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# Presidential Documents

**Title 3—**

## The President

**Executive Order 14052 of November 15, 2021**

## Implementation of the Infrastructure Investment and Jobs Act

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to effectively implement the historic infrastructure investments in the Infrastructure Investment and Jobs Act (the Act), it is hereby ordered as follows:

**Section 1**. *Background.* The Infrastructure Investment and Jobs Act is a once-in-a-generation investment in our Nation's infrastructure and competitiveness. It will help rebuild America's roads, bridges, and rails; expand access to clean drinking water; work to ensure access to high-speed internet throughout the Nation; tackle the climate crisis; advance environmental justice; and invest in communities that have too often been left behind. It will accomplish all of this while driving the creation of good-paying union jobs and growing the economy sustainably and equitably for decades to come.

Critical to achieving these goals will be the effective implementation of the Act by my Administration, as well as by State, local, Tribal, and territorial governments.

**Sec. 2**. *Implementation Priorities.* In implementing the Act, all agencies (as described in section 3502(1) of title 44, United States Code, except for the agencies described in section 3502(5) of title 44), shall, as appropriate and to the extent consistent with law, prioritize:

(a) investing public dollars efficiently, working to avoid waste, and focusing on measurable outcomes for the American people;

(b) increasing the competitiveness of the United States economy, including through implementing the Act's Made-in-America requirements and bolstering United States manufacturing and supply chains;

(c) improving job opportunities for millions of Americans by focusing on high labor standards for these jobs, including prevailing wages and the free and fair chance to join a union;

(d) investing public dollars equitably, including through the Justice40 Initiative, which is a Government-wide effort toward a goal that 40 percent of the overall benefits from Federal investments in climate and clean energy flow to disadvantaged communities;

(e) building infrastructure that is resilient and that helps combat the crisis of climate change; and

(f) effectively coordinating with State, local, Tribal, and territorial governments in implementing these critical investments.

**Sec. 3**. *Infrastructure Implementation Task Force.* (a) There is established within the Executive Office of the President the Infrastructure Implementation Task Force (Task Force). The function of the Task Force is to coordinate effective implementation of the Infrastructure Investment and Jobs Act and other related significant infrastructure programs within the executive branch.

(b) The Assistant to the President for Economic Policy and Director of the National Economic Council shall serve as Co-Chair of the Task Force.

(c) There is established within the Executive Office of the President the position of White House Infrastructure Coordinator, who shall serve as Co-Chair of the Task Force.

(d) In addition to the Co-Chairs, the Task Force shall consist of the following members:

(i) the Secretary of the Interior;

(ii) the Secretary of Agriculture;

(iii) the Secretary of Commerce;

(iv) the Secretary of Labor;

(v) the Secretary of Transportation;

(vi) the Secretary of Energy;

(vii) the Administrator of the Environmental Protection Agency;

(viii) the Director of the Office of Management and Budget;

(ix) the Director of the Office of Personnel Management;

(x) the Assistant to the President and Director of the Domestic Policy Council;

(xi) the Assistant to the President and National Climate Advisor; and

(xii) the heads of such other executive departments, agencies, and offices as the Co-Chairs may from time to time invite to participate.

(e) The Co-Chairs may coordinate subgroups consisting of Task Force members or their designees, as appropriate.

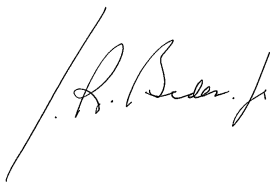
**Sec. 4**. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.



THE WHITE HOUSE,
*November 15, 2021.*

[FR Doc. 2021–25286
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Billing code 3395–F2–P

# Presidential Documents

**Executive Order 14053 of November 15, 2021**

## Improving Public Safety and Criminal Justice for Native Americans and Addressing the Crisis of Missing or Murdered Indigenous People

By the authority vested in me as President by the Constitution and the laws of the United States of America, I hereby order as follows:

**Section 1**. *Policy.* The safety and well-being of all Native Americans is a top priority for my Administration. My Administration will work hand in hand with Tribal Nations and Tribal partners to build safe and healthy Tribal communities and to support comprehensive law enforcement, prevention, intervention, and support services.

Generations of Native Americans have experienced violence or mourned a missing or murdered family member or loved one, and the lasting impacts of such tragedies are felt throughout the country. Native Americans face unacceptably high levels of violence, and are victims of violent crime at a rate much higher than the national average. Native American women, in particular, are disproportionately the victims of sexual and gender-based violence, including intimate partner homicide. Research shows that approximately half of Native American women have experienced sexual violence and that approximately half have experienced physical violence by an intimate partner. LGBTQ+ Native Americans and people who identify as ''Two-Spirit'' people within Tribal communities are also often the targets of violence. And the vast majority of Native American survivors report being victimized by a non-Native American individual.

For far too long, justice has been elusive for many Native American victims, survivors, and families. Criminal jurisdiction complexities and resource constraints have left many injustices unaddressed. Some progress has been made, particularly on Tribal lands. Given that approximately 70 percent of American Indian and Alaska Natives live in urban areas and part of this epidemic of violence is against Native American people in urban areas, we must continue that work on Tribal lands but also build on existing strategies to identify solutions directed toward the particular needs of urban Native Americans.

In 2020, bipartisan members of the 116th Congress took an important step forward through the passage of two pieces of legislation—Savanna's Act and the Not Invisible Act of 2019—that include important provisions for improving law enforcement and justice protocols as well as improving access to data to address missing or murdered indigenous people. My Administration is committed to fully implementing these laws and working with the Congress to fund these programs for Native Americans. Earlier this year, the Secretary of the Interior and the Attorney General announced a Joint Commission, established pursuant to the Not Invisible Act, that includes: representatives of Tribal, State, and local law enforcement; Tribal judges; Native American survivors of human trafficking; health care and mental health practitioners who have experience working with Native American survivors of human trafficking and sexual assault; Urban Indian Organizations focused on violence against women and children; and family members of missing or murdered indigenous people. The Commission will work to address the persistent violence endured by Native American families and communities across the country. In addition, the Department of the Interior

has established a special unit to focus resources on active and unsolved missing persons cases.

But more work is needed to address the crisis of ongoing violence against Native Americans—and of missing or murdered indigenous people. Previous executive action has not achieved changes sufficient to reverse the epidemic of missing or murdered indigenous people and violence against Native Americans. The Federal Government must prioritize addressing this issue and its underlying causes, commit the resources needed to tackle the high rates of violent crime that Native Americans experience over the long term, coordinate and provide resources to collect and analyze data, and work closely with Tribal leaders and community members, Urban Indian Organizations, and other interested parties to support prevention and intervention efforts that will make a meaningful and lasting difference on the ground.

It is the policy of my Administration to work directly with Tribal Nations to strengthen public safety and criminal justice in Indian Country and beyond, to reduce violence against Native American people, and to ensure swift and effective Federal action that responds to the problem of missing or murdered indigenous people. My Administration understands that Native American people, particularly the survivors of violence, know best what their communities need to make them safer. Consistent engagement, commitment, and collaboration will drive long-term improvement to public safety for all Native Americans.

**Sec. 2**. *Coordination of a Federal Law Enforcement Strategy to Prevent and Respond to Violence Against Native Americans.* The Attorney General, working with the Secretary of the Interior and the heads of other executive departments and agencies (agencies) as appropriate, shall assess and build on existing efforts to develop a coordinated and comprehensive Federal law enforcement strategy to prevent and respond to violence against Native Americans, including to address missing or murdered indigenous people where the Federal Government has jurisdiction. The strategy shall set out a plan to address unsolved cases involving Native Americans; provide for coordination among the Department of Justice, the Department of the Interior, and the Department of Homeland Security in their efforts to end human trafficking; seek to strengthen and expand Native American participation in the Amber Alert in Indian Country initiative; and build on and enhance national training programs for Federal agents and prosecutors, including those related to trauma-informed and victim-centered interview and investigation techniques. The strategy shall also include protocols for effective, consistent, and culturally and linguistically appropriate communication with families of victims and their advocates, including through the creation of a designated position within the Department of Justice assigned the function of serving as the outreach services liaison for criminal cases where the Federal Government has jurisdiction. The Attorney General and the Secretary of the Interior shall report to the President within 240 days of the date of this order describing the strategy developed and identifying additional resources or other support necessary to implement that strategy.

**Sec. 3**. *Supporting Tribal and Other Non-Federal Law Enforcement Efforts to Prevent and Respond to Violence Against Native Americans.* (a) The Attorney General and the Secretary of the Interior, working with the heads of other agencies as appropriate, shall develop guidance, identify leading practices, and provide training and technical assistance, consistent with applicable law and available appropriations, to:

(i) assist Tribal governments in implementing special domestic violence criminal jurisdiction pursuant to the Violence Against Women Reauthorization Act of 2013, enabling them to prosecute certain non-Indian defendants for domestic violence and dating violence offenses in Indian Country, and also assist Tribes in implementing any relevant Tribal provisions in subsequent Violence Against Women Act reauthorization legislation;

(ii) assist Tribal governments within Oklahoma, consistent with the United States Supreme Court's decision in *McGirt* v. *Oklahoma,* 140 S. Ct. 2452

(2020), to build capacity to handle cases within their criminal jurisdiction, including the capacity to provide victim services;

(iii) promote coordination of Federal, State, local, and Tribal law enforcement, including, as appropriate, through the development and support of Tribal Community Response Plans;

(iv) continue to assist Tribal law enforcement and judicial personnel with training, as described in 25 U.S.C. 2451, on the investigation and prosecution of offenses related to illegal narcotics and on alcohol and substance abuse prevention and treatment; and

(v) assist Tribal, State, and local law enforcement entities' ability to apply linguistically appropriate, trauma-informed, and victim-centered practices when working with victims of crime, and to develop prevention strategies and recognize the indicators of human trafficking affecting Native Americans.

(b) The Attorney General and the Secretary of the Interior shall continue to assess their respective grantmaking operations to evaluate whether any changes, consistent with applicable law, are warranted to make that grantmaking more equitable for Tribal applicants seeking support for law enforcement purposes and for the provision of services to victims and survivors.

**Sec. 4**. *Improving Data Collection, Analysis, and Information Sharing.* (a) The Attorney General, in coordination with the Secretary of the Interior and the Secretary of Health and Human Services (HHS), as appropriate, shall sustain efforts to improve data collection and information-sharing practices, conduct outreach and training, and promote accurate and timely access to information services regarding crimes or threats against Native Americans, including in urban areas, such as through the National Crime Information Center, the Next Generation Identification system, and the National Violent Death Reporting System, as appropriate and consistent with applicable law.

(b) The Attorney General shall take steps, consistent with applicable law, to expand the number of Tribes participating in the Tribal Access Program for National Crime Information, which provides Tribes access to national crime information systems for federally authorized purposes.

