of rebates remaining after prepayment until the following MLR reporting year. We are additionally finalizing the proposal to amend § 158.241(a) to allow issuers to provide rebates in form of a premium credit prior to the date that the rules previously provided. We do not expect these provisions to have a significant quantitative impact as they will not change the rebate amounts provided by issuers to enrollees. Since it is easiest and most cost-effective for issuers to conduct rebate disbursement activities all at once, the additional rebates will generally be paid during the following year's disbursement cyclethat is, if 95 percent of rebates for 2020 was prepaid during Jan.-July 2021, the remainder will be paid no later than Sept. 2022 (possibly earlier in 2022 if the issuer decides to prepay again). However, we note that there may be some increased administrative burden on issuers that owe rebates remaining after prepayment associated with good faith efforts to locate enrollees, if any, with whom they no longer have a direct economic relationship.

14. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that this rule will be reviewed by all affected issuers, states, PBMs, and some individuals and other entities that commented on the proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that

not all commenters reviewed the proposed rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of affected entities and commenters to be a fair estimate of the number of reviewers of this rule.

We are required to issue a substantial portion of this rule each year under our regulations and we estimate that approximately half of the remaining provisions would cause additional regulatory review burden that stakeholders do not already anticipate. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore, for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule, excluding the portion of the rule that we are required to issue each year.

Using the wage information from the BLS for medical and health service managers (Code 11-9111), we estimate that the cost of reviewing this rule is \$110.74 per hour, including overhead and fringe benefits.355 Assuming an average reading speed, we estimate that it will take approximately 1 hours to review the relevant portions of this final rule that causes unanticipated burden. We assume that 750 entities will review this final rule. For each entity that reviews the rule, the estimated cost is approximately \$110.74. Therefore, we estimate that the total cost of reviewing this regulation is approximately \$83,055 $($110.74 \times 750 \text{ reviewers}).$

D. Regulatory Alternatives Considered

In developing the policies contained in this final rule, we considered numerous alternatives to the presented proposals. Below we discuss the key regulatory alternatives that we considered.

Under part 153 of this final rule, we are finalizing an approach to recalibrate the risk adjustment models for the 2022 benefit year using 2016, 2017, and 2018 enrollee-level EDGE data. The purpose of using these data years is to better ensure that the applicable benefit year's risk adjustment model coefficients can be included in the applicable benefit year's proposed payment notice. As part of our consideration of proposals to recalibrate the risk adjustment models for the 2022 benefit year, we also considered recalibrating the models using the 2017,

 $^{^{355}\,}https://www.bls.gov/oes/current/oes_nat.htm.$

³⁵⁶ As detailed above, the one exception relates to RXC 09, which involved the use of only 2016 and 2017 enrollee-level data to develop the applicable 2022 benefit year coefficients and interaction terms.

2018, and 2019 benefit year enrollee-level EDGE data. If we had proposed that approach, we would not have been able to provide the proposed coefficients in the proposed rule and would have had to instead display draft coefficients only reflective of the 2017 and 2018 benefit years of enrollee-level EDGE data. This approach would not have achieved the desired policy goals—namely, to respond to stakeholder requests for HHS to take steps to provide the draft and final coefficients at an earlier time.

We also considered alternatives to the proposed model specification changes and revised enrollment duration factors that we are not finalizing in this rulemaking. For example, we initially considered adding only a non-linear term or only adopting new HCC counts terms for all enrollees to the adult and child risk adjustment models. As described earlier in this final rule, we had convergence issues with the non-linear model specifications and concerns that the HCC counts terms approach posed significant gaming concerns when pursued separately.

In addition to the non-linear and HCC counts model specifications, we also considered alternatives to the two-stage specification and HCC interacted counts model. Specifically, we tested various alternative caps for the weights based on the distribution of costs, but found the finalized caps resulted in better prediction on average. For the prediction weights, we tested various alternative forms of weights, including reciprocals of square root of prediction, log of prediction, and residuals from first step estimation, but the reciprocal of the capped predictions resulted in better predictive ratios for low-cost enrollees compared to any of the other weights.

For the interacted HCC counts factors, we tested several HCCs and considered adding and removing certain HCCs from the list in Table 3 in the proposed rule. We choose the list of HCCs in Table 3 of the proposed rule because including those HCCs most improved prediction for enrollees with the highest costs, multiple HCCs, and with these specific HCCs. For the HCC interacted counts, we also considered various alternatives to structure the interacted HCC counts, such as applying individual interacted HCC counts factors (between 1-10 based on the number of HCCs an enrollee has) to each of the selected HCCs included in the models (instead of combining all of the selected HCCs into two severity and transplant indicator groups). We choose the proposed model specifications because they would add fewer additional factors to the models

without sacrificing any significant predictive accuracy. However, as noted above, after consideration of comments, we are not finalizing the adoption of the either the proposed two-stage model specification or interacted HCC counts factors in the adult and child models or the accompanying removal of the existing severity illness indicators from the adult models.

For the enrollment duration factors in the adult risk adjustment models, we proposed modifying the enrollment duration factors to apply monthly duration factors of up to 6 months for those with HCCs. The purpose of this proposed change was to address the underprediction of plan liability for adults with HCCs. As part of this assessment, we considered whether enrollment duration factors by market type may be warranted. However, as described earlier in this final rule, we did not find a major distinction in market-specific incremental monthly enrollment duration factor risk scores after isolating the enrollment duration factors to enrollees with HCCs. However, as detailed above, after consideration of comments, we are not finalizing the adoption of the new proposed adult model enrollment duration factors or the accompanying removal of the current adult model enrollment duration factors.

In regards to the changes to § 155.320, we considered taking no action to modify the requirement that when an Exchange does not reasonably expect to obtain sufficient verification data related to enrollment in or eligibility for employer sponsored coverage that the Exchange must select a statistically significant random sample of applicants and attempt to verify their attestation with the employer listed on their Exchange application. However, based on HHS's experience conducting sampling, this manual verification process requires significant resources for a low return on investment, as using this method HHS identified only a small population of applicants who received APTC/CSR payments inappropriately. We ultimately determined that a verification process for employersponsored coverage should be one that is evidence or risk-based and that not taking enforcement action against Exchanges that do not conduct random sampling was appropriate as we anticipate future rulemaking is necessary to ensure that Exchanges have more flexibility for such verifications.

We considered taking no action regarding our policy to add a new § 155.420(a)(4)(iii)(C) to allow enrollees and their dependents to enroll in a new

QHP of a lower metal level 357 if they qualify for a special enrollment period due to becoming newly ineligible for APTC. However, based on questions and concerns from agents and brokers, the previous policy prevents some enrollees from maintaining continuous coverage because they lose a significant amount of financial assistance that would help them purchase coverage, and cannot enroll in a new, less costly QHP of a lower metal level. HHS believes this policy is unlikely to result in adverse selection, and may improve the risk pool by supporting continued health insurance enrollment by healthy individuals who would be forced to end coverage in response to an increase in premium.

We also considered whether to provide additional flexibility to allow enrollees and their dependents who become newly eligible for APTC in accordance with section 155.420(d)(6)(i) or (ii) to enroll in a QHP of a higher metal level, because we recognize becoming newly eligible for APTC may increase the affordability of higher metal level plans for some individuals. However, as discussed in the proposed rule, we believed including this flexibility would largely exempt the special enrollment periods at paragraph (d)(6)(i) and (ii) from the rules at 155.420(a)(4)(iii), which might make it likely that more individuals would change coverage levels in response to health status changes. More importantly, while we believe the flexibilities for individuals who become newly ineligible for APTC are needed in order to promote continuous coverage for individuals who can no longer afford their original plan choice, no similar affordability and continuous coverage concerns exist for enrolled consumers who gain APTC eligibility during the coverage year. However, as noted in preamble, we received several comments requesting that HHS provide this flexibility for enrollees who newly become eligible for APTC. Therefore,

³⁵⁷ Section 1302(d) of the ACA describes the various metal levels of coverage based on AV, and section 2707(a) of the PHS Act directs health insurance issuers that offer non-grandfathered $% \left(x\right) =\left(x\right) +\left(health insurance coverage in the individual or small group market to ensure that such coverage includes the EHB package, which includes the requirement to offer coverage at the metal levels of coverage described in section 1302(d) of the ACA. Consumerfacing HealthCare.gov content explains that metal levels serve as an indicator of "how you and your plan split the costs of your health care," noting that lower levels like bronze plans have lower monthly premiums but higher out of pocket costs when consumers access care, while higher levels like gold have higher monthly premiums but lower out of pocket costs to access care—see https:// www.healthcare.gov/choose-a-plan/planscategories/.

while we did not propose additional plan flexibility for enrollees who become newly eligible for APTC, we will continue to study potential policies to promote continuous coverage and provide consumers with flexibility.

We considered taking no action regarding our policy to add a new § 155.420(c)(5) to allow a qualified individual, dependent or enrollee that did not receive timely notice of a triggering event or was otherwise reasonably unaware that a triggering event described in § 155.420(d) occurred to select a new plan within 60 days of the date he or she knew, or reasonably should have known, of the occurrence of the triggering event. However, in some circumstances this would result in consumers, through no fault of their own, being unable to access a special enrollment period for which they were eligible. Additionally, we considered not adding new § 155.420(b)(5) to provide a qualified individual, dependent, or enrollee described in new $\S 155.420(c)(5)$ with the option for a retroactive effective date. Failing to provide the option for a retroactive effective date would necessarily result in a gap in coverage, and therefore hinder a consumer's ability to maintain continuous coverage.