(c) The Attorney General, in coordination with the Secretary of the Interior and the Secretary of HHS, shall develop a strategy for ongoing analysis of data collected on violent crime and missing persons involving Native Americans, including in urban Indian communities, to better understand the extent and causes of this crisis. Within 240 days of the date of this order, the Attorney General, the Secretary of the Interior, and the Secretary of HHS shall report jointly to the President on the strategy they have developed to conduct and coordinate that analysis and shall identify additional resources or other support necessary to implement that strategy.

(d) The Attorney General shall assess the current use of DNA testing and DNA database services to identify missing or murdered indigenous people and any responsible parties, including the unidentified human remains, missing persons, and relatives of missing persons indices of the Combined DNA Index System and the National Missing and Unidentified Persons System. Within 240 days of the date of this order, the Attorney General shall report the outcome of this assessment to the President, along with recommendations to improve the use and accessibility of DNA database services.

(e) The Secretary of HHS shall evaluate the adequacy of research and data collection efforts at the Centers for Disease Control and Prevention and the National Institutes of Health in accurately measuring the prevalence and effects of violence against Native Americans, especially those living in urban areas, and report to the President within 180 days of the date of this order on those findings and any planned changes to improve those research and data collection efforts.

**Sec. 5**. *Strengthening Prevention, Early Intervention, and Victim and Survivor Services.* (a) The Secretary of HHS, in consultation with the Secretary of the Interior and Tribal Nations and after conferring with other agencies, researchers, and community-based organizations supporting indigenous wellbeing, including Urban Indian Organizations, as appropriate, shall develop a comprehensive plan to support prevention efforts that reduce risk factors for victimization of Native Americans and increase protective factors, including by enhancing the delivery of services for Native American victims and survivors, as well as their families and advocates. The comprehensive plan shall, to the extent possible, build on the existing evidence base. The plan shall include strategies for improving mental and behavioral health; providing substance abuse services; providing family support, including high-quality early childhood programs for victims and survivors with young children; and preventing elder abuse, gender-based violence, and human trafficking. In addition, the plan shall also include community-based strategies that improve community cohesion and cultural connectivity and preservation, educational programs to increase empowerment and self-advocacy, and strategies to encourage culturally and linguistically appropriate, trauma-informed, and victim-centered service delivery to Native Americans, including for survivors of gender-based violence. The Secretary of HHS shall report to the President within 240 days of the date of this order describing the plan and actions taken and identifying any additional resources or other support needed.

(b) The Secretary of HHS and the Secretary of the Interior shall review procedures within their respective departments for reporting child abuse and neglect, including barriers to reporting, and shall take appropriate action to make reporting of child abuse and neglect by the Indian Health Service easier and more streamlined. In addition, the Secretaries shall assess and identify ways to expand Native American access to child advocacy center services such as pediatric medical forensic examination services, mental health care providers with advanced training in child trauma, and culturally and linguistically appropriate activities and services geared toward pediatric patients. The Secretaries shall report to the President within 180 days of the date of this order describing actions taken, findings from the assessment, and planned actions to expand access, and identifying any additional resources or other support needed.

(c) The Secretary of the Interior, consulting with the Attorney General and the Secretary of HHS, as appropriate, shall evaluate the effectiveness of existing technical assistance and judicial support services for Tribes to provide community-based conflict resolution, as well as culturally and linguistically appropriate, trauma-informed, and victim-centered strategies, including traditional healing services and healing courts, and shall identify and make improvements as needed. The Secretary of the Interior shall report to the President within 180 days of the date of this order describing the evaluation findings and the improvements implemented.

**Sec. 6**. *Consultation and Engagement.* In accordance with the Presidential Memorandum of January 26, 2021 (Tribal Consultation and Strengthening Nation-to-Nation Relationships), the Departments of Justice, the Interior, HHS, Energy, and Homeland Security shall conduct timely consultations with Tribal Nations and shall engage Native American communities to obtain their comments and recommendations regarding implementing sections 2 through 5 of this order. Tribal consultation and engagement shall continue as the strategies required by this order are implemented.

**Sec. 7**. *Definitions.* For the purposes of this order:

(a) ''Tribal Nation'' means an American Indian or Alaska Native tribe, band, nation, pueblo, village, or community that the Secretary of the Interior acknowledges as a federally recognized tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994, 25 U.S.C. 5130, 5131.

(b) ''Native American'' and ''Native'' mean members of one or more Tribal Nations.

(c) ''Urban Indian Organization'' means a nonprofit corporate body situated in an urban center, governed by an urban Indian controlled board of directors, and providing for the maximum participation of all interested Indian groups and individuals, which body is capable of legally cooperating with other public and private entities, pursuant to 25 U.S.C. 1603(29).

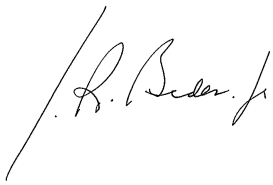
**Sec. 8**. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.



THE WHITE HOUSE,
*November 15, 2021.*

[FR Doc. 2021–25287
Filed 11–17–21; 8:45 am]
Billing code 3395–F2–P

# Rules and Regulations

Federal Register
Vol. 86, No. 220
Thursday, November 18, 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.

## DEPARTMENT OF AGRICULTURE

### Agricultural Marketing Service

### 7 CFR Part 987

**[Doc. No. AMS–SC–21–0056; SC21–987–1 FR]**

## Domestic Dates Produced or Packed in Riverside County, California; Increased Assessment Rate

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** This rule implements a recommendation from the California Date Administrative Committee (Committee) to increase the assessment rate for the 2020–21 and subsequent crop years. The assessment rate will remain in effect indefinitely unless modified, suspended, or terminated.

**DATES:** Effective December 20, 2021.

**FOR FURTHER INFORMATION CONTACT:** Barry Broadbent, Senior Marketing Specialist, West Region Branch, Market Development Division, Specialty Crops Program, AMS, USDA; Telephone: (503) 326–2724, or Email: *Barry.Broadbent@usda.gov.*

Small businesses may request information on complying with this regulation by contacting Richard Lower, Market Development Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, or Email: *Richard.Lower@usda.gov.*

**SUPPLEMENTARY INFORMATION:** This action, pursuant to 5 U.S.C. 553, amends regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This final rule is issued under Marketing Order No. 987, as amended (7 CFR part 987), regulating the handling of domestic dates produced or packed in Riverside County, California. Part 987, (referred to as the ''Order''), is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.'' The Committee locally administers the Order and is comprised of producers and producer-handlers operating within the area of production.

The Department of Agriculture (USDA) is issuing this final rule in conformance with Executive Orders 12866 and 13563. 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, reducing costs, harmonizing rules, and promoting flexibility. This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review.

This final rule has been reviewed under Executive Order 13175—Consultation and Coordination with Indian Tribal Governments, which requires agencies to consider whether their rulemaking actions would have tribal implications. The Agricultural Marketing Service (AMS) has determined that this rule is unlikely to have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the Order now in effect, California date handlers are subject to assessments. Funds to administer the Order are derived from such assessments. The assessment rate is applicable to all assessable dates for the 2020–21 crop year, and will continue until amended, suspended, or terminated.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act (7 U.S.C. 608(15)(A)), any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

The Order provides authority for the Committee, with the approval of USDA, to formulate an annual budget of expenses and collect assessments from handlers to administer the program. The members are familiar with the Committee's needs and with the costs of goods and services in their local area and can formulate an appropriate budget and assessment rate. The assessment rate is formulated and discussed in a public meeting. Thus, all directly affected persons have an opportunity to participate and provide input.

This rule increases the assessment rate from $0.15 per hundredweight, the rate that was established for the 2018–19 and subsequent crop years, to $0.20 per hundredweight of dates handled for the 2020–21 and subsequent crop years. The Committee recommended the increased assessment rate to compensate for increasing administrative expenses. The higher assessment rate will provide sufficient funds to cover most of the 2020–21 crop year anticipated expenses, with the balance coming from other income and the Committee's financial reserve.

The Committee met on June 25, 2020, and unanimously recommended increasing the assessment rate from $0.15 per hundredweight to $0.20 per hundredweight to fund necessary administrative expenses and maintain a sufficient operating reserve. The assessment rate increase will provide sufficient funds to cover most of the Committee's 2020–21 crop year budgeted expenses, with the balance coming from other revenue sources and reserve funds.

The Committee estimates the 2020–21 domestic date crop to be 32,000,000 pounds (320,000 hundredweight), which is expected to generate $64,000 in assessment income at the $0.20 per

hundredweight assessment rate. The Committee anticipates other income of approximately $5,000. Total income of $69,000, combined with $6,250 from the financial reserve, will provide enough funds to cover 2020–21 crop year budgeted expenditures. Reserve funds remaining at the end of the 2020–21 crop year are expected to be $28,750.

The Committee's budget for the 2020–21 crop year is estimated to be $75,250. The Committee's expenses include $47,000 for management, $19,250 for office administration, and $9,000 for the financial audit. In comparison, the previous crop year's total budget was $74,200, and the administrative expenses were $43,000, $21,200, and $10,000, respectively.

The assessment rate recommended by the Committee was derived by considering anticipated expenses, the expected volume of dates handled, and the amount of funds available in the operating reserve. Income derived from handler assessments of $64,000 (320,000 hundredweight assessed at a rate of $0.20 per hundredweight) will be adequate to cover most of the Committee's budgeted expenses of $75,250, with the balance covered from $5,000 in other income and $6,250 from reserve funds. After expending $6,250, the ending 2020–21 crop year balance in the financial reserve is expected to be $28,750, which would be less than the average of the annual expenses of the preceding five years as mandated by § 987.72(d).

The assessment rate established by this rule will continue in effect indefinitely unless modified, suspended, or terminated by USDA upon recommendation and information submitted by the Committee or other available information.

Although this assessment rate will be in effect for an indefinite period, the Committee will continue to meet prior to or during each crop year to recommend a budget of expenses and consider recommendations for modification of the assessment rate. The dates and times of Committee meetings are available from the Committee or USDA. Meetings are public and held virtually or in a hybrid style with participants having a choice whether to attend in person or virtually. All interested persons may express their views at these meetings. USDA will evaluate Committee recommendations and other available information to determine whether modification of the assessment rate is needed. Further rulemaking will be undertaken as necessary. The Committee's budget for subsequent crop years will be reviewed and, as appropriate, approved by USDA.

**Final Regulatory Flexibility Analysis**

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), AMS has considered the economic impact of this rule on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 70 date producers in the production area and 11 date handlers subject to regulation under the Order. The Small Business Administration defines small agricultural producers as those having annual receipts of less than $1,000,000, and small agricultural service firms as those whose annual receipts are less than $30,000,000. (13 CFR 121.201)

According to the National Agricultural Statistics Service (NASS), data for the most-recently completed crop year (2019) shows that the producer price for fresh market California dates was $4,130 per ton. With the estimated 16,000-ton crop, the total farm gate value for California date producers was approximately $66,080,000 (16,000 times $4,130). Therefore, the average fresh market date revenue for the 70 producers within the production area is approximately $944,000 ($66,080,000 divided by 70). Thus, assuming a normal bell-curve distribution of receipts among producers, AMS estimates the majority of producers would qualify as small businesses under the SBA definition.