We also considered limiting the applicability of the policy to add a new § 155.420(c)(5) to a qualified individual, enrollee, or dependent who does not receive notice or become reasonably aware of the occurrence of a triggering event until more than 15 days after the triggering event. However, failing to apply the new § 155.420(c)(5) to qualified individuals, enrollees, or dependents who receive notice or become reasonably aware of the occurrence of a triggering event 15 days or less after the triggering event and eliminating the option for a retroactive effective date for those individuals would result in a gap in coverage for such individuals and hinder their ability to maintain continuous coverage.

We considered taking no action regarding our policy to add new paragraph (d)(15) to § 155.420 to specify that complete cessation of employer contributions or government subsidies to COBRA continuation coverage is a special enrollment period triggering event. However, codifying this policy in regulation provides transparency to a long-standing interpretation of the Exchanges on the Federal platform. Additionally, codifying this policy in regulation ensures alignment across all Exchanges and in the off-Exchange individual market.

For the revisions to § 156.295 and addition of § 184.50 to require certain

prescription drug reporting, we considered, but did not yet require, the reporting of data described in section 1150A(b)(1) broken down by pharmacy type (which includes an independent pharmacy, chain pharmacy, supermarket pharmacy, or mass merchandiser pharmacy that is licensed as a pharmacy by the state and that dispenses medication to the general public). As mentioned in this final rule, we are aware that it is not currently possible to report such data by pharmacy type because pharmacy type is not a standard classification currently captured in industry databases or files. While we believe the imposition of this level of reporting would impose unreasonable burden at this time, we intend to begin collecting this information in the future.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act, (5 U.S.C. 601, et seq.), requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of the final rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The RFA generally defines a "small entity" as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-forprofit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of "small entity." HHS uses a change in revenues of more than 3 to 5 percent as its measure of significant economic impact on a substantial number of small entities.

In this rule, we finalize standards for the risk adjustment program, which are intended to stabilize premiums and reduce incentives for issuers to avoid higher-risk enrollees. We believe that health insurance issuers and group health plans would be classified under the North American Industry Classification System code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of \$41.5 million or less are considered small entities for these North American Industry Classification System codes. Issuers could possibly be classified in 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard would be \$35 million or less.358 We believe that few, if any,

insurance companies underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) fall below these size thresholds. Based on data from MLR annual report 359 submissions for the 2019 MLR reporting year, approximately 77 out of 479 issuers of health insurance coverage nationwide had total premium revenue of \$41.5 million or less. This estimate may overstate the actual number of small health insurance companies that may be affected, since over 67 percent of these small companies belong to larger holding groups, and many, if not all, of these small companies are likely to have nonhealth lines of business that will result in their revenues exceeding \$41.5 million. Therefore, we do not expect the provisions of this rule to affect a substantial number of small entities.

In this rule, we are requiring certain QHP issuers or their PBMs to report certain prescription drug information to CMS. We are not aware of any QHP issuer or PBM that contracts with a QHP issuer to administer their prescription drug benefit which would be considered a "small entity" under the RFA.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule under title XVIII, title XIX, or part B of title 42 of the Act may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. While this rule is not subject to section 1102 of the Act, we have determined that this rule will not affect small rural hospitals. Therefore, the Secretary has determined that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

F. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any federal mandate that may result in expenditures in any one year by a state, local, or Tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. In 2021 that threshold is approximately \$158

 $^{^{358}\,}https://www.sba.gov/document/support-table-size-standards.$

 $^{^{359}\,\}mathrm{Available}$ at https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html.

million. Although we have not been able to quantify all costs, we expect the combined impact on state, local, or Tribal governments and the private sector to be below the threshold.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a final rule that imposes substantial direct costs on state and local governments, preempts state law, or otherwise has federalism implications. In our view, while this final rule will not impose substantial direct requirement costs on state and local governments, this regulation has federalism implications due to potential direct effects on the distribution of power and responsibilities among the state and federal governments relating to determining standards relating to health insurance that is offered in the individual and small group markets.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have federalism implications or limit the policy making discretion of the states, we have engaged in efforts to consult with and work cooperatively with affected states, including participating in conference calls with and attending conferences of the NAIC, and consulting with state insurance officials on an individual basis.

While developing this rule, we attempted to balance the states' interests in regulating health insurance issuers with the need to ensure market stability. By doing so, we complied with the requirements of Executive Order 13132.

Because states have flexibility in designing their Exchange and Exchangerelated programs, state decisions will ultimately influence both administrative expenses and overall premiums. States are not required to establish an Exchange or risk adjustment program. For states that elected previously to operate an Exchange, those states had the opportunity to use funds under Exchange Planning and Establishment Grants to fund the development of data. Accordingly, some of the initial cost of creating programs was funded by Exchange Planning and Establishment Grants. After establishment, Exchanges must be financially self-sustaining, with revenue sources at the discretion of the state. A user fee is assessed on issuers under all existing Exchange models, including State Exchanges where the user fee is assessed by the state, SBE-FPs, and the FFEs.

H. Congressional Review Act

This final rule is subject to the Congressional Review Act provisions of

the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801, et seq.), which specifies that before a rule can take effect, the federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report containing a copy of the rule along with other specified information, and has been transmitted to the Congress and the Comptroller for review. Pursuant to the Congressional Review Act, the Office of Information and Regulatory Affairs designated this final rule as a "major rule" as that term is defined in 5 U.S.C. 804(2), because it is likely to result in an annual effect on the economy of \$100 million or more.

I, Elizabeth Richter, Acting Administrator of the Centers for Medicare & Medicaid Services, approved this document on April 21, 2021.

List of Subjects

45 CFR Part 147

Age discrimination, Citizenship and naturalization, Civil rights, Health care, Health insurance, Individuals with disabilities, Intergovernmental relations, Reporting and recordkeeping requirements, Sex discrimination.

45 CFR Part 150

Administrative practice and procedure, Health care, Health insurance, Penalties, Reporting and recordkeeping requirements.

45 CFR Part 153

Administrative practice and procedure, Health care, Health insurance, Health records, Intergovernmental relations, Organization and functions (Government agencies), Reporting and recordkeeping requirements.

45 CFR Part 155

Administrative practice and procedure, Advertising, Age discrimination, Brokers, Civil rights, Citizenship and naturalization, Conflict of interests, Consumer protection, Grant programs—health, Grants administration, Health care, Health insurance, Health maintenance organizations (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Intergovernmental relations, Loan programs—health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, Sex discrimination, State and local governments, Technical assistance, Taxes, Women, Youth.

45 CFR Part 156

Administrative practice and procedure, Advertising, Advisory committees, Age discrimination, Alaska, Brokers, Citizenship and naturalization, Civil rights, Conflict of interests, Consumer protection, Grant programs health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Intergovernmental relations, Loan programs—health, Medicaid, Organization and functions (Government agencies), Prescription drugs, Public assistance programs, Reporting and recordkeeping requirements, Sex discrimination, State and local governments, Sunshine Act, Technical assistance, Women, Youth.

45 CFR Part 158

Administrative practice and procedure, Claims, Health care, Health insurance, Penalties, Reporting and recordkeeping requirements.

45 CFR Part 184

Administrative practice and procedure, Consumer protection, Health care, Health insurance, Health maintenance organization (HMO), Organization and functions (Government agencies), Prescription Drugs, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, under the authority at 5 U.S.C. 301, the Department of Health and Human Services proposes to amend 45 CFR subtitle A, subchapter B, as set forth below.

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

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

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92, as amended, and section 3203, Pub. L. 116–136, 134 Stat. 281.

■ 2. Section 147.104 is amended by revising paragraphs (b)(2)(ii) and (4)(ii) to read as follows:

§ 147.104 Guaranteed availability of coverage.

- (b) * * *
- (2) * * *
- (ii) In applying this paragraph (b)(2), a reference in § 155.420 (other than in §§ 155.420(a)(5) and (d)(4)) of this subchapter to a "QHP" is deemed to refer to a plan, a reference to "the

Exchange" is deemed to refer to the applicable State authority, and a reference to a "qualified individual" is deemed to refer to an individual in the individual market. For purposes of § 155.420(d)(4) of this subchapter, "the Exchange" is deemed to refer to the Exchange or the health plan, as applicable.

* * * * * * * * * (4) * * *

(ii) In the individual market, subject to § 155.420(c)(5) of this subchapter, individuals must be provided 60 calendar days after the date of an event described in paragraph (b)(2) and (3) of this section to elect coverage, as well as 60 calendar days before certain triggering events as provided for in § 155.420(c)(2) of this subchapter.

PART 150—CMS ENFORCEMENT IN GROUP AND INDIVIDUAL INSURANCE MARKETS

■ 3. The authority citation for part 150 is revised to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92, as amended.

§150.103 [Amended]

■ 4. In § 150.103, amend the definition of "Complaint" by removing the word "HIPAA" and adding in its place "PHS Act".

§ 150.205 [Amended]

■ 5. In § 150.205, amend paragraph (e)(2) by removing the word "HIPAA" and adding in its place "PHS Act".

§150.213 [Amended]

■ 6. In § 150.213, amend paragraph (b) by removing the word "HIPAA" and adding in its place "PHS Act".