Furthermore, USDA Market News reported an average terminal market price of $50.88 per 11-pound carton for the 2019–20 crop year. With approximately 32,000,000 pounds handled, the industry would have shipped an estimated 2,909,091 11-pound cartons (32,000,000 divided by 11) of packaged dates for a total value of $148,014,550 (2,909,091 times $50.88). With 11 date handlers within the production area, the average revenue per handler is estimated to be $13,455,868 for the 2019–20 crop year ($148,014,550 divided by 11). Thus, most California date handlers would be considered small businesses under the SBA definition.

This final rule increases the assessment rate collected from handlers for the 2020–21 and subsequent crop years from $0.15 to $0.20 per hundredweight of dates handled. The Committee unanimously recommended 2020–21 crop year expenditures of $75,250 and an assessment rate of $0.20 per hundredweight of dates, which is $0.05 higher than the rate currently in effect. The quantity of assessable dates for the 2020–21 crop year is estimated to be 32,000,000 pounds (320,000 hundredweight). The $0.20 per hundredweight assessment rate is expected to provide $64,000 in assessment income. Income derived from handlers' assessments, plus $5,000 of other income and $6,250 from the Committee's authorized reserve, will be adequate to cover the Committee's budgeted expenses for the 2020–21 crop year.

The total budget recommended by the Committee for the 2020–21 crop year is $75,250, compared to $74,200 for the 2019–20 crop year. The Committee recommended the higher assessment rate to fully fund ongoing program expenses without depleting its operating reserve.

The income generated from the higher assessment rate, combined with other income and a small amount from the financial reserve, will be sufficient to cover anticipated 2020–21 expenses and to maintain a financial reserve within the limit specified by the Order.

Section 987.72(d) states that the Committee may maintain an operating monetary reserve not to exceed the average of one year's expenses incurred during the most recent five preceding crop years, except that an established reserve need not be reduced to conform to any recomputed average. The Committee estimated that funds in its reserve were approximately $35,000 at the beginning of the 2020–21 crop year. It expects to utilize $6,250 of the reserve during the year, leaving a reserve of approximately $28,750 to start the 2021–22 crop year, which would be within the limit specified in the Order.

The Committee reviewed and unanimously recommended 2020–21 crop year expenditures of $75,250. The Committee considered several factors before making its recommendation, including the size of the anticipated 2020–21 crop, the Committee's estimated 2020–21 reserve carry-in, other sources of income, and its anticipated expenses. Further, the Committee considered several alternative expenditure levels and assessment rates, including not changing the assessment rate or adjusting expenses. Ultimately, the Committee recommended the $0.20 per hundredweight assessment rate to fund

the program's expenses and maintain its reserve at a reasonable level.

A review of historical and preliminary information pertaining to the upcoming crop year indicates that the producer price for the 2020–21 crop year is estimated to be $201.50 per hundredweight of dates. Utilizing that price, the estimated crop size, and the $0.20 per hundredweight assessment rate, the estimated assessment revenue for the 2020–21 crop year as a percentage of total producer revenue is approximately 0.1 percent ($0.20 per hundredweight divided by $201.50 per hundredweight).

This action increases the assessment obligation imposed on handlers. While assessments impose some additional costs on handlers, the costs are minimal and uniform on all handlers. Some of the additional costs may be passed on to producers. However, these costs are offset by the benefits derived by the operation of the Order. In addition, the Committee meetings were widely publicized throughout the California date industry. All interested persons were invited to attend the meetings and encouraged to participate in Committee deliberations on all issues. The June 25, 2020 Committee meeting was a virtually held public meeting and all entities, both large and small, were able to express views on this issue. Interested persons were invited to submit comments on the proposed rule, including the regulatory and information collection impacts of this action on small businesses.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Order's information collection requirements have been previously approved by the Office of Management and Budget (OMB) and assigned OMB No. 0581–0178 Vegetable and Specialty Crops. No changes in those requirements are necessary as a result of this action. Should any changes become necessary, they would be submitted to OMB for approval.

This final rule will not impose any additional reporting or recordkeeping requirements on either small or large California date handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this final rule.

A proposed rule concerning this action was published in the **Federal Register** on August 26, 2021 (86 FR 47599). Copies of the proposal were provided by the Committee to members and handlers. Finally, the proposed rule was made available through the internet by USDA and the **Federal Register**. A 15-day comment period ending September 10, 2021, was provided to allow interested persons to respond to the proposal. No comments were received. Accordingly, no changes will be made to the rule as proposed.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *http://www.ams.usda.gov/rules-regulations/moa/small-businesses.* Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant material presented, including the information and recommendation submitted by the Committee and other available information, it is hereby found that this rule will tend to effectuate the declared policy of the Act.

**List of Subjects in 7 CFR Part 987**

Dates, Marketing agreements, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 987 is amended as follows:

## PART 987—DOMESTIC DATES PRODUCED OR PACKED IN RIVERSIDE, CALIFORNIA

■ 1. The authority citation for part 987 continues to read as follows:

**Authority:** 7 U.S.C. 601–674.

■ 2. Section 987.339 is revised to read as follows:

### § 987.339 Assessment rate.

On and after October 1, 2020, an assessment rate of $0.20 per hundredweight is established for dates produced or packed in Riverside County, California.

**Erin Morris,**

*Associate Administrator, Agricultural Marketing Service.*

[FR Doc. 2021–25115 Filed 11–17–21; 8:45 am]

BILLING CODE 3410–02–P

## CONSUMER PRODUCT SAFETY COMMISSION

## 16 CFR Part 1227

**[Docket No. CPSC–2013–0019]**

## Safety Standard for Carriages and Strollers

**AGENCY:** Consumer Product Safety Commission.

**ACTION:** Direct final rule.

**SUMMARY:** In March 2014, the U.S. Consumer Product Safety Commission (CPSC) published a consumer product safety standard for carriages and strollers under section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA). The CPSIA sets forth a process for updating mandatory standards for durable infant or toddler products that are based on a voluntary standard when a voluntary standards organization revises the standard. This direct final rule updates the mandatory standard for carriages and strollers to incorporate by reference ASTM's 2021 version of the voluntary standard.

**DATES:** The rule is effective on February 15, 2022, unless CPSC receives a significant adverse comment by December 20, 2021. If CPSC receives such a comment, it will publish a document in the **Federal Register**, withdrawing this direct final rule before its effective date. The incorporation by reference of the publication listed in this rule is approved by the Director of the Federal Register as of February 15, 2022.

**ADDRESSES:** You may submit comments, identified by Docket No. CPSC–2013–0019, by any of the following methods:

*Electronic Submissions:* Submit electronic comments to the Federal eRulemaking Portal at: *https://www.regulations.gov.* Follow the instructions for submitting comments. The CPSC does not accept comments submitted by electronic mail (email), except through *https://www.regulations.gov* and as described below. The CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

*Mail/Hand Delivery/Courier Written Submissions:* Submit comments by mail/hand delivery/courier to: Division of the Secretariat, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7479. Alternatively, as a temporary option during the COVID–19 pandemic, you can email such submissions to: *cpsc-os@cpsc.gov.*

*Instructions:* All submissions received must include the agency name and docket number for this direct final rule. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to: *https://www.regulations.gov.* Do not submit electronically confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If you wish to submit such information, please submit it according to the instructions for written submissions.

*Docket:* For access to the docket to read background documents or comments received, go to: *https://www.regulations.gov,* and insert the docket number, CPSC- 2013–0019, into the ''Search'' box, and follow the prompts.

**FOR FURTHER INFORMATION CONTACT:** Keysha Walker, Compliance Officer, Office of Compliance and Field Operations, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814–4408; telephone: 301–504–6820; email: *kwalker@cpsc.gov.*

**SUPPLEMENTARY INFORMATION:**

## A. Background

### *1. Statutory Authority*

Section 104(b)(1)(B) of the CPSIA, also known as the Danny Keysar Child Product Safety Notification Act, requires the Commission to promulgate consumer product safety standards for durable infant or toddler products. The law requires these standards to be ''substantially the same as'' applicable voluntary standards or more stringent than the voluntary standards if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product.

The CPSIA also sets forth a process for updating CPSC's durable infant or toddler standards when the voluntary standard upon which the CPSC standard was based is changed. Section 104(b)(4)(B) of the CPSIA provides that if an organization revises a standard that has been adopted, in whole or in part, as a consumer product safety standard under this subsection, it shall notify the Commission. In addition, the revised voluntary standard shall be considered to be a consumer product safety standard issued by the Commission under section 9 of the Consumer Product Safety Act (CPSA) (15 U.S.C. 2058), effective 180 days after the date on which the organization notifies the Commission (or such later date specified by the Commission in the **Federal Register**) unless, within 90 days after receiving that notice, the Commission notifies the organization that it has determined that the proposed revision does not improve the safety of the consumer product covered by the standard and that the Commission is retaining the existing consumer product safety standard.

### *2. The Carriage and Stroller Standard*

On March 10, 2014, the Commission published a final rule issuing a standard for carriages and strollers that incorporated by reference the standard in effect at that time, ASTM F833–13b, with a modification to address potential hazardous openings created by adjustable grab bar/tray and foot rest configurations. 79 FR 13208. The standard was codified in the Commission's regulations at 16 CFR part 1227. There have been several revisions to the ASTM standard. On June 9, 2016, the Commission incorporated by reference ASTM F833–15, as the mandatory standard for carriages and strollers. 81 FR 37128. On August 2, 2019, the Commission incorporated by reference ASTM F833–19, as the mandatory standard for carriages and strollers. 84 FR 37763. ASTM F833–19 is the current mandatory standard incorporated by reference in 16 CFR part 1227.

On August 19, 2021, ASTM notified CPSC that it had revised the voluntary standard for carriages and strollers, approving ASTM F833–21 on June 15, 2021.[1] As discussed in this preamble, based on CPSC staff's review of ASTM F833–21, the Commission will allow the revised voluntary standard to become the mandatory standard because the revised requirements in the voluntary standard either improve the safety of carriages and strollers, or are safety neutral. Accordingly, by operation of law under section 104(b)(4)(B) of the CPSIA, ASTM F833–21 will become the mandatory consumer product safety standard for carriages and strollers on February 15, 2022. 15 U.S.C. 2056a(b)(4)(B). This direct final rule updates 16 CFR part 1227 to incorporate by reference the revised voluntary standard, ASTM F833–21.

## B. Revisions to ASTM F833

The ASTM standard for carriages and strollers establishes performance requirements, test methods, and labeling requirements to address hazards to children associated with carriages and strollers including stability, brakes, restraint systems, latches and folding mechanisms, structural integrity, cords, wheel detachments, and entrapment. ASTM has revised the ASTM F833–19 voluntary standard for carriages and strollers. On June 15, 2021, ASTM approved a revised version, ASTM F833–21, which was published in August 2021. This section describes the changes in ASTM F833–21. The 2021 revision contains editorial, non-substantive changes, as well as several substantive changes to improve the requirements. We summarize the differences and the CPSC's assessment of the revisions below.