§ 150.303 [Amended]

■ 7. In § 150.303, amend paragraph (a) introductory text by removing the word "HIPAA" and adding in its place "PHS Act".

§ 150.305 [Amended]

■ 8. In § 150.305, amend paragraphs (a)(1), (a)(2), (b)(1), and (c)(1) by removing the word "HIPAA" each time it appears and adding in its place "PHS Act".

§150.311 [Amended]

■ 9. In § 150.311, amend paragraph (g) by removing the word "HIPAA" and adding in its place "PHS Act".

§150.313 [Amended]

■ 10. In § 150.313, amend paragraph (b) by removing the word "HIPAA" and adding in its place "PHS Act".

■ 11. Amend § 150.401 by revising the definitions of "Filing date" and "Hearing" to read as follows:

§ 150.401 Definitions.

* * * * *

Filing date means the date filed electronically.

Hearing includes a hearing on a written record as well as an in-person, telephone, or video teleconference hearing.

* * * * *

§ 150.419 [Amended]

- 12. In § 150.419, amend paragraph (a) by removing the phrase "or by telephone" and adding in its place the phrase "by telephone, or by video teleconference".
- 13. Amend § 150.427 by revising paragraph (a) introductory text and paragraph (b) to read as follows:

§ 150.427 Form and service of submissions.

(a) Every submission filed with the ALJ must be filed electronically and include:

* * * * *

- (b) A party filing a submission with the ALJ must, at the time of filing, serve a copy of such submission on the opposing party. An intervenor filing a submission with the ALJ must, at the time of filing, serve a copy of the submission on all parties. If a party is represented by an attorney, service must be made on the attorney. An electronically filed submission is considered served on all parties using the electronic filing system.
- 14. Revise § 150.431 to read as follows:

§ 150.431 Acknowledgment of request for hearing.

After receipt of the request for hearing, the ALJ assigned to the case or someone acting on behalf of the ALJ will send a written notice to the parties that acknowledges receipt of the request for hearing, identifies the docket number assigned to the case, and provides instructions for filing submissions and other general information concerning procedures. The ALJ will set out the next steps in the case either as part of the acknowledgement or on a later date.

■ 15. Amend § 150.441 by revising paragraph (e) to read as follows:

§ 150.441 Prehearing conferences.

* * * * *

(e) Establishing a schedule for an inperson, telephone, or video teleconference hearing, including setting deadlines for the submission of written direct testimony or for the written reports of experts.

* * * * * *

§ 150.447 [Amended]

■ 16. In § 150.447, amend paragraph (a) by removing the phrase "or by telephone" and adding in its place the phrase "by telephone, or by video teleconference".

PART 153—STANDARDS RELATED TO REINSURANCE, RISK CORRIDORS, AND RISK ADJUSTMENT UNDER THE AFFORDABLE CARE ACT

■ 17. The authority citation for part 153 continues to read as follows:

Authority: 42 U.S.C. 18031, 18041, and 18061 through 18063.

■ 18. Section 153.320 is amended by revising paragraph (c) as follows:

§ 153.320 Federally certified risk adjustment methodology.

* * * * *

- (c) Use of methodology for States that do not operate a risk adjustment program. HHS will specify in notice-and-comment rulemaking by HHS in advance of the applicable benefit year, the Federally certified risk adjustment methodology that will apply in States that do not operate a risk adjustment program.
- 19. Section 153.410 is amended by revising paragraph (d) to read as follows:

§ 153.410 Requests for reinsurance payment.

* * * * *

- (d) Audits and compliance reviews. HHS or its designee may audit or conduct a compliance review of an issuer of a reinsurance-eligible plan to assess its compliance with the applicable requirements of this subpart and subpart H of this part. Compliance reviews conducted under this section will follow the standards set forth in § 156.715 of this subchapter.
- (1) Notice of audit. HHS will provide at least 30 calendar days advance notice of its intent to conduct an audit of an issuer of a reinsurance-eligible plan.
- (i) Conferences. All audits will include an entrance conference at which the scope of the audit will be presented and an exit conference at which the initial audit findings will be discussed.
 - (ii) [Reserved]
- (2) Compliance with audit activities. To comply with an audit under this section, the issuer must:
- (i) Ensure that its relevant employees, agents, contractors, subcontractors,

downstream entities, and delegated entities cooperate with any audit or compliance review under this section;

- (ii) Submit complete and accurate data to HHS or its designees that is necessary to complete the audit, in the format and manner specified by HHS, no later than 30 calendar days after the initial audit response deadline established by HHS at the entrance conference described in paragraph (d)(1)(i) of this section for the applicable benefit year;
- (iii) Respond to all audit notices, letters, and inquiries, including requests for supplemental or supporting information, as requested by HHS, no later than 15 calendar days after the date of the notice, letter, request, or inquiry; and
- (iv) In circumstances in which an issuer cannot provide the requested data or response to HHS within the timeframes under paragraph (d)(2)(ii) or (iii) of this section, as applicable, the issuer may make a written request for an extension to HHS. The extension request must be submitted within the timeframe established under paragraph (d)(2)(ii) or (iii) of this section, as applicable, and must detail the reason for the extension request and the good cause in support of the request. If the extension is granted, the issuer must respond within the timeframe specified in HHS's notice granting the extension
- (3) Preliminary audit findings. HHS will share its preliminary audit findings with the issuer, who will then have 30 calendar days to respond to such findings in the format and manner specified by HHS.
- (i) If the issuer does not dispute or otherwise respond to the preliminary findings, the audit findings will become final.
- (ii) If the issuer responds and disputes the preliminary findings, HHS will review and consider such response and finalize the audit findings after such review.
- (4) Final audit findings. If an audit results in the inclusion of a finding in the final audit report, the issuer must comply with the actions set forth in the final audit report in the manner and timeframe established by HHS, and the issuer must complete all of the following:
- (i) Within 45 calendar days of the issuance of the final audit report, provide a written corrective action plan to HHS for approval.
 - (ii) Implement that plan.
- (iii) Provide to HHS written documentation of the corrective actions once taken.

- (5) Failure to comply with audit activities. If an issuer fails to comply with the audit activities set forth in this subsection in the manner and timeframes specified by HHS:
- (i) HHS will notify the issuer of reinsurance payments received that the issuer has not adequately substantiated; and
- (ii) HHS will notify the issuer that HHS may recoup any payments identified in paragraph (5)(i) of this section.
- 20. Section 153.620 is amended by revising paragraph (c) to read as follows:

§ 153.620 Compliance with risk adjustment standards.

* * * * *

- (c) Audits and compliance reviews. HHS or its designee may audit or conduct a compliance review of an issuer of a risk adjustment covered plan to assess its compliance with respect to the applicable requirements in this subpart and subpart H of this part. Compliance reviews conducted under this section will follow the standards set forth in § 156.715 of this subchapter.
- (1) Notice of audit. HHS will provide at least 30 calendar days advance notice of its intent to conduct an audit of an issuer of a risk adjustment covered plan.
- (i) Conferences. All audits will include an entrance conference at which the scope of the audit will be presented and an exit conference at which the initial audit findings will be discussed.
 - (ii) [Reserved]
- (2) Compliance with audit activities. To comply with an audit under this section, the issuer must:
- (i) Ensure that its relevant employees, agents, contractors, subcontractors, downstream entities, and delegated entities cooperate with any audit or compliance review under this section;
- (ii) Submit complete and accurate data to HHS or its designees that is necessary to complete the audit, in the format and manner specified by HHS, no later than 30 calendar days after the initial audit response deadline established by HHS at the audit entrance conference described in paragraph (c)(1)(i) of this section for the applicable benefit year;
- (iii) Respond to all audit notices, letters, and inquiries, including requests for supplemental or supporting information, as requested by HHS, no later than 15 calendar days after the date of the notice, letter, request, or inquiry; and
- (iv) In circumstances in which an issuer cannot provide the requested data or response to HHS within the timeframes under paragraphs (c)(2)(ii) or (iii) of this section, as applicable, the

- issuer may make a written request for an extension to HHS. The extension request must be submitted within the timeframe established under paragraphs (c)(2)(ii) or (iii) of this section, as applicable, and must detail the reason for the extension request and the good cause in support of the request. If the extension is granted, the issuer must respond within the timeframe specified in HHS's notice granting the extension of time.
- (3) Preliminary audit findings. HHS will share its preliminary audit findings with the issuer, who will then have 30 calendar days to respond to such findings in the format and manner specified by HHS.
- (i) If the issuer does not dispute or otherwise respond to the preliminary findings, the audit findings will become final.
- (ii) If the issuer responds and disputes the preliminary findings, HHS will review and consider such response and finalize the audit findings after such review.
- (4) Final audit findings. If an audit results in the inclusion of a finding in the final audit report, the issuer must comply with the actions set forth in the final audit report in the manner and timeframe established by HHS, and the issuer must complete all of the following:
- (i) Within 45 calendar days of the issuance of the final audit report, provide a written corrective action plan to HHS for approval.
 - (ii) Implement that plan.
- (iii) Provide to HHS written documentation of the corrective actions once taken.
- (5) Failure to comply with audit activities. If an issuer fails to comply with the audit activities set forth in this subsection in the manner and timeframes specified by HHS:
- (i) HHS will notify the issuer of the risk adjustment (including high-cost risk pool) payments that the issuer has not adequately substantiated; and
- (ii) HHS will notify the issuer that HHS may recoup any risk adjustment (including high-cost risk pool) payments identified in paragraph (c)(5)(i) of this section.
- 21. Section 153.630 is amended by—
- a. Revising paragraph (d)(3); and
- b. Adding paragraphs (g)(4) and (5). The revisions read as follows:

§ 153.630 Data validation requirements when HHS operates risk adjustment.

- * * *
- (d) * * *
- (3) An issuer may appeal the findings of a second validation audit (if applicable) or the calculation of a risk

score error rate as result of risk adjustment data validation, under the process set forth in § 156.1220 of this subchapter.

* * * * * (g) * * *

(4) The issuer only offered small group market carryover coverage during the benefit year that is being audited.

- (5) The issuer was the sole issuer in the state market risk pool during the benefit year that is being audited and did not participate in any other market risk pools in the State during the benefit year that is being audited.
- 22. Section 153.710 is amended—
- a. By redesignating paragraphs (e) through (g), as paragraphs (f) through (h), respectively;
- b. By adding a new paragraph (e); and
- c. In newly redesignated paragraph (h) introductory text by removing the reference "paragraph (g)(3)" and adding in its place the reference "paragraph (h)(3)".

The addition reads as follows:

§ 153.710 Data requirements.

* * * * *

(e) Materiality threshold. HHS will consider a discrepancy reported under paragraph (d)(2) of this section to be material if the amount in dispute is equal to or exceeds 1 percent of the applicable payment or charge payable to or due from the issuer for the benefit year, or \$100,000, whichever is less.

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

■ 23. The authority citation for part 155 continues to read as follows:

Authority: 42 U.S.C. 18021–18024, 18031–18033, 18041–18042, 18051, 18054, 18071, and 18081–18083.

- 24. Section 155.20 is amended by—
- a. Adding, in alphabetical order, the definition of "Agent or broker direct enrollment technology provider";
- b. Removing the definition of "Direct enrollment technology provider";
- c. Adding, in alphabetical order, the definition of "Qualified health plan issuer direct enrollment technology provider";
- d. Revising the definition of "Webbroker".

The additions and revision read as follows:

§ 155.20 Definitions.

* * * * *

Agent or broker direct enrollment technology provider means a type of

web-broker business entity that is not a licensed agent or broker under State law and has been engaged or created by, or is owned by an agent or broker, to provide technology services to facilitate participation in direct enrollment under §§ 155.220(c)(3) and 155.221.

* Qualified health plan issuer direct enrollment technology provider means a business entity that provides technology services or provides access to an information technology platform to QHP issuers to facilitate participation in direct enrollment under §§ 155.221 or 156.1230, including a web-broker that provides services as a direct enrollment technology provider to QHP issuers. A OHP issuer direct enrollment technology provider that provides technology services or provides access to an information technology platform to a QHP issuer will be a downstream or delegated entity of the QHP issuer that participates or applies to participate

* * * * *

as a direct enrollment entity.

Web-broker means an individual agent or broker, group of agents or brokers, or business entity registered with an Exchange under § 155.220(d)(1) that develops and hosts a non-Exchange website that interfaces with an Exchange to assist consumers with direct enrollment in QHPs offered through the Exchange as described in § 155.220(c)(3) or § 155.221. The term also includes an agent or broker direct enrollment technology provider.

■ 25. Section 155.205 is amended by revising paragraphs (c)(2)(i)(B), (c)(2)(iii)(B), (c)(2)(iv) introductory text, and (c)(2)(iv)(C) to read as follows:

§ 155.205 Consumer assistance tools and programs of an Exchange.

(C) * * * *

- (c) * * * (2) * * *
- (2) * * * (i) * * *
- (B) For a web-broker, beginning November 1, 2015, or when such entity has been registered with the Exchange for at least 1 year, whichever is later, this standard also includes telephonic interpreter services in at least 150 languages.

* * * * * * (iii) * * *

(B) For a web-broker, beginning when such entity has been registered with the Exchange for at least 1 year, this standard also includes taglines on website content and any document that is critical for obtaining health insurance coverage or access to health care services through a QHP for qualified individuals, applicants, qualified

employers, qualified employees, or enrollees. Website content or documents are deemed to be critical for obtaining health insurance coverage or access to health care services through a QHP if they are required to be provided by law or regulation to a qualified individual, applicant, qualified employer, qualified employee, or enrollee. Such taglines must indicate the availability of language services in at least the top 15 languages spoken by the limited English proficient population of the relevant State or States, as determined in guidance published by the Secretary. A web-broker that is licensed in and serving multiple States may aggregate the limited English populations in the States it serves to determine the top 15 languages required for taglines. A webbroker may satisfy tagline requirements with respect to website content if it posts a Web link prominently on its home page that directs individuals to the full text of the taglines indicating how individuals may obtain language assistance services, and if it also includes taglines on any critical standalone document linked to or embedded in the website.

(iv) For Exchanges, QHP issuers, and web-brokers, website translations.

(C) For a web-broker, beginning on the first day of the individual market open enrollment period for the 2017 benefit year, or when such entity has been registered with the Exchange for at least 1 year, whichever is later, content that is intended for qualified individuals, applicants, qualified employers, qualified employees, or enrollees on a website that is maintained by the webbroker must be translated into any non-English language that is spoken by a limited English proficient population that comprises 10 percent or more of the population of the relevant State, as determined in guidance published by the Secretary.

■ 26. Section 155.220 is amended by adding paragraph (c)(6) to read as follows:

§ 155.220 Ability of States to permit agents and brokers and web-brokers to assist qualified individuals, qualified employers, or qualified employees enrolling in QHPs.

(C) * * * * * *

(6) In addition to applicable requirements under § 155.221(b)(4), a web-broker must demonstrate operational readiness and compliance with applicable requirements prior to the web-broker's internet website being used to complete an Exchange eligibility application or a QHP selection, which

may include submission or completion, in the form and manner specified by HHS, of the following:

- (i) Operational data including licensure information, points of contact, and third-party relationships;
- (ii) Enrollment testing, prior to approval or renewal;
- (iii) Website reviews performed by HHS;
- (iv) Security and privacy assessment documentation, including:
 - (A) Penetration testing results;
- (B) Security and privacy assessment reports;
 - (C) Vulnerability scan results:
- (D) Plans of action and milestones; and
- (E) System security and privacy plans.
- (v) Agreements between the webbroker and HHS.

* * * * *

- 27. Section 155.221 is amended—
- \blacksquare a. By revising paragraphs (b)(1), (3), and (4);
- b. By redesignating paragraphs (c) through (h) as paragraphs (d) through (i), respectively.
- c. By adding new paragraph (c); and
- d. By amending newly redesignated paragraphs (g) introductory text, (g)(6), (g)(7), and (h) by removing the reference to "paragraph (e)" and adding in its place a reference to "paragraph (f)".

The additions and revisions read as follows:

§ 155.221 Standards for direct enrollment entities and for third parties to perform audits of direct enrollment entities.

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

(1) Display and market QHPs offered through the Exchange, individual health insurance coverage as defined in § 144.103 of this subchapter offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits), and any other products, such as excepted benefits, on at least three separate website pages on its non-Exchange website, except as permitted under paragraph (c) of this section;

(3) Limit marketing of non-QHPs during the Exchange eligibility application and QHP selection process in a manner that minimizes the likelihood that consumers will be confused as to which products and plans are available through the Exchange and which products and plans are not, except as permitted under paragraph (c)(1) of this section;

(4) Demonstrate operational readiness and compliance with applicable requirements prior to the direct enrollment entity's internet website being used to complete an Exchange eligibility application or a QHP selection, which may include submission or completion, in the form and manner specified by HHS, of the following:

- (i) Business audit documentation including:
- (A) Notices of intent to participate including auditor information;
- (B) Documentation packages including privacy questionnaires, privacy policy statements, and terms of service; and
- (C) Business audit reports including testing results.
- (ii) Security and privacy audit documentation including:
- (A) Interconnection security agreements;
- (B) Security and privacy controls assessment test plans;
- (C) Security and privacy assessment reports;
- (D) Plans of action and milestones;
- (E) Privacy impact assessments;
- (F) System security and privacy plans;
- (G) Incident response plans; and
- (H) Vulnerability scan results.
- (iii) Eligibility application audits performed by HHS;
- (iv) Online training modules offered by HHS; and
- (v) Agreements between the direct enrollment entity and HHS.
- (c) Exceptions to direct enrollment entity display and marketing requirement. For the Federallyfacilitated Exchanges, a direct
- enrollment entity may: (1) Display and market QHPs offered through the Exchange and individual health insurance coverage as defined in § 144.103 of this subchapter offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits) on the same website pages when assisting individuals who have communicated receipt of an offer of an individual coverage health reimbursement arrangement as described in § 146.123(c) of this subchapter, as a standalone benefit, or in addition to an offer of an arrangement under which the individual may pay the portion of the premium for individual health insurance coverage that is not covered by an individual coverage health reimbursement arrangement using a salary reduction arrangement pursuant to a cafeteria plan under section 125 of the Internal Revenue Code, but must clearly distinguish between the QHPs offered through the Exchange and individual health insurance coverage offered outside the Exchange (including QHPs and non-

QHPs other than excepted benefits), and prominently communicate that advance payments of the premium tax credit and cost-sharing reductions are available only for QHPs purchased through the Exchange, that advance payments of the premium tax credit are not available to individuals who accept an offer of an individual coverage health reimbursement arrangement or who opt out of an individual coverage health reimbursement arrangement that is considered affordable, and that a salary reduction arrangement under a cafeteria plan may only be used toward the cost of premiums for plans purchased outside the Exchange; and

(2) Display and market Exchangecertified stand-alone dental plans offered outside the Exchange and noncertified stand-alone dental plans on the same website pages.