### *1. Substantive Changes*

#### Allowance for a Concrete Floor Test Surface

ASTM F833–19 Section 4.1 specifies that testing be conducted ''on a concrete floor that shall be covered with ⅛-in. (3-mm) thick vinyl floor covering, unless test instructs differently.'' ASTM F833–21 replaces, in section 4.1, the word ''shall'' with ''may,'' allowing for testing on the originally specified surface, or on an uncovered concrete floor. This change applies to all carriages and stroller tests, except parking brake testing (Section 7.6), which is conducted on a horizontal test surface covered with 60 grit sandpaper, and wheel detachment from axle testing (Section 7.13.1), which is conducted on a table.

CPSC staff assessed the effect of the new test surface requirement and found that the allowing for testing on the originally specified surface, or on an uncovered concrete floor, did not have an impact on test results. Staff concluded that the allowance for an uncovered concrete floor test surface in addition to the current concrete floor covered with ⅛-inch-thick vinyl floor test surface does not affect the safety of carriages and strollers, because test results should be the same on either surface. In addition, staff determined that the revised language would be consistent with other ASTM juvenile product standards. Based on staff's assessment, the Commission concludes that the new test surface requirement is neutral with respect to the safety of carriages and strollers.

#### Summary List of References on Combination Unit of a Car Seat on a Stroller

ASTM F833–19 provided the impact test in Section 6.7.1 with its corresponding test method in Section 7.11, and the head entrapment requirement in Section 6.10 with its test

[1] ASTM published ASTM F833–21 in August 2021.

method in 7.18. However, these sections were not included in the summary list of requirements that apply to a combination unit of a car seat on a stroller in Section 6.6.1. ASTM F833–21 now adds references to Section 6.7.1 and Section 6.10, as well as their corresponding test methods, to the list of requirements in Section 6.6.1. Section 6.7.1 applies to a ''combination unit of a car seat on a carriage, stroller, or convertible carriage/stroller'' and Section 6.10 applies to a ''combination unit of a rear-facing car seat on a stroller or convertible carriage/stroller.'' Staff's review showed that the additions to the list of requirements that apply to a combination unit of a car seat on a stroller in Section 6.6.1 is neutral with respect to safety and does not affect the safety of carriages and strollers, because there are no changes to the requirements, test methods, or category of product to which they apply. This addition simply restates the requirements with which a combination unit of a car seat on a stroller must conform. Based on staff's assessment, the Commission concludes that the addition of the references is neutral to the safety of carriages and strollers.

Addition of Parking Brake Mechanism Test Methods

ASTM F833–19 section 6.1.3 specifies that ''[e]ach parking brake shall be constructed so that it cannot be disengaged by the child within the unit when the child is secured in the unit in accordance with the instructional literature.'' ASTM F833–21 replaces this text and adds three alternative test methods in new sections 6.3.1.1, 6.3.1.2, and 6.3.1.3, for evaluating the parking brake release mechanism for each seating position of the product as follows:

- Section 6.3.1.1: Each parking brake mechanism is outside of the access zone, which is defined as: The volume above the seat within a 21.7-inch radius from the mid-point of the junction line on the uncompressed upper surface of the seat unit and extending 21.5 inches to each side (as shown in Figure 7 of ASTM F833–21) and a 2-inch band extending inward from each side of the seat/leg rest edge and downward for 5.9 inches from the uncompressed upper surface of the seat (as shown in Figure 8 of ASTM F833–21). The space located behind the backrest is excluded from the parking brake access zone for single-occupant strollers but is included for multi-occupant product configurations if it enters another parking brake access zone.
- Section 6.3.1.2: The parking brake release mechanism consists of one single-action release mechanism that shall not be released when a force of 10 lbf (45 N) or a torque of 3 lbf-in. (0.34 Nm) is applied directly to the release mechanism in the direction tending to release it.
- Section 6.3.1.3: The parking brake release mechanism is a double-action release mechanism, which is defined in ASTM F833–21 as, ''a release mechanism that requires either two consecutive actions, the first of which must be maintained while the second is carried out, or two separate and independent single-action locking mechanisms that must be activated simultaneously to fully release.''

Staff's review of ASTM F833–19, shows that existing section 6.1.3, which provides that ''[e]ach parking brake shall be constructed so that it cannot be disengaged by the child within the unit'' lacks specificity and fails to provide a test protocol or evaluation method. The assessment of whether a child can disengage the parking brake is currently left up to the testing laboratory's test personnel discretion, which could result in a lack of consistency and repeatability of testing between testing laboratories. Although staff is not aware of any incidents involving the child disengaging the parking brake, the potential for a child to disengage the parking brake is a foreseeable hazard. To address this hazard, ASTM F833–21 adds a test method that includes a defined access zone, a specific force and torque, and an evaluation of the mechanism that is based on similar testing used in other standards.

Staff's assessment of section 6.3.1.1 shows that this test improves the safety of the standard by defining an access zone, and accounting for products with multiple seats that may provide easier access to the parking brake mechanism. Staff's assessment of section 6.3.1.2 shows that this test improves safety by adding a force and torque requirement where there was none previously. Finally, staff's review of the section 6.3.1.3 shows that although the specific reference to a double-action release mechanism was added in this section, the definition for a double-action release mechanism has been in existence since the ASTM F833–13a version of the standard. Staff's assessment shows that the addition of this reference in this section improves safety by specifying the basis for evaluating the parking brake system. Based on staff's assessment, the Commission concludes that the addition of parking braking mechanism test methods improves the safety of carriages and strollers.

*2. Non-Substantive Changes*

ASTM made minor formatting changes to the ASTM F833–21 including: (1) Renumbering figures to account for two new parking brake figures (Figures 7 and 8 of ASTM F833–21), (2) addition of hyphens to compound adjectives, (3) addition of units to the first value in range, and (4) revision of punctuation and spacing. The Commission finds that all the non-substantive changes made in ASTM F833–21 are neutral regarding safety for carriages and strollers because they are editorial in nature.

Based on CPSC's review of ASTM F833–21, the Commission will allow the revised standard to become the mandatory standard for carriages and strollers, without modification. This direct final rule updates 16 CFR part 1227 to incorporate by reference the revised voluntary standard, ASTM F833–21.

**C. Incorporation by Reference**

Section 1227.2 of the direct final rule incorporates by reference ASTM F833–21. The Office of the Federal Register (OFR) has regulations regarding incorporation by reference. 1 CFR part 51. Under these regulations, agencies must discuss, in the preamble to a final rule, ways in which the material the agency incorporates by reference is reasonably available to interested parties, and how interested parties can obtain the material. In addition, the preamble to the final rule must summarize the material. 1 CFR 51.5(b).

In accordance with the OFR regulations, section B. Revisions to ASTM F833, of this preamble summarizes the major provisions of ASTM F833–21 that the Commission incorporates by reference into 16 CFR part 1227. The standard is reasonably available to interested parties. Until the direct final rule takes effect, a read-only copy of ASTM F833–21 is available for viewing on ASTM's website at: *https://www.astm.org/CPSC.htm.* Once the rule takes effect, a read-only copy of the standard will be available for viewing on the ASTM website at: *https://www.astm.org/READINGLIBRARY/.* Interested parties can also schedule an appointment to inspect a copy of the standard at CPSC's Division of the Secretariat, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone: 301–504–7479; email: *cpsc-os@cpsc.gov.* Interested parties can purchase a copy of ASTM F833–21 from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West

Conshohocken, PA 19428–2959 USA; phone; 610–832–9585; *www.astm.org.*

**D. Certification**

Section 14(a) of the Consumer Product Safety Act (CPSA; 15 U.S.C. 2051–2089) requires manufacturers of products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard, or regulation under any other act enforced by the Commission, to certify that the products comply with all applicable CPSC requirements. 15 U.S.C. 2063(a). Such certification must be based on a test of each product, or on a reasonable testing program, or, for children's products, on tests of a sufficient number of samples by a third party conformity assessment body accredited by CPSC to test according to the applicable requirements. As noted, standards issued under section 104(b)(1)(B) of the CPSIA are ''consumer product safety standards.'' Thus, they are subject to the testing and certification requirements of section 14 of the CPSA.

Because carriages and strollers are children's products, a CPSC-accepted third party conformity assessment body must test samples of the products. Products subject to part 1227 also must comply with all other applicable CPSC requirements, such as the lead content requirements in section 101 of the CPSIA,[2] the phthalates prohibitions in section 108 of the CPSIA [3] and 16 CFR part 1307, the tracking label requirements in section 14(a)(5) of the CPSA,[4] and the consumer registration form requirements in section 104(d) of the CPSIA.[5]

**E. Notice of Requirements**

In accordance with section 14(a)(3)(B)(iv) of the CPSIA, the Commission has previously published a notice of requirements (NOR) for accreditation of third party conformity assessment bodies for testing carriages and strollers (79 FR 13208 (March 10, 2014)). The NORs provided the criteria and process for our acceptance of accreditation of third party conformity assessment bodies for testing carriages and strollers to 16 CFR part 1227. The NORs are listed in the Commission's rule, ''Requirements Pertaining to Third Party Conformity Assessment Bodies.'' 16 CFR part 1112.

The revisions to ASTM F833–21 will not require any significant changes in the way that third party conformity assessment bodies test carriages and strollers. Therefore, the Commission considers existing CPSC-accepted testing laboratories that have demonstrated competence for testing in accordance with ASTM F833–19 will have the competence to test in accordance with the revised standard ASTM F833–21 as well. Accordingly, the existing NOR for this standard will remain in place, and CPSC-accepted third party conformity assessment bodies are expected to update the scope of the testing laboratories' accreditations to reflect the revised standard in the normal course of renewing their accreditations.

**F. Direct Final Rule Process**

The Commission is issuing this rule as a direct final rule. Although the Administrative Procedure Act (APA; 5 U.S.C. 551–559) generally requires agencies to provide notice of a rule and an opportunity for interested parties to comment on it, section 553 of the APA provides an exception when the agency, ''for good cause finds,'' that notice and comment are ''impracticable, unnecessary, or contrary to the public interest.'' *Id.* 553(b)(B). The Commission concludes that when it updates a reference to an ASTM standard that the Commission incorporated by reference under section 104(b) of the CPSIA, notice and comment are not necessary.

Under the process set out in section 104(b)(4)(B) of the CPSIA, when ASTM revises a standard that the Commission has previously incorporated by reference under section 104(b)(1)(B) of the CPSIA, that revision will become the new CPSC standard, unless the Commission determines that ASTM's revision does not improve the safety of the product. Thus, unless the Commission makes such a determination, the ASTM revision becomes CPSC's mandatory standard by operation of law. The Commission is allowing ASTM F833–21 to become CPSC's new mandatory standard. The purpose of this direct final rule is to update the reference in the Code of Federal Regulations (CFR) so that it reflects the version of the standard that takes effect by statute. This rule updates the reference in the CFR, but under the update provision of section 104 of the CPSIA, ASTM F833–21 takes effect as the new CPSC standard for carriages and strollers, even if the Commission does not issue this rule. Thus, public comments would not alter substantive changes to the standard or the effect of the revised standard as a consumer product safety standard under section 104(b) of the CPSIA. Under these circumstances, notice and comment are unnecessary.

In Recommendation 95–4, the Administrative Conference of the United States (ACUS) endorsed direct final rulemaking as an appropriate procedure to expedite rules that are noncontroversial and that are not expected to generate significant adverse comments. *See* 60 FR 43108 (Aug. 18, 1995). ACUS recommends that agencies use the direct final rule process when they act under the ''unnecessary'' prong of the good cause exemption in 5 U.S.C. 553(b)(B). Consistent with the ACUS recommendation, the Commission is publishing this rule as a direct final rule, because CPSC does not expect any significant adverse comments.

Unless CPSC receives a significant adverse comment within 30 days of this notification, the rule will become effective on February 15, 2022. In accordance with ACUS's recommendation, the Commission considers a significant adverse comment to be ''one where the commenter explains why the rule would be inappropriate,'' including an assertion challenging ''the rule's underlying premise or approach,'' or a claim that the rule ''would be ineffective or unacceptable without change.'' 60 FR 43108, 43111. As noted, this rule merely updates a reference in the CFR to reflect a change that occurs by statute.

If the Commission receives a significant adverse comment, the Commission will withdraw this direct final rule. Depending on the comment and other circumstances, the Commission may then incorporate the adverse comment into a subsequent direct final rule or publish a notice of proposed rulemaking, providing an opportunity for public comment.

**G. Regulatory Flexibility Act**

The Regulatory Flexibility Act (RFA; 5 U.S.C. 601–612) generally requires agencies to review proposed and final rules for their potential economic impact on small entities, including small businesses, and prepare regulatory flexibility analyses. 5 U.S.C. 603, 604. The RFA applies to any rule that is subject to notice and comment procedures under section 553 of the APA. *Id.* As discussed in section F. Direct Final Rule Process of this preamble, the Commission has determined that notice and the opportunity to comment are unnecessary for this rule. Therefore, the RFA does not apply. CPSC also notes the limited nature of this document, which merely updates the incorporation by reference to reflect the mandatory CPSC standard that takes effect under section 104 of the CPSIA.

[2] 15 U.S.C. 1278a.

[3] 15 U.S.C. 2057c.

[4] 15 U.S.C. 2063(a)(5).

[5] 15 U.S.C. 2056a(d).

**H. Paperwork Reduction Act**

The current mandatory standard for carriages and strollers includes requirements for marking, labeling, and instructional literature that constitute a ''collection of information,'' as defined in the Paperwork Reduction Act (PRA; 44 U.S.C. 3501–3521). While the revised mandatory standard updates the provisions for marking, labeling, and instructional literature regarding consistency and clarity to be consistent with other ASTM voluntary standards, the revised mandatory standard does not alter these requirements substantively. The Commission took the steps required by the PRA for information collections when it adopted 16 CFR part 1227, including obtaining approval and a control number. Because the information collection is unchanged, the revision does not affect the information collection requirements or approval related to the standard.

**I. Environmental Considerations**

The Commission's regulations provide a categorical exclusion for the Commission's rules from any requirement to prepare an environmental assessment or an environmental impact statement where they ''have little or no potential for affecting the human environment.'' 16 CFR 1021.5(c)(2). This rule falls within the categorical exclusion, so no environmental assessment or environmental impact statement is required.

**J. Preemption**

Section 26(a) of the CPSA provides that where a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a requirement dealing with the same risk of injury unless the state requirement is identical to the Federal standard. 15 U.S.C. 2075(a). Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to CPSC for an exemption from this preemption under certain circumstances. Section 104(b) of the CPSIA deems rules issued under that provision ''consumer product safety standards.'' Therefore, once a rule issued under section 104 of the CPSIA takes effect, it will preempt in accordance with section 26(a) of the CPSA.

**K. Effective Date**

Under the procedure set forth in section 104(b)(4)(B) of the CPSIA, when a voluntary standards organization revises a standard that the Commission adopted as a mandatory standard, the revision becomes the CPSC standard within 180 days of notification to the Commission, unless the Commission determines that the revision does not improve the safety of the product, or the Commission sets a later date in the **Federal Register**. 15 U.S.C. 2056a(b)(4)(B). The Commission is taking neither of those actions with respect to the standard for carriages and strollers. Therefore, ASTM F833–21 automatically will take effect as the new mandatory standard for carriages and strollers on February 15, 2022, 180 days after the Commission received notice of the revision on August 19, 2021. As a direct final rule, unless the Commission receives a significant adverse comment within 30 days of this notification, the rule will become effective on February 15, 2022.

**L. Congressional Review Act**

The Congressional Review Act (CRA; 5 U.S.C. 801–808) states that before a rule may take effect, the agency issuing the rule must submit the rule, and certain related information, to each House of Congress and the Comptroller General. 5 U.S.C. 801(a)(1). The CRA submission must indicate whether the rule is a ''major rule.'' The CRA states that the Office of Information and Regulatory Affairs (OIRA) determines whether a rule qualifies as a ''major rule.'' Pursuant to the CRA, this rule does not qualify as a ''major rule,'' as defined in 5 U.S.C. 804(2). To comply with the CRA, CPSC will submit the required information to each House of Congress and the Comptroller General.

**List of Subjects in 16 CFR Part 1227**

Consumer protection, Imports, Incorporation by reference, Infants and children, Law enforcement, Safety, Toys.

For the reasons stated above, the Commission amends title 16 CFR chapter II as follows:

## PART 1227—SAFETY STANDARD FOR CARRIAGES AND STROLLERS

■ 1. The authority citation for part 1227 continues to read as follows:

**Authority:** The Consumer Product Safety Improvement Act of 2008, Pub. L. 110–314, 104, 122 Stat. 3016 (August 14, 2008); Pub. L. 112–28, 125 Stat. 273 (August 12, 2011).

■ 2. Revise § 1227.2 to read as follows:

**§ 1227.2 Requirements for carriages and strollers.**

Each carriage and stroller shall comply with all applicable provisions of ASTM F833–21, Standard Consumer Safety Performance Specification for Carriages and Strollers, approved June 15, 2021. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A read-only copy of the standard is available for viewing on the ASTM website at *https://www.astm.org/READINGLIBRARY/.* You may obtain a copy from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959; phone: (610) 832–9585; *www.astm.org.* You may inspect a copy at the Division of the Secretariat, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone (301) 504–7479, email: *cpsc-os@cpsc.gov,* or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

**Alberta E. Mills,**

*Secretary, U.S. Consumer Product Safety Commission.*

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## COMMODITY FUTURES TRADING COMMISSION

## 17 CFR Part 12

**RIN 3038–AF17**

## Changing Position Title of Judgment Officer to Administrative Judge

**AGENCY:** Commodity Futures Trading Commission.

**ACTION:** Final rule.

**SUMMARY:** The Commodity Futures Trading Commission (Commission or CFTC) is adopting technical amendments to its Rules Relating to Reparations to change the position title of the Judgment Officer to Administrative Judge and to incorporate gender neutral language, where applicable.

**DATES:** Effective November 18, 2021.

**FOR FURTHER INFORMATION CONTACT:** Eugene Smith, Director, Office of Proceedings, Commodity Futures Trading Commission, at (202) 418–5395 or *esmith@cftc.gov,* Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.

**SUPPLEMENTARY INFORMATION:** In February 2013, the Commission amended 17 CFR parts 10 and 12 to clarify the role and authority of its

Judgment Officers.[1] In this rulemaking, the Commission is adopting technical amendments to 17 CFR part 12 that more accurately describe the duties performed by the adjudicator in reparations cases and other administrative proceedings by changing the title of Judgment Officer to Administrative Judge. The technical amendments adopted in this final rule simplify and improve the language of the rules by using plain language for the adjudicator instead of the overly legalistic term ''Judgment Officer,'' and by incorporating gender neutral language into part 12, where applicable; thereby, making the rules easier to understand.

**Related Matters**

*A. Administrative Procedure Act*

The amendments to the Commission's regulations in this rulemaking do not establish any new substantive or legislative rules, but rather are technical amendments to its Rules Relating to Reparations to change the position title of the Judgment Officer to Administrative Judge and to incorporate gender neutral language, where applicable. The amendments to the Commission's regulations relate solely to agency management, organization, procedure, and practice and provide technical corrections of a minor and administrative nature. Therefore, this rulemaking is excepted from the public rulemaking provisions of the Administrative Procedure Act.[2] Additionally, an agency may issue a new rule in some circumstances without publication in the **Federal Register** of a notice of proposed rulemaking with an opportunity for comment if the agency for ''good cause'' finds (and incorporates the finding and a brief statement of the reasons therefor in the rules issued) that notice and public procedure thereon are ''impracticable, unnecessary, or contrary to the public interest.'' [3] As noted earlier, the amendments to part 12 are technical edits to improve the language of the rules and incorporate gender neutral language. Good cause thus exists as the final rule implements changes that affect internal agency management, organization and procedure that exempts it from notice and comment rulemaking. Further, as the revisions to the Commission's regulations in this rulemaking will not cause any party to undertake efforts to comply with the regulations as revised, the Commission has determined to make this rulemaking effective upon publication in the **Federal Register**.[4]

*B. Regulatory Flexibility Act*

The Regulatory Flexibility Act requires the Commission to consider whether the regulations it adopts will have a significant economic impact on a substantial number of small entities.[5] The Commission is obligated to conduct a regulatory flexibility analysis for any rule for which the agency publishes a general notice of proposed rulemaking pursuant to section 553(b) of the Administrative Procedure Act or any other law.[6] This rulemaking is excepted from the public rulemaking provisions of the Administrative Procedure Act. Accordingly, the Commission is not required to conduct a regulatory flexibility analysis for this rulemaking.

*C. Paperwork Reduction Act*

The Commission may not conduct or sponsor, and a respondent is not required to respond to, a collection of information contained in a rulemaking unless the information collection displays a currently valid control number issued by the Office of Management and Budget (OMB) pursuant to the Paperwork Reduction Act of 1995 (Paperwork Reduction Act).[7] This final rule does not contain a collection of information as defined in the Paperwork Reduction Act and, therefore, is not subject to the requirements of the Paperwork Reduction Act.

*D. Cost-Benefit Analysis*

Section 15 of the Commodity Exchange Act, as amended by the Commodity Futures Modernization Act of 2000, provides that before promulgating a regulation under the Act or issuing an order, the Commission shall consider the costs and benefits of the action of the Commission.[8] These rules govern internal agency organization, procedure, and practice, and therefore the Commission finds that none of the considerations enumerated in section 15(a)(2) of the Commodity Exchange Act, as amended, are applicable to these rules.