* * * * *

■ 28. Effective May 5, 2021 amend § 155.320 by—

- a. Revising paragraph (c)(3)(iii)(A); and
- b. Removing and reserving paragraphs (c)(3)(iii)(D) and (vi)(C)(2).

The revision read as follows:

§ 155.320 Verification process related to eligibility for insurance affordability programs.

* * * * (c) * * *

(3) * * *

(3) * * * * (iii) * * *

(A) Except as specified in paragraph (c)(3)(iii)(B) and (C) of this section, if an applicant's attestation, in accordance with paragraph (c)(3)(ii)(B) of this section, indicates that a tax filer's annual household income has increased or is reasonably expected to increase from the data described in paragraph (c)(3)(ii)(A) of this section for the benefit year for which the applicant(s) in the tax filer's family are requesting coverage and the Exchange has not verified the applicant's MAGI-based income through the process specified in paragraph (c)(2)(ii) of this section to be within the applicable Medicaid or CHIP MAGIbased income standard, the Exchange must accept the applicant's attestation regarding a tax filer's annual household income without further verification.

■ 29. Section 155.420 is amended by—

- a. Revising paragraph (a)(4)(ii)(B);
- b. Adding paragraph (a)(4)(ii)(C);
- c. Revising paragraphs (a)(4)(iii) introductory text and (b)(2)(iv);
- \blacksquare d. Adding paragraph (b)(5);
- e. Revising paragraph (c)(2);
- f. Adding paragraphs (c)(5) and (d)(15); and

■ g. Revising paragraph (e)(1). The revisions and additions read as follows:

§ 155.420 Special enrollment periods.

(a) * * * (4) * * *

(ii') * * *

(B) Beginning January 2022, if an enrollee and his or her dependents become newly ineligible for cost-sharing reductions in accordance with paragraph (d)(6)(i) or (ii) of this section and are enrolled in a silver-level QHP, the Exchange must allow the enrollee and his or her dependents to change to a QHP one metal level higher or lower, if they elect to change their QHP enrollment; or

(C) No later than January 1, 2024, if an enrollee and his or her dependents become newly ineligible for advance payments of the premium tax credit in accordance with paragraph (d)(6)(i) or (ii) of this section, the Exchange must allow the enrollee and his or her dependents to change to a QHP of any metal level, if they elect to change their OHP enrollment;

(iii) For the other triggering events specified in paragraph (d) of this section, except for paragraphs (d)(2)(i), (4), (6)(i) and (6)(ii) of this section for becoming newly eligible or ineligible for CSRs or, no later than January 1, 2024 newly ineligible for APTC, (d)(8), (9), (10) and (12) of this section:

* * (b) * * * (2) * * *

(iv) If a qualified individual, enrollee, or dependent, as applicable, loses coverage as described in paragraph (d)(1) or (d)(6)(iii) of this section, gains access to a new QHP as described in paragraph (d)(7) of this section, becomes newly eligible for enrollment in a QHP through the Exchange in accordance with § 155.305(a)(2) as described in paragraph (d)(3) of this section, becomes newly eligible for advance payments of the premium tax credit in conjunction with a permanent move as described in paragraph (d)(6)(iv) of this section, or is enrolled in COBRA continuation coverage and employer contributions to or government subsidies of this coverage completely cease as described in paragraph (d)(15) of this section, and if the plan selection is made on or before the day of the triggering event, the Exchange must ensure that the coverage effective date is the first day of the month following the date of the triggering event. If the plan selection is made after the date of the triggering event, the Exchange must ensure that coverage is effective in accordance with paragraph (b)(1) of this section or on the

first day of the following month, at the option of the Exchange.

(5) Option for earlier effective dates due to untimely notice of triggering event. At the option of a qualified individual, enrollee or dependent who is eligible to select a plan during a period provided for under paragraph (c)(5) of this section, the Exchange must provide the earliest effective date that would have been available under paragraph (b) of this section, based on the applicable triggering event under paragraph (d) of this section. (c) * * *

(2) Advanced availability. A qualified individual or his or her dependent who is described in paragraph (d)(1), (d)(6)(iii), or (d)(15) of this section has 60 days before or after the triggering event to select a QHP. At the option of the Exchange, a qualified individual or his or her dependent who is described in paragraph (d)(7) of this section; who is described in paragraph (d)(6)(iv) of this section and becomes newly eligible for advance payments of the premium tax credit as a result of a permanent move to a new State; or who is described in paragraph (d)(3) of this section and becomes newly eligible for enrollment in a QHP through the Exchange because he or she newly satisfies the requirements under § 155.305(a)(2), has 60 days before or after the triggering event to select a QHP.

(5) Availability for individuals who did not receive timely notice of triggering events. If a qualified individual, enrollee, or dependent did not receive timely notice of an event that triggers eligibility for a special enrollment period under this section, and otherwise was reasonably unaware that a triggering event described in paragraph (d) of this section occurred, the Exchange must allow the qualified individual, enrollee, or when applicable, his or her dependent to select a new plan within 60 days of the date that he or she knew, or reasonably should have known, of the occurrence of the triggering event.

(d) * * *

(15) The qualified individual or his or her dependent is enrolled in COBRA continuation coverage for which an employer is paying all or part of the premiums, or for which a government entity is providing subsidies, and the employer completely ceases its contributions to the qualified individual's or dependent's COBRA continuation coverage or government

subsidies completely cease. The triggering event is the last day of the period for which COBRA continuation coverage is paid for or subsidized, in whole or in part, by an employer or government entity. For purposes of this paragraph, "COBRA continuation coverage" has the meaning provided for in § 144.103 of this subchapter and includes coverage under a similar State program.

(e) * * *

(1) Failure to pay premiums on a timely basis, including COBRA continuation coverage premiums prior to expiration of COBRA continuation coverage, except for circumstances in which an employer completely ceases its contributions to COBRA continuation coverage, or government subsidies of COBRA continuation coverage completely cease as described in paragraph (d)(15) of this section, or

PART 156—HEALTH INSURANCE **ISSUER STANDARDS UNDER THE** AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO **EXCHANGES**

■ 30. The authority citation for part 156 is revised to read as follows:

Authority: 42 U.S.C. 18021-18024, 18031-18032, 18041-18042, 18044, 18054, 18061, 18063, 18071, 18082, and 26 U.S.C. 36B.

- 31. Section 156.50 is amended by—
- a. Revising the heading for paragraph (c);
- \blacksquare b. Revising paragraph (c)(2);
- c. Adding paragraph (c)(3);
- d. Revising the heading for paragraph (d); and
- e. Revising paragraphs (d)(1) introductory text, (d)(2) introductory text, (d)(2)(i)(A), (B), (d)(2)(ii), (d)(2)(iii)(B), (d)(3) introductory text, (d)(4) through (6), and (d)(7)introductory text.

The revisions and addition read as follows:

§ 156.50 Financial support. *

(c) Requirement for Exchange user fees. * *

*

(2) To support the functions of State Exchanges on the Federal platform, unless the State Exchange and HHS agree on an alternative mechanism to collect the funds, a participating issuer offering a plan through a State Exchange on the Federal Exchange platform for certain Exchange functions described in § 155.200 of this subchapter, as specified in a Federal platform agreement, must remit a user fee to

HHS, in the timeframe and manner established by HHS, equal to the product of the sum of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for State Exchanges on the Federal platform for the applicable benefit year, multiplied by the monthly premium charged by the issuer for each policy under the plan where enrollment is through the State-based Exchange on the Federal platform.

(3) A participating issuer offering a plan through an State-based Exchange on the Federal platform that has adopted the Direct Enrollment option or Federally-facilitated Exchange that has adopted the direct enrollment option as described in § 155.221(j) of this subchapter, as specified in a Federal agreement with HHS, must remit a user fee to HHS each month, in the timeframe and manner established by HHS, equal to the product of the monthly user fee rate for the applicable benefit year specified in an annual HHS notice of benefit and payment parameters published in advance of the applicable benefit year and the monthly premium charged by the issuer for each policy under the plan where enrollment is through the State-based Exchange on the Federal platform that has adopted the Direct Enrollment option or Federally-facilitated Exchange that has adopted the direct enrollment option.