*E. Congressional Review Act*

This final rule is not a rule as defined in the Congressional Review Act.[9]

**List of Subjects in 17 CFR Part 12**

Administrative practice and procedure, Consumer protection, Organization and functions (Government agencies), Reparations.

For the reasons stated in the preamble, the Commodity Futures Trading Commission amends 17 CFR part 12 as set forth below:

## PART 12—RULES RELATING TO REPARATIONS

■ 1. The authority citation for part 12 continues to read as follows:

**Authority:** 7 U.S.C. 2(a)(12), 12a(5), and 18.

■ 2. Revise § 12.2 to read as follows:

### § 12.2 Definitions.

For purposes of this part:

*Act* means the Commodity Exchange Act, as amended, 7 U.S.C. 1, *et seq.*

*Administrative Judge* means an employee of the Commission who is authorized to conduct all reparations proceedings. In appropriate circumstances, the functions of an Administrative Judge may be performed by an Administrative Law Judge.

*Administrative Law Judge* means an administrative law judge appointed pursuant to the provisions of 5 U.S.C. 3105.

*Commission* means the Commodity Futures Trading Commission.

*Commission decisional employee* means an employee or employees of the Commission who are or may reasonably be expected to be involved in the decisionmaking process in any proceeding, including, but not limited to: An Administrative Judge; members of the personal staffs of the Commissioners, but not the Commissioners themselves; members of the staffs of the Administrative Law Judges, but not an Administrative Law Judge; members of the staffs of the Administrative Judges; members of the Office of the General Counsel; members of the staff of the Office of Proceedings; and other Commission employees who may be assigned to hear or to participate in the decision of a particular matter.

*Complainant* means a person who, individually or jointly with others, has applied to the Commission for a reparation award pursuant to section 14(a) of the Act, but shall not include a cross claimant or any other type of

[1] Proceedings Before the Commodity Futures Trading Commission, 78 FR 12933 (Feb. 26, 2013).

[2] 5 U.S.C. 553(a) and (b)(A). Rulemaking procedures do not apply, to the extent that there is involved a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts or to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice.

[3] 5 U.S.C. 553(b).

[4] Section 553(d) of the APA, 5 U.S.C. 553(d), provides, in part, that a rule may not be made effective less than 30 days before its effective date except as otherwise provided by the agency for good cause found and published with the rule.

[5] *See* 5 U.S.C. 601 *et seq.*

[6] 5 U.S.C. 601(2).

[7] *See* 44 U.S.C. 3501 *et seq.*

[8] 7 U.S.C. 19(a).

[9] *See* 5 U.S.C. 801 through 808.

third-party claimant. The term ''complainant'' under this part applies equally to two or more persons who have applied jointly for a reparation award.

*Complaint* means any document which constitutes an application for a reparation award pursuant to section 14(a) of the Act, regardless of whether it is denominated as such.

*Counterclaim* means an application for a reparation award by a respondent against a complainant which satisfies the requirements of § 12.19. A counterclaim does not mean a cross claim or other type of third party claim.

*Director of the Office of Proceedings* means an employee of the Commission who serves as the administrative head of that Office, with responsibility and authority to assure that the rules in this part are administered in a manner which will effectuate the purposes of section 14(b) of the Act. The Director is authorized to convene meetings of all personnel in the Office of Proceedings, including Administrative Judges, Administrative Law Judges, and the Judges' personally assigned law clerks. The Director shall have the authority to delegate their duties to administer §§ 12.15, 12.24, 12.26, and 12.27, and, shall have the authority to assign and, if necessary, reassign the duties of, and set reasonable standards for performance for, all personnel in the Office, including the Administrative Judges, but not including Administrative Law Judges and their personally assigned law clerks.

*Ex parte communication* means an oral or written communication not on the public record with respect to which reasonable prior notice to all parties is not given, but does not include:

(1) A discussion, after consent has been obtained from all of the named parties, between a party and an Administrative Judge or Administrative Law Judge, or the staffs of the foregoing, pertaining solely to the possibility of settling the case without the need for a decision;

(2) Requests for status reports, including questions relating to service of the complaint, and the registration status of any persons, on any matter or proceeding covered by this part; or

(3) Requests made to the Office of Proceedings or the Office of the General Counsel for interpretation of this part.

*Formal decisional procedure* means, where the amount of total damages claimed exceeds $30,000, exclusive of interest and costs, a procedure elected by the complainant or a respondent where the parties may be granted an oral hearing. A formal decisional proceeding is governed by subpart E of this part.

*Hearing* means that part of a proceeding which involves the submission of proof, either by oral presentation or written submission.

*Interested person* means any party, and includes any person or agency permitted limited participation or to state views in a reparation proceeding, or other person who might be adversely affected or aggrieved by the outcome of a proceeding (including the officers, agents, employees, associates, affiliates, attorneys, accountants or other representatives of such persons), and any other person having a direct or indirect pecuniary or other interest in the outcome of a proceeding.

*Office of the General Counsel* refers to the members of the Commission's staff who provide assistance to the Commission in its direct review of any proceeding conducted pursuant to this part.

*Office of Proceedings* means that Office within the Commission comprised of the Administrative Law Judges, Administrative Judges, the Director of that Office, the Proceedings Clerk, and members of the staffs of the foregoing, which administers the rules in this part, other than the rules in this part authorizing direct review by the Commission.

*Order* means the whole or any part of a final procedural or substantive disposition of a reparation proceeding by the Commission, an Administrative Law Judge, an Administrative Judge, or the Proceedings Clerk.

*Party* means a complainant, respondent or any other person or agency named or admitted as a party in a reparation matter.

*Person* means any individual, association, partnership, corporation or trust.

*Pleading* means the complaint, the answer to the complaint, any supplement or amendment thereto, and any reply to the foregoing.

*Proceeding* means a case in which the pleadings have been forwarded and in which a procedure has been commenced pursuant to § 12.26.

*Proceedings Clerk* means that member of the Commission's staff in the Office of Proceedings who shall maintain the Commission's reparation docket, assign reparation cases to an appropriate decisionmaking official, and act as custodian of the records of proceedings.

*Punitive damages* means damages awarded (no more than two times the amount of actual damages) in the case of any action arising from a willful and intentional violation in the execution of an order on the floor of a contract market. An order does not have to be actually executed to render a violation subject to punitive damages. As a prerequisite to an award of punitive damages, a complainant must claim actual and punitive damages, prove actual damages, and demonstrate that punitive damages are appropriate.

*Registrant* means any person who—

(1) Was registered under the Act at the time of the alleged violation;

(2) Is subject to reparation proceedings by virtue of section 4m of the Commodity Exchange Act, regardless of whether such person was ever registered under the Act; or

(3) Is otherwise subject to reparation proceedings under the Act.

*Reparation award* means the amount of monetary damages a party may be ordered to pay.

*Respondent* means any person or persons against whom a complainant seeks a reparation award pursuant to section 14(a) of the Act.

*Summary decisional procedure* means, where the amount of total damages claimed does not exceed $30,000, exclusive of interest and costs, a procedure elected by the complainant or the respondent wherein an oral hearing need not be held and proof in support of each party's case may be supplied in the form and manner prescribed by § 12.208. A summary decisional proceeding is governed by subpart D of this part.

*Voluntary decisional procedure* means, regardless of the amount of damages claimed, a procedure which the complainant and the respondent have chosen voluntarily to submit their claims and counterclaims, allowable under this part, for an expeditious resolution by an Administrative Judge. By electing the voluntary decisional procedure, parties agree that a decision issued by an Administrative Judge shall be without accompanying findings of fact and shall be final without right of Commission review or judicial review. A voluntary decisional proceeding is governed by subpart C of this part.

■ 3. Amend § 12.5 as follows:

■ a. Revise paragraph (a); and

■ b. Remove the undesignated paragraph following paragraph (a).

The revision reads as follows:

**§ 12.5 Computation of time.**

(a) *In general.* In computing any period of time prescribed by the rules in this part or allowed by the Commission, the Director of the Office of Proceedings, an Administrative Judge, or an Administrative Law Judge, the day of the act, event, or default from which the designated period of time begins to run is not to be included. The last day of the period so computed is to be included unless it is a Saturday, a Sunday, or a

legal holiday, in which event the period runs until the end of the next day which is not a Saturday, a Sunday, or a legal holiday. Intermediate Saturdays, Sundays, and legal holidays shall be excluded from the computation only when the period of time prescribed or allowed is less than seven (7) days.

* * * * *

■ 4. In § 12.6, revise paragraph (a) to read as follows:

**§ 12.6 Extensions of time; adjournments; postponements.**

(a) *In general.* Except as otherwise provided by law or by the rules in this part, for good cause shown, the Commission, or an Administrative Judge, Administrative Law Judge, or the Director of the Office of Proceedings, before whom a matter is then pending, on their own motion or the motion of a party, may at any time extend or shorten the time limit prescribed by the rules in this part for filing any document. In any instance in which a time limit is not prescribed for an action to be taken concerning any matter, the Commission or one of the other officials mentioned above may set a time limit for that action.

* * * * *

■ 5. In § 12.7, republish paragraph (c) heading and revise paragraph (c)(1) to read as follows:

**§ 12.7 Ex parte communications in reparation proceedings.**

* * * * *

(c) *Sanctions.* (1) Upon receipt of an *ex parte* communication knowingly made or knowingly caused to be made by a party in violation of the prohibition contained in paragraph (a)(1) of this section, the Commission, Administrative Law Judge, or an Administrative Judge may, to the extent consistent with the interests of justice and the policy of the Act, require the parties to show cause why their claims or interest in the proceeding should not be dismissed, denied, disregarded, or otherwise adversely affected on account of such violation.

* * * * *

■ 6. Revise § 12.8 to read as follows:

**§ 12.8 Separation of functions.**

(a) An Administrative Judge, or Administrative Law Judge, will not be responsible to or subject to the supervision or direction of any officer, employee, or agent of the Commission engaged in the performance of investigative or prosecutorial functions for the Commission.

(b) No officer, employee, or agent of the Federal Government engaged in the performance of investigative or prosecutorial functions in connection with any proceeding shall, in that proceeding or a factually related proceeding, participate or advise in the decision of an Administrative Judge, or Administrative Law Judge, except as a witness in the proceeding, without the express written consent of the parties to the proceeding. This paragraph (b) shall not apply to the Commissioners.

■ 7. In § 12.9, republish paragraph (a) heading and revise paragraphs (a)(1) and (b) to read as follows:

**§ 12.9 Practice before the Commission.**

(a) *Practice*—(1) *By non-attorneys.* Individuals may appear *pro se* (on their own behalf); a general partner may represent the partnership; a *bona fide* officer of a corporation, trust, or association may represent the corporation, trust, or association.

* * * * *

(b) *Debarment of counsel or representative during the course of a proceeding.* (1) Whenever, while a proceeding is pending before them, an Administrative Judge or an Administrative Law Judge finds that a person acting as counsel or representative for any party to the proceeding is guilty of contemptuous conduct, such official may order that such person be precluded from further acting as counsel or representative in the proceeding. An immediate appeal to the Commission may be taken from any such order, pursuant to the provisions of § 12.309, but the proceeding shall not be delayed or suspended pending disposition of the appeal; *Provided,* that the official may suspend the proceedings for a reasonable time for the purpose of enabling the party to obtain other counsel or representative.

(2) Whenever the Administrative Judge or Administrative Law Judge has issued an order precluding a person from further acting as counsel or representative in a proceeding, such official, within a reasonable time thereafter, shall submit to the Commission a report of the facts and circumstances surrounding the issuance of the order and shall recommend what action the Commission should take respecting the appearance of such person as counsel or representative in other proceedings before the Commission.

* * * * *

■ 8. In § 12.10, revise paragraphs (b) and (c) to read as follows:

**§ 12.10 Service.**

* * * * *

(b) *Service of orders and decisions.* A copy of all notices, rulings, opinions, and orders of the Proceedings Clerk, the Director of the Office of Proceedings, an Administrative Judge, an Administrative Law Judge, the General Counsel or any employee under the General Counsel's supervision as the General Counsel may designate, or the Commission shall be served by the Proceedings Clerk on each of the parties. The Commission, in its discretion and with due consideration for the convenience of the parties, may serve the aforementioned documents to the parties by electronic means.

(c) *Designation of person to receive service.* The first page of the first document filed in a proceeding by a party or participant shall include the contact information of a person authorized to receive service on their behalf. Thereafter, service of documents shall be made upon the person authorized unless service on the party is ordered by an Administrative Judge, an Administrative Law Judge or the Commission, or unless no person authorized to receive service can be found, or unless the person authorized to receive service is changed by the party upon due notice to all other parties.

■ 9. In § 12.11, republish paragraph (d) heading and revise paragraphs (d)(1), (d)(2) introductory text, and (d)(2)(i) and (iii) to read as follows:

**§ 12.11 Formalities of filing of documents with the Proceedings Clerk.**

* * * * *

(d) *Signature*—(1) *Manner.* The original of all papers must be signed in ink by persons filing the same or by their duly authorized agents or attorneys.

(2) *Effect.* The signature on any document of persons acting either for themselves or as attorney or agent for another constitutes certification by them that:

(i) They have read the document and know the contents thereof;

* * * * *

(iii) To the best of their knowledge, information and belief, every statement contained in the document is true and not misleading; and

* * * * *

■ 10. In § 12.12, revise paragraphs (b) introductory text and (b)(1) and (3) to read as follows:

**§ 12.12 Signature.**

* * * * *

(b) *Effect.* The signature on any document of any persons acting either for themselves or as attorney or agent for another constitutes certification by them that:

(1) They have read the document subscribed and know the contents thereof;

* * * * *

(3) To the best of their knowledge, information, and belief, every statement contained in the document is true and not misleading; and

* * * * *

■ 11. In § 12.13, revise paragraph (b)(2) to read as follows:

**§ 12.13 Complaint; election of procedure.**

* * * * *

(b) * * *

(2) *Subscription and verification of the complaint.* Each complaint shall be signed personally by an individual complainant or by a duly authorized officer or agent of a complainant who is not a natural person. Complainant's signature shall be given under oath or affirmation under penalty of law attesting either that complainant knows the facts set forth in the complaint to be true, or believes the facts set forth to be true, in which event the information upon which complainant formed that belief shall be set forth with particularity.

* * * * *

■ 12. Revise § 12.14 to read as follows:

**§ 12.14 Withdrawal of complaint.**

At any time prior to service of notification to the complainant pursuant to § 12.15(a) of the Director of the Office of Proceedings' determination to forward the complaint to a registrant, complainant may file a written notice of withdrawal of the complaint which shall terminate the Commission's consideration of the complaint without prejudice to complainant's right to re-file a reparations complaint based upon the same set of facts within two years after the cause of action accrues. If the complainant has previously filed a notice of withdrawal of a complaint based upon the same set of facts, the notice of withdrawal of complaint shall terminate the case with prejudice to complainant's rights to re-file a complaint in reparations based on the same set of facts, but such termination shall be regarded by the Commission as without prejudice to complainant's right to seek redress in such alternative forums as may be available for adjudication of the claims.

■ 13. In § 12.15, revise paragraph (b) to read as follows:

**§ 12.15 Notification of complaint.**

* * * * *

(b) *Determination not to forward complaint.* The Director may, in their discretion, refuse to forward a complaint as to a particular respondent if it appears that the matters alleged therein are not cognizable in reparations, or that grounds exist pursuant to § 12.24(c) or (d) for refusing to forward the complaint. If the Director of the Office of Proceedings should determine not to forward the complaint to all registrants named in the complaint in accordance with this section, no proceeding shall be held thereon and the complainant shall be notified to that effect. If the Director determines to forward the complaint as to less than all of the registrants, the complainant shall be so notified. A termination of the complaint as to any registrant shall be regarded by the Commission as without prejudice to the right of the complainant to seek such alternative forms of relief as may be available.

■ 14. Revise § 12.17 to read as follows:

**§ 12.17 Satisfaction of complaint.**

A respondent may satisfy the complaint:

(a) By paying to the complainant either the amount to which the complainant claims to be entitled as set forth in the complaint or such other amount as the complainant will accept in satisfaction of the claim; and

(b) By submitting to the Commission notice of satisfaction and withdrawal of the complaint, duly executed by the complainant and the respondent.

■ 15. In § 12.18, revise paragraphs (b), (c), and (d) to read as follows:

**§ 12.18 Answer; election of procedure.**

* * * * *

(b) *Motion for reconsideration of determination to forward the complaint.* An answer may include a motion for reconsideration of the determination to forward the complaint, specifying the grounds therefor, which the Director of the Office of Proceedings, in their discretion, may grant by terminating the case pursuant to § 12.27, or deny by forwarding the pleadings and matters of record for an elected decisional proceeding pursuant to § 12.26. The inclusion in an answer of a motion for reconsideration shall not preclude a respondent, if the motion is denied, from moving for dismissal at a later stage of the proceeding for the same reasons cited in a motion for reconsideration pursuant to this paragraph (b).

(c) *Subscription and verification of the answer.* An answer shall be signed personally by each registrant on behalf of whom it is filed or by a duly authorized officer or agent of any such registrant who is not a natural person. Each registrant's signature shall be given under oath, or by affirmation under penalty of law, attesting that the signer has read the answer; that to the best of the signer's knowledge all of the statements in the answer, the counterclaim (if any), and the materials required by this part to be appended thereto, are accurate and true, and that the answer (and counterclaim, if any) has not been interposed for delay.

(d) *Affidavit of service.* The registrant shall file with the answer an affidavit showing that a true copy of the answer has been served upon the complainant, either personally or by first-class mail addressed to the complainant at the address set forth in the complaint.

* * * * *

■ 16. In § 12.20, revise paragraphs (a) and (c) to read as follows:

**§ 12.20 Response to counterclaim; reply; election of procedure.**

(a) *Response to counterclaim.* If an answer asserts a counterclaim, the complainant shall, within thirty (30) days after service of the answer by the respondent:

(1) Satisfy the counterclaim as if it were a complaint, in the manner prescribed by § 12.17; or

(2) File a reply to the counterclaim with the Commission.

* * * * *

(c) *Election of decisional procedure.* If neither the complainant nor the respondent, in the complaint or answer respectively, has previously made an election of the summary decisional procedure or the formal decisional procedure, the complainant may make such an election in the reply.

■ 17. In § 12.21, revise paragraph (a) to read as follows:

**§ 12.21 Voluntary dismissal.**

(a) At any time after the Director of the Office of Proceedings has served notification to the parties pursuant to § 12.15 of the Director's determination to forward the complaint to the respondent for a response, either the complainant or the respondent may obtain dismissal of the complaint (or the proceeding, if one has commenced) by filing a stipulation of dismissal, duly executed by all of the complainants and each respondent against whom the complaint has been forwarded (or added as a party in the course of a proceeding); *provided however,* that if the stipulation is filed after any respondent has filed an answer, the terms of the stipulation shall include a dismissal of any counterclaims in the answer.

* * * * *

■ 18. In § 12.22, revise paragraph (b) to read as follows:

**§ 12.22 Default proceedings.**

* * * * *

(b) *Default procedure.* Upon a party's failure to respond timely to a complaint or counterclaim as prescribed in §§ 12.16 and 12.20, or timely to comply with § 12.25(b) or (c), the Director of the Office of Proceedings shall forward the pleadings, and other materials then of record, to an Administrative Judge or Administrative Law Judge who may thereafter enter findings and conclusions concerning the questions of violations and damages and, if warranted, enter a reparation award against the non-responding party. If the facts which are treated as admitted are considered insufficient to support a violation or the amount of reparations sought, the Administrative Judge or Administrative Law Judge may order production of supplementary evidence from the party not in default and may enter a default order and an award based thereon.

* * * * *

■ 19. In § 12.23, revise paragraph (b) to read as follows:

**§ 12.23 Setting aside of default.**

* * * * *

(b) *Default order final.* A default order that has become final pursuant to § 12.22(c) shall not be set aside except upon a motion filed and served by the defaulted party showing that the defaulted party should be relieved from the default order because of fraud perpetrated on a decisionmaking official or the Commission, mistake, excusable neglect, or because the order is void for want of jurisdiction. Such a motion shall also show that, if the default order were set aside, there would be a reasonable likelihood of success for the defaulted party's claim or defense on the merits and that no party would be prejudiced thereby. Motions to set aside a final default order for fraud, mistake, or excusable neglect shall be filed within one year after the order was issued. All motions to set aside default orders shall be decided, in the first instance, by the official who issued the order. A denial of a motion to set aside a default order that has become final shall be treated as an initial decision, which may be appealed to the Commission in accordance with the requirements of § 12.401. A grant of a motion to set aside a final default order shall be treated as a nonfinal order which may be appealed only in accordance with the requirements of § 12.309.

■ 20. In § 12.24, revise paragraphs (a)(1)(iii) and (e) to read as follows:

**§ 12.24 Parallel proceedings.**

(a) * * *

(1) * * *

(iii) Is governed by a compulsory counterclaim rule of Federal court procedure which required the complainant in reparations to assert all of complainant's claims (including those based on alleged violations of the Commodity Exchange Act, and any regulation or order issued thereunder) as counterclaims in that proceeding;

* * * * *

(e) *Exceptions.* At the time notice of a parallel proceeding is filed pursuant to paragraph (b) of this section, or any time thereafter, any party, or the receiver or trustee, may file and serve upon other parties a statement in support of or in opposition to any action taken or to be taken pursuant to paragraph (c) or (d) of this section. This statement shall be addressed to the Office of Proceedings, attention of the Proceedings Clerk. Upon receipt of any such statement, the Proceedings Clerk shall immediately forward the statement to the official with responsibility over the case. The notice and the statements filed by the parties shall be reviewed by that official who, on or before the effective date of action taken pursuant to paragraphs (c)(1) and (2) and (d)(1) and (2) of this section, may take such actions as, in the official's opinion, are necessary to ensure that the parties to the matter or proceedings are not unduly prejudiced.