(d) Adjustment of Exchange user fees. (1) A participating issuer offering a plan through a Federally-facilitated Exchange or State Exchange on the Federal platform may qualify for an adjustment of the Federally-facilitated Exchange user fee specified in paragraph (c)(1) of this section, the State Exchange on the Federal platform user fee specified in paragraph (c)(2) of this section, or the user fee specified in paragraph (c)(3) of this section, applicable to issuers participating in a State Exchange on the Federal platform or a Federallyfacilitated Exchange that has adopted the direct enrollment option under § 155.221(j) of this subchapter, the extent that the participating issuer-

(2) For a participating issuer described in paragraph (d)(1) of this section to receive an adjustment of a user fee under this section—

(i) *

(A) Identifying information for the participating issuer and each third party administrator that received a copy of the self-certification referenced in 26 CFR 54.9815-2713A(a)(4) or 29 CFR 2590.715-2713A(a)(4) with respect to which the participating issuer seeks an adjustment of the user fee specified in

paragraph (c)(1), (2), or (3) of this section, as applicable, whether or not the participating issuer was the entity that made the payments for contraceptive services;

(B) Identifying information for each self-insured group health plan with respect to which a copy of the selfcertification referenced in 26 CFR 54.9815-2713A(a)(4) or 29 CFR 2590.715-2713A(a)(4) was received by a third party administrator and with respect to which the participating issuer seeks an adjustment of the user fee specified in paragraph (c)(1), (2), or (3) of this section, as applicable; and

(ii) Each third party administrator that intends to seek an adjustment on behalf of a participating issuer of the Federallyfacilitated Exchange user fee, the Statebased Exchange on the Federal platform user fee, or the user fee applicable to issuers participating in a State-based Exchange on the Federal platform or a Federally-facilitated Exchange that has adopted the direct enrollment option § 155.221(j) of this subchapter based on payments for contraceptive services, must submit to HHS a notification of such intent, in a manner specified by HHS, by the 60th calendar day following the date on which the third party administrator receives the applicable copy of the self-certification referenced in 26 CFR 54.9815-2713A(a)(4) or 29 CFR 2590.715-2713A(a)(4).

(iii) *

(B) Identifying information for each self-insured group health plan with respect to which a copy of the selfcertification referenced in 26 CFR 54.9815-2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4) was received by the third party administrator and with respect to which the participating issuer seeks an adjustment of the user fee specified in paragraph (c)(1), (2), or (3)of this section, as applicable;

(3) If the requirements set forth in paragraph (d)(2) of this section are met, the participating issuer will be provided a reduction in its obligation to pay the user fee specified in paragraph (c)(1), (2), or (3) of this section, as applicable, equal in value to the sum of the following:

(4) If the amount of the adjustment under paragraph (d)(3) of this section is greater than the amount of the participating issuer's obligation to pay the user fee specified in paragraph (c)(1), (2), or (3) of this section, as applicable, in a particular month, the participating issuer will be provided a

credit in succeeding months in the amount of the excess.

(5) Within 60 days of receipt of any adjustment of a user fee under this section, a participating issuer must pay each third party administrator with respect to which it received any portion of such adjustment an amount that is no less than the portion of the adjustment attributable to the total dollar amount of the payments for contraceptive services submitted by the third party administrator, as described in paragraph (d)(2)(iii)(D) of this section. No such payment is required with respect to the allowance for administrative costs and margin described in paragraph (d)(3)(ii) of this section. This paragraph does not apply if the participating issuer made the payments for contraceptive services on behalf of the third party administrator, as described in paragraph (d)(1)(i) of this section, or is in the same issuer group as the third party administrator.

(6) A participating issuer that receives an adjustment in the user fee specified in paragraph (c)(1), (2), or (3) of this section for a particular calendar year must maintain for 10 years following that year, and make available upon request to HHS, the Office of the Inspector General, the Comptroller General, and their designees, documentation demonstrating that it timely paid each third party administrator with respect to which it received any such adjustment any amount required to be paid to the third party administrator under paragraph (d)(5) of this section.

(7) A third party administrator of a plan with respect to which an adjustment of the user fee specified in paragraph (c)(1), (2), or (3) of this section is received under this section for a particular calendar year must maintain for 10 years following that year, and make available upon request to HHS. the Office of the Inspector General, the Comptroller General, and their designees, all of the following documentation:

■ 32. Section 156.130 is amended by revising paragraph (e) to read as follows:

§ 156.130 Cost-sharing requirements.

(e) Premium adjustment percentage. The premium adjustment percentage is the percentage (if any) by which the average per capita premium for health insurance coverage for the preceding calendar year exceeds such average per capita premium for health insurance for 2013. HHS may publish the annual premium adjustment percentage in

guidance in January of the calendar year preceding the benefit year for which the premium adjustment percentage is applicable, unless HHS proposes changes to the methodology, in which case, HHS will publish the annual premium adjustment percentage in an annual HHS notice of benefit and payment parameters or another appropriate rulemaking.

* * * * *

- 33. Section 156.295 is amended by—
- a. Revising the section heading and paragraphs (a) introductory text, (a)(1) and (a)(2) introductory text,
- b. Removing paragraph (a)(3); and■ c. Revising paragraph (b) introductory text.

The revisions read as follows:

§ 156.295 Prescription drug distribution and cost reporting by QHP issuers.

- (a) General requirement. In a form, manner, and at such times specified by HHS, a QHP issuer that administers a prescription drug benefit without the use of a pharmacy benefit manager must provide to HHS the following information:
- (1) The percentage of all prescriptions that were provided under the QHP through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed compared to all drugs dispensed;
- (2) The aggregate amount, and the type of rebates, discounts or price concessions (excluding bona fide service fees) that the QHP issuer negotiates that are attributable to patient utilization under the QHP, and the aggregate amount of the rebates, discounts, or price concessions that are passed through to the QHP issuer, and the total number of prescriptions that were dispensed.
- (b) Limitation on disclosure.
 Information disclosed by a QHP issuer under this section shall not be disclosed by HHS, except that HHS may disclose the information in a form which does not disclose the identity of a specific QHP or prices charged for specific drugs, for the following purposes:
- 34. Section 156.420 is amended by revising paragraphs (a)(1)(i), (a)(2)(i) and (a)(3)(i) to read as follows:

*

§156.420 Plan variations.

- (a) * * *
- (1) * * *
- (i) An annual limitation on cost sharing no greater than the reduced maximum annual limitation on cost

sharing specified in the annual HHS guidance or notice of benefit and payment parameters for such individuals, and

* * * * * * (2) * * *

(i) An annual limitation on cost sharing no greater than the reduced maximum annual limitation on cost sharing specified in the annual HHS guidance or notice of benefit and payment parameters for such individuals, and

* * * *

(i) An annual limitation on cost sharing no greater than the reduced maximum annual limitation on cost sharing specified in the annual HHS guidance or notice of benefit and payment parameters for such individuals, and

* * * * *

■ 35. Section 156.480 is amended by revising the section heading and paragraph (c) to read as follows:

§ 156.480 Oversight of the administration of the advance payments of the premium tax credit, cost-sharing reductions, and user fee programs.

* * * * *

- (c) Audits and compliance reviews. HHS or its designee may audit or conduct a compliance review of an issuer offering a QHP through an Exchange to assess its compliance with the applicable requirements of this subpart and 45 CFR 156.50. Compliance reviews conducted under this section will follow the standards set forth in § 156.715.
- (1) Notice of audit. HHS will provide at least 30 calendar days advance notice of its intent to conduct an audit of an issuer under this section.
- (i) Conferences. All audits will include an entrance conference at which the scope of the audit will be presented and an exit conference at which the initial audit findings will be discussed.
 - (ii) [Reserved]
- (2) Compliance with audit activities. To comply with an audit under this section, the issuer must:
- (i) Ensure that its relevant employees, agents, contractors, subcontractors, downstream entities, and delegated entities cooperate with any audit or compliance review under this section;
- (ii) Submit complete and accurate data to HHS or its designees that is necessary to complete the audit, in the format and manner specified by HHS, no later than 30 calendar days after the initial audit response deadline established by HHS at the entrance conference described under paragraph

- (c)(1)(i) of this section for the applicable benefit year;
- (iii) Respond to all audit notices, letters, and inquiries, including requests for supplemental or supporting information, as requested by HHS, no later than 15 calendar days after the date of the notice, letter, request, or inquiry; and
- (iv) In circumstances in which an issuer cannot provide the requested data or response to HHS within the timeframes under paragraph (c)(2)(ii) or (iii) of this section, as applicable, the issuer may make a written request for an extension to HHS. The extension request must be submitted within the timeframe established under paragraph (c)(2)(ii) or (iii), as applicable, and must detail the reason for the extension request and the good cause in support of the request. If the extension is granted, the issuer must respond within the timeframe specified in HHS's notice granting the extension of time.
- (3) Preliminary audit findings. HHS will share its preliminary audit findings with the issuer, who will then have 30 calendar days to respond to such findings in the format and manner specified by HHS.
- (i) If the issuer does not dispute or otherwise respond to the preliminary findings, the audit findings will become final.
- (ii) If the issuer responds and disputes the preliminary findings, HHS will review and consider such response and finalize the audit findings after such review
- (4) Final audit findings. If an audit results in the inclusion of a finding in the final audit report, the issuer must comply with the actions set forth in the final audit report in the manner and timeframe established by HHS, and the issuer must complete all of the following:
- (i) Within 45 calendar days of the issuance of the final audit or compliance review report, provide a written corrective action plan to HHS for approval.
 - (ii) Implement that plan.
- (iii) Provide to HHS written documentation of the corrective actions once taken.
- (5) Failure to comply with audit activities. If an issuer fails to comply with the audit activities set forth in this section in the manner and timeframes specified by HHS:
- (i) HHS will notify the issuer of payments received under this subpart that the issuer has not adequately substantiated; and
- (ii) HHS will notify the issuer that HHS may recoup any payments

identified in paragraph (c)(5)(i) of this section.

(6) Circumstances requiring HHS enforcement. If HHS determines that the State Exchange or State-based Exchange on the Federal platform is not enforcing or fails to substantially enforce the requirements of this subpart or § 156.50, then HHS may do so and may pursue the imposition of civil money penalties as specified in § 156.805 for noncompliance by QHP issuers participating in the State Exchange or State Exchange on the Federal platform.

Subpart I—Enforcement Remedies in the Exchanges

- 36. Subpart I is amended by revising the heading as set forth above.
- 37. Section 156.800 is amended by revising paragraphs (a) introductory text, and (b) as follows:

§ 156.800 Available remedies; Scope.

(a) Kinds of sanctions. HHS may impose the following types of sanctions on QHP issuers in an Exchange that are not in compliance with Exchange standards applicable to issuers offering QHPs in an Exchange:

* * * *

- (b) Scope. Sanctions under subpart I are applicable for non-compliance with QHP issuer participation standards and other standards applicable to issuers offering QHPs in a Federally-facilitated Exchange. Sanctions under paragraph (a)(1) of this section are also applicable for non-compliance by QHP issuers participating in State Exchanges and State-based Exchanges on the Federal platform when HHS is responsible for enforcement of the requirements in subpart E of this part and 45 CFR 156.50.
- 38. Section 156.805 is amended by—
- a. Revising paragraphs (a)

introductory text and (a)(5)(i); and

■ b. Adding paragraph (f).

The revisions and addition read as follows:

§156.805 Bases and process for imposing civil money penalties in Federally-facilitated Exchanges.

(a) Grounds for imposing civil money penalties. Civil money penalties may be imposed on an issuer in an Exchange if, based on credible evidence, HHS has reasonably determined that the issuer has engaged in one or more of the following actions:

* * * * * (5) * * *

(i) To HHS or an Exchange; or

* * * * *

- (f) Circumstances requiring HHS enforcement in State Exchanges and State-based Exchanges on the Federal platform. (1) HHS will enforce the requirements of subpart E of this part and 45 CFR 156.50 if a State Exchange or State-based Exchange on the Federal platform notifies HHS that it is not enforcing these requirements or if HHS makes a determination using the process set forth at 45 CFR 150.201, et seq. that a State Exchange or State-based Exchange on the Federal platform is failing to substantially enforce these requirements.
- (2) If HHS is responsible under paragraph (f)(1) of this section for enforcement of the requirements set forth in subpart E of this part or 45 CFR 156.50, HHS may impose civil money penalties on an issuer in a State Exchange or State-based Exchange on the Federal platform, in accordance with the bases and process for imposing civil money penalties set forth in this section.

Subpart J—Administrative Review of QHP Issuer Sanctions

- 39. Amend Subpart J by revising the heading to read as set forth above.
- 40. Section 156.901 is amended by revising the definitions of "Filing date" and "Hearing" to read as follows.

§ 156.901 Definitions.

Filing date means the date filed electronically.

Hearing includes a hearing on a written record as well as an in-person, telephone, or video teleconference hearing.

■ 41. Section 156.903 is amended by revising paragraph (a) as follows:

§ 156.903 Scope of Administrative Law Judge's (ALJ) authority.

(a) The ALJ has the authority, including all of the authority conferred by the Administrative Procedure Act (5 U.S.C. 554a), to adopt whatever procedures may be necessary or proper to carry out in an efficient and effective manner the ALJ's duty to provide a fair and impartial hearing on the record and to issue an initial decision concerning the imposition of a civil money penalty of a QHP offered in a Federallyfacilitated Exchange, State Exchange, and State-based Exchange on the Federal platform, or the decertification of a QHP offered in a Federallyfacilitated Exchange.

■ 42. Section 156.919 is amended by revising paragraph (a) to read as follows:

§156.919 Forms of hearing.

- (a) All hearings before an ALJ are on the record. The ALJ may receive argument or testimony in writing, in person, by telephone, or by video teleconference. The ALJ may receive testimony by telephone only if the ALJ determines that doing so is in the interest of justice and economy and that no party will be unduly prejudiced. The ALJ may require submission of a witness' direct testimony in writing only if the witness is available for cross-examination.
- 43. Section 156.927 is amended by revising paragraphs (a) introductory text and (b) to read as follows:

§ 156.927 Form and service of submissions.

(a) Every submission filed with the ALJ must be filed electronically and include:

* * * * *

- (b) A party filing a submission with the ALJ must, at the time of filing, serve a copy of such submission on the opposing party. An intervenor filing a submission with the ALJ must, at the time of filing, serve a copy of the submission on all parties. If a party is represented by an attorney, service must be made on the attorney. An electronically filed submission is considered served on all parties using the electronic filing system.
- 44. Section 156.931 is revised to read as follows:

§ 156.931 Acknowledgement of request for hearing.

After receipt of the request for hearing, the ALJ assigned to the case or someone acting on behalf of the ALJ will send a written notice to the parties that acknowledges receipt of the request for hearing, identifies the docket number assigned to the case, and provides instructions for filing submissions and other general information concerning procedures. The ALJ will set out the next steps in the case either as part of the acknowledgement or on a later date.

■ 45. Section 156.941 is amended by revising paragraph (e) to read as follows:

§ 156.941 Prehearing conferences.

- (e) Establishing a schedule for an inperson, telephone, or video teleconference hearing, including setting deadlines for the submission of written direct testimony or for the written reports of experts.
- 46. Section 156.947 is amended by revising paragraph (a) to read as follows:

§ 156.947 The record.

(a) Any testimony that is taken inperson, by telephone, or by video teleconference is recorded and transcribed. The ALJ may order that other proceedings in a case, such as a prehearing conference or oral argument of a motion, be recorded and transcribed.

* * * * *

- 47. Section 156.1210 is amended by—
- a. Revising paragraph (a);

■ b. Redesignating paragraph (b) as paragraph (d); and

c. Adding new paragraphs (b) and (c). The additions read as follows:

§156.1210 Dispute submission.

(a) Responses to reports. Within 90 calendar days of the date of a payment and collections report from HHS, the issuer must, in a form and manner specified by HHS or the State Exchange describe to HHS or the State Exchange (as applicable) any inaccuracies it identifies in the report.

(b) Inaccuracies identified after 90-day period. With respect to an inaccuracy described under paragraph (a) of this section that is identified and submitted to HHS or the State Exchange (as applicable) by the issuer after the end of the 90-day period described in such paragraph, HHS will consider and work with the issuer or the State Exchange (as applicable) to resolve the inaccuracy so long as—

(1) The issuer promptly notifies HHS or the State Exchange (as applicable) upon identifying the inaccuracy, but in no case later than 15 calendar days after identifying the inaccuracy; and

(2) The failure to identify the inaccuracy and submit it to HHS or the State Exchange (as applicable) in a timely manner was not unreasonable or due to the issuer's misconduct or

negligence.

(c) Deadline for describing inaccuracies. To be eligible for resolution under paragraph (b) of this section, an issuer must describe all inaccuracies identified in a payment and collections report before the later of—

(1) The end of the 3-year period beginning at the end of the plan year to which the inaccuracy relates; or

(2) The date by which HHS notifies issuers that the HHS audit process with respect to the plan year to which such inaccuracy relates has been completed.

(3) If a payment error is discovered after the timeframes set forth in paragraph (c)(1) and (2) of this section, the issuer must notify HHS, the State Exchange, or SBE–FP (as applicable) and repay any overpayments to HHS.

■ 48. Section 156.1215 is amended by revising paragraph (b) to read as follows:

§ 156.1215 Payment and collections processes.

* * * * *

- (b) Netting of payments and charges for later years. As part of its payment and collections process, HHS may net payments owed to issuers and their affiliates operating under the same tax identification number against amounts due to the Federal government from the issuers and their affiliates under the same taxpayer identification number for advance payments of the premium tax credit, advance payments of and reconciliation of cost-sharing reductions, payment of Federallyfacilitated Exchange user fees, payment of State Exchanges utilizing the Federal platform user fees, and risk adjustment, reinsurance, and risk corridors payments and charges.
- 49. Section 156.1220 is amended by— ■ a. Revising paragraphs (a)(1)(vii) and (a)(3)(ii):
- b. Redesignating paragraphs (a)(3)(iii) through (vi) as (a)(3)(iv) through (vii), respectively; and
- c. Adding new paragraph (a)(3)(iii).

 The revision and addition reads as follows:

§ 156.1220 Administrative appeals.

(a) * * * * (1) * * *

(vii) The findings of a second validation audit as a result of risk adjustment data validation (if applicable) with respect to risk adjustment data for the 2016 benefit year and beyond; or

* * * * * *

(ii) For a risk adjustment payment or charge, including an assessment of risk adjustment user fees, within 30 calendar days of the date of the notification under § 153.310(e) of this subchapter;

(iii) For the findings of a second validation audit (if applicable), or the calculation of a risk score error rate as a result of risk adjustment data validation, within 30 calendar days of publication of the applicable benefit year's Summary Report of Benefit Year Risk Adjustment Data Validation Adjustments to Risk Adjustment Transfers;

* * * * *

PART 158—ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS

■ 50. The authority citation for part 158 continues to read as follows:

Authority: 42 U.S.C. 300gg-18.

■ 51. Section 158.103 is amended by adding the definition for "Prescription drug rebates and other price concessions" in alphabetical order to read as follows:

§158.103 Definitions.

* * * *

Prescription drug rebates and other price concessions means all remuneration received by or on behalf of an issuer, including remuneration received by and on behalf of entities providing pharmacy benefit management services to the issuer, that decrease the costs of a prescription drug covered by the issuer, regardless from whom the remuneration is received (for example, pharmaceutical manufacturer, wholesaler, retail pharmacy, or vendor). Prescription drug rebates and other price concessions include discounts, charge backs or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits to the extent the value of these items reduce costs for the issuer, and excluding bona fide service fees. Prescription drug rebates and other price concessions exclude any remuneration, coupons, or price concessions for which the full value is passed on to the enrollee. Bona fide service fees mean fees paid by a drug manufacturer to an entity providing pharmacy benefit management services to the issuer that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

§ 158.221 [Amended]

- 52. Effective May 5, 2021 amend § 158.221 by removing paragraph (b)(8) and redesignating paragraph (b)(9) as paragraph (b)(8).
- \blacksquare 53. Section 158.240 is amended by adding paragraph (g) to read as follows:

§ 158.240 Rebating premium if the applicable medical loss ratio standard is not met.

* * * * *

(g) Rebate prepayment and safe harbor. An issuer may choose to pay a portion or all of its estimated rebate amount for a given MLR reporting year to enrollees in any form specified in § 158.241 prior to the rebate payment

deadlines set forth in §§ 158.240(e) and 158.241(a)(2) and in advance of submitting the MLR report required in § 158.110 to the Secretary. Issuers that choose to prepay a portion or all of their rebates must do so for all eligible enrollees in a given state and market in a non-discriminatory manner, and consistently with State law or other applicable state authority. If, after submitting the MLR report required in § 158.110, an issuer determines that its rebate prepayment amount in a given state and market is at least 95 percent, but less than 100 percent, of the total rebate amount owed for the applicable MLR reporting year to enrollees in that state and market, the issuer may, without penalty or late payment interest under paragraph (f) of this section, provide the remaining rebate amount to those enrollees no later than the rebate deadlines in §§ 158.240(e) and 158.241(a)(2) applicable to the following MLR reporting year. If the total rebate owed to an enrollee for the MLR reporting year is above the de minimis threshold established in § 158.243(a), the issuer cannot treat the remaining rebate owed to an enrollee after prepayment as de minimis, even if the remaining rebate is below the de minimis threshold.

■ 54. Section 158.241 is amended by revising paragraph (a)(2) to read as follows:

§ 158.241 Form of rebate.

(2) For each of the 2011, 2012, and 2013 MLR reporting years, any rebate provided in the form of a premium credit must be provided by applying the full amount due to the first month's premium that is due on or after August 1 following the MLR reporting year. If the amount of the rebate exceeds the premium due for August, then any overage shall be applied to succeeding premium payments until the full amount of the rebate has been credited. Beginning with the 2014 MLR reporting year, any rebate provided in the form of a premium credit must be provided by applying the full amount due to the first month's premium that is due on or after September 30 following the MLR reporting year. If the amount of the rebate exceeds the premium due for October, then any overage shall be applied to succeeding premium payments until the full amount of the rebate has been credited. Beginning with rebates due for the 2020 MLR reporting year, any rebate provided in the form of a premium credit must be provided by applying the full amount due to the monthly premium that is due no later than October 30 following the

MLR reporting year. If the amount of the rebate exceeds the monthly premium, then any overage shall be applied to succeeding premium payments until the full amount of the rebate has been credited.

■ 55. Subchapter E as added in final rule published on November 27, 2019 (84 FR 65524) and effective on January 1, 2021 is amended by adding part 184 to read as follows:

PART 184—PHARMACY BENEFIT MANAGER STANDARDS UNDER THE AFFORDABLE CARE ACT

184.10 Basis and scope.

184.20 Definitions.

Prescription drug distribution and cost reporting by pharmacy benefit managers.

Authority: 42 U.S.C. 1302, 1320b-23.

§ 184.10 Basis and scope.

- (a) Basis. (1) This part implements section 1150A, Pharmacy Benefit Managers Transparency Requirements, of title XI of the Social Security Act.
 - (2) [Reserved]
- (b) *Scope*. This part establishes standards for Pharmacy Benefit Managers that administer prescription drug benefits for health insurance issuers that offer Qualified Health Plans with respect to the offering of such plans.

§ 184.20 Definitions.

The following definitions apply to this part, unless the context indicates otherwise:

Health insurance issuer has the meaning given to the term in § 144.103 of this subtitle.

Plan year has the meaning given to the term in § 156.20 of this subchapter.

Qualified health plan has the meaning given to the term in § 156.20 of this subchapter.

Qualified health plan issuer has the meaning given to the term in § 156.20 of this subchapter.

§ 184.50 Prescription drug distribution and cost reporting by pharmacy benefit managers.

- (a) General requirement. In a form, manner, and at such times specified by HHS, any entity that provides pharmacy benefits management services on behalf of a qualified health plan (QHP) issuer must provide to HHS the following information:
- (1) The percentage of all prescriptions that were provided under the QHP through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a

generic drug was available and dispensed compared to all drugs dispensed;

- (2) The aggregate amount, and the type of rebates, discounts or price concessions (excluding bona fide service fees) that the pharmacy benefits manager (PBM) negotiates that are attributable to patient utilization under the QHP, and the aggregate amount of the rebates, discounts, or price concessions that are passed through to the QHP issuer, and the total number of prescriptions that were dispensed.
- (i) Bona fide service fees means fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.
 - (ii) [Reserved]
- (3) The aggregate amount of the difference between the amount the QHP issuer pays its contracted PBM and the amounts that the PBM pays retail pharmacies, and mail order pharmacies, and the total number of prescriptions that were dispensed.
- (b) Limitations on disclosure. Information disclosed by a PBM under this section shall not be disclosed by HHS or by a QHP receiving the information, except that HHS may disclose the information in a form which does not disclose the identity of a specific PBM, QHP, or prices charged for drugs, for the following purposes:
- (1) As HHS determines to be necessary to carry out section 1150A or part D of title XVIII of the Act;
- (2) To permit the Comptroller General to review the information provided;
- (3) To permit the Director of the Congressional Budget Office to review the information provided; or
- (4) To States to carry out section 1311 of the Affordable Care Act.
- (c) Penalties. A PBM that fails to report the information described in paragraph (a) of this section to HHS on a timely basis or knowingly provides false information will be subject to the provisions of section 1927(b)(3)(C) of the Act.

Dated: April 27, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2021-09102 Filed 4-30-21; 8:45 am] BILLING CODE 4150-28-P

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Federal Register

Vol. 86, No. 85

Wednesday, May 5, 2021

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FEDERAL REGISTER PAGES AND DATE, MAY

23237–23576	3
23577-23842	4
23843-24296	5

CFR PARTS AFFECTED DURING MAY

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

the revision date of each title.	
3 CFR	30 CFR
Proclamations:	25023606
1018923843	31 CFR
1019023845	
1019123847	Proposed Rules:
1019223849	10023877
1019323851	
1019423853	33 CFR
1019523855	10023608, 23865
1019623857	11723278, 23609
1019723859	16523279, 23611, 23613,
1019823861	23865
10100	40123241
6 CFR	Proposed Rules:
3723237	11723639, 23880
3720237	1172000, 2000
10 CFR	34 CFR
Proposed Rules:	Proposed Rules:
43023635	Ch. II23304
43123875	
	40 CFR
11 CFR	Proposed Rules:
Proposed Rules:	8123309
11323300	42 CFR
12 CFR	-
124223577	51023496
124223577	45 CFR
13 CFR	14724140
12623863	15024140
12020000	15324140
14 CFR	15524140
_	15624140
1323241	15824140
3923593, 23595, 23599	18424140
24423260	10424140
25923260	46 CFR
38323241	
40623241	22123241
Proposed Rules:	30723241
Ch. I23876	34023241
3923301	35623241
Ch. II23876	Proposed Rules:
Ch. III23876	Ch. II23876
15 CFR	47 CFR
Ch. XV23271	223281, 23614
	1523281
19 CFR	2023614
Ch. I23277	6823614
011. 120211	7323866, 23868
21 CFR	9023281
130823602	9523281
10002002	Proposed Rules:
23 CFR	1523323
Proposed Rules:	7323340
Ch. I23876	9023323
Ch. II23876	9523323
Ch. III23876	
	48 CFR
26 CFR	Proposed Rules:
5323865	Ch. 1223876

49 CFR	223	23241	241	23241	Ch. VIII	23876
10723241	224	23241	242	23241	Ch. X	23876
	225	23241	243	23241	Ch. XI	23876
17123241	227	23241	244	23241		
19023241	228	23241	272	23241	50 OFD	
20923241	229	23241	386	23241	50 CFR	
21323241		23241	578		17	23869
21423241		23241	1570	23629	648	23633
21523241		23241	1582		660	23872
21623241		23241	Proposed Rules:		Proposed Rules	
21723241	235	23241	Ch. I	23876	17	23882
21823241	236	23241	Ch. II	23876	20	23641
21923241	237	23241	Ch. III		32	23794
22023241		23241	Ch. V			23794
22123241		23241	Ch. VI			23657
22223241	240	23241	Ch.VII	23876	660	23659

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's List of Public Laws.

Last List April 27, 2021

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