* * * * *

■ 21. In § 12.25, revise paragraphs (b) and (c) to read as follows:

**§ 12.25 Filing fees.**

* * * * *

(b) *Fees payable upon filing an answer.* (1) If a complainant, in the complaint, has elected the voluntary decisional procedure, a respondent who, in the answer, elects the summary decisional procedure (available only where the amount of damages claimed in the complaint or as counterclaims does not exceed $30,000) shall, at the time of filing the answer, pay a filing fee of $75.00.

(2) If a complainant, in the complaint, has elected the voluntary decisional procedure, a respondent who, in the answer, elects the formal decisional procedure (available only where the amount of damages claimed in the complaint or as counterclaims exceeds $30,000) shall, at the time of filing the answer, pay a filing fee of $200.00.

(c) *Fees payable upon filing a reply.* In any case in which a counterclaim has been made, unless a complainant in the complaint, or the respondent in an answer, has elected the summary decisional procedure or the formal decisional procedure a complainant, who in the reply elects either of these procedures, shall, at the time of filing the reply, pay a filing fee of $75.00 or $200.00, respectively, depending whether the procedure elected by complainant is pursuant to subpart D or E of this part.

■ 22. Revise § 12.26 to read as follows:

**§ 12.26 Commencement of a reparation proceeding.**

(a) *Commencement of voluntary decisional proceeding.* Where complainant and respondent in the complaint and answer have elected the voluntary decisional procedure pursuant to subpart C of this part and the complainant has paid the filing fee required by § 12.25, the Director of the Office of Proceedings shall, if in the Director's opinion the facts warrant taking such action, forward the pleadings and all materials of record to the Proceedings Clerk for a proceeding to be conducted in accordance with subpart C of this part. The Proceedings Clerk shall forthwith notify the parties of such action. Such notification shall be accompanied by an order issued by the Proceedings Clerk requiring the parties to complete all discovery, as provided in subpart B of this part, within 50 days thereafter. A voluntary decisional proceeding commences upon service of such notification and order. As soon as practicable after service of such notification, the Proceedings Clerk shall assign the case to an Administrative Judge for a final decision.

(b) *Commencement of summary decisional proceeding.* Where the amount claimed as damages, exclusive of interest and costs, in the complaint or in counterclaim does not exceed $30,000, and either a complainant or a respondent in the complaint, answer, or reply, has elected the summary decisional procedure pursuant to subpart D of this part, and has paid the filing fee required by § 12.25, the Director of the Office of Proceedings shall, if in the Director's opinion the facts warrant taking such action, forward the pleadings and all materials of record to the Proceedings Clerk for a proceeding to be conducted in accordance with subpart D of this part. The Proceedings Clerk shall forthwith notify the parties of such action. Such notification shall be accompanied by an order issued by the Proceedings Clerk requiring the parties to complete all discovery, as provided in subpart B of this part, within 50 days thereafter. A summary decisional proceeding commences upon service of such

notification. As soon as practicable after service of such notification, the Proceedings Clerk shall assign the case to an Administrative Judge for disposition.

(c) *Commencement of formal decisional proceeding.* Where the amount claimed as damages in the complaint or as counterclaims exceeds $30,000, exclusive of interest and costs, and either a complainant or a respondent in the complaint, answer or reply, has elected the formal decisional procedure pursuant to subpart E of this part, and has paid the filing fee required by § 12.25, the Director of the Office of Proceedings shall, if in the Director's opinion the facts warrant taking such action, forward the pleadings and the materials of record to the Proceedings Clerk for a proceeding to be conducted in accordance with subpart E of this part. The Proceedings Clerk shall forthwith notify the parties of such action. Such notification shall be accompanied by an order issued by the Proceedings Clerk requiring the parties to complete all discovery, as provided in subpart B of this part, within 50 days thereafter. A formal decisional proceeding commences upon service of such notification and order. As soon as practicable after service of such notification, the Proceedings Clerk shall assign the case to an Administrative Judge. All provisions of this part that refer to and grant authority to or impose obligations upon an Administrative Law Judge shall be read as referring to and granting authority to and imposing obligations upon the Administrative Judge.

■ 23. In § 12.30, revise paragraph (c) to read as follows:

**§ 12.30 Methods of discovery.**

* * * * *

(c) *Sanctions for abuse of discovery.* If an Administrative Law Judge or an Administrative Judge finds that any party, without substantial justification, has necessitated the filing of a motion for a protective order or for an order compelling discovery, or any other discovery-related motions, that party shall, if the motion is granted, be ordered to pay, at the termination of the proceeding, the reasonable expenses of the moving party incurred in filing the motion, unless the decisionmaking official finds that circumstances exist which would make an award of such expenses unjust. If a decisionmaking official finds that any party, without substantial justification, has filed a motion for a protective order or for an order compelling discovery, or any discovery-related motions, that party shall, if the motion is denied, be ordered to pay, at the termination of the proceeding, the reasonable expenses of an adverse party incurred in opposing the motion, unless the decisionmaker finds that circumstances exist which would make an award of such expenses unjust.

* * * * *

■ 24. In § 12.33, revise paragraphs (b), (c), and (d) to read as follows:

**§ 12.33 Admissions.**

* * * * *

(b) *Reply.* Each matter of which an admission is requested shall be separately set forth. The matter is admitted unless within twenty (20) days after service of the request, the party upon whom the request is directed files and serves upon the party requesting a verified written answer or objection to the matter. If objection is made, the reasons therefor shall be stated. The answer shall specifically deny the matter or set forth in detail the reasons why the answering party cannot truthfully admit or deny the matter. A denial shall fairly meet the substance of the requested admission and when good faith requires that an answering party qualify the answer and deny only a part of the matter of which an admission is requested, the answering party shall specify so much of it as is true and qualify or deny the remainder. Answering parties may not give a lack of information or knowledge as a reason for failure to admit or deny unless they state that they have made reasonable inquiry and that the information known or reasonably available to them is insufficient to enable them to admit or deny. Parties who consider that a matter of which an admission has been requested presents a genuine issue for trial may not, on that ground alone, object to the request; they may deny the matter or set forth reasons why they cannot admit or deny it.

(c) *Determining sufficiency of answers or objections.* The party who has requested the admissions may move to determine the sufficiency of the answers or objections. Unless the objecting party sustains the burden of showing that the objection is justified, the official presiding over discovery shall order that an answer be served. If such official determines that an answer does not comply with the requirements of this section, that official may order either that the matter is admitted or that an amended answer be served.

(d) *Effect of admission.* Any matter admitted under this section is conclusively established and may be used as proof against the party who made the admission. However, the discovery or decisionmaking official may permit withdrawal or amendment when the presentation of the merits of the proceeding will be served thereby and the party who obtains the admission fails to satisfy such official that withdrawal or amendments will prejudice them in maintaining an action or defense on the merits.

■ 25. Revise § 12.34 to read as follows:

**§ 12.34 Discovery by a decisionmaking official.**

(a) *Applicability.* The provisions of this section shall apply to all decisional proceedings commenced pursuant to § 12.26. For the purposes of this section, the term ''decisionmaking official'' shall mean an Administrative Judge or Administrative Law Judge assigned to render a decision in the proceeding.

(b) *Production of documents and tangible things*—(1) *Order for production.* A decisionmaking official may, upon the official's own motion, order a party or non-party to produce copies of specifically designated documents, papers, books, accounts, or tangible things (or categories of any of the foregoing) which are in the possession, custody or control of the party, non-party or agent thereof, against whom the order is directed. Except as provided in paragraph (b)(2) of this section, a party or nonparty ordered to produce documents or any of the items under this paragraph (b)(1) shall file and serve the documents and items listed in the order within twenty (20) days from the date of service of the order, or within such period of time as the decisionmaking official may direct. The decisionmaking official may issue subpoenas to compel the production by parties or non-parties of such documents and tangible things as are described in this section.

(2) *Trade secrets, commercially sensitive or confidential information.* If any party or person against whom an order to produce has been directed acting in good faith has reason to believe that any documents or other tangible thing ordered to be produced contains a trade secret, or commercially sensitive or other confidential information, the party or person may, in lieu of serving any such document, in accordance with paragraph (b)(1) of this section, file and serve a written request for confidential treatment of such documents. Any such request for confidential treatment shall be accompanied by a verified statement identifying with particularity the information on those documents considered to be trade secrets, commercially sensitive or confidential information, with reasons therefor, and

indicating which portions, if any, of those documents may be served on other parties without disclosure of such information. Upon considering a request for confidential treatment in accordance with this paragraph (b)(2), the decisionmaking official may, if upon a finding that the information identified in the request warrants confidential treatment and is not probative of any material fact in controversy, make copies of the documents produced, delete such information from the copies, and serve the copies as modified upon the other parties, with or without an appropriate protective order limiting dissemination to the parties and their counsel, if any.

(3) *Inability to produce.* Any party or person who cannot produce documents or other tangible things called for in an order for production, because those documents or things are not in their possession, custody, or control, shall file and serve within the time provided in paragraph (b)(1) of this section a verified statement identifying the documents which cannot be produced and setting forth with particularity the reasons for non-production.

(c) *Order for written testimony.* The decisionmaking official may, upon the official's own motion, order a party or non-party witness to submit verified statements or written responses to interrogatories, or both, as to all relevant matters within the party's personal knowledge which are required in response to the order. A party or person ordered to file affidavits and/or verified written responses to interrogatories shall file and serve the documents within such period of time as the decisionmaking official may direct. The official may issue subpoenas to compel the filing by parties or non-parties of such verified statements and written responses as are described in this paragraph (c).

■ 26. In § 12.35, revise the introductory text to read as follows:

**§ 12.35 Consequence of a party's failure to comply with a discovery order.**

If a party fails to comply with an order compelling discovery, or an order issued pursuant to § 12.34, the official assigned to render the decision in the case may, upon motion by a party or on the official's own motion, take such action in regard thereto as is just, including but not limited to the following:

* * * * *

■ 27. In § 12.101, revise the section heading and the introductory text to read as follows:

**§ 12.101 Functions and responsibilities of the Administrative Judge.**

The Administrative Judge shall be responsible for the fair and orderly conduct of the proceeding and shall have the authority:

* * * * *

■ 28. Revise § 12.102 to read as follows:

**§ 12.102 Disqualification of Administrative Judge.**

(a) *At their own request.* An Administrative Judge may withdraw from a voluntary decisional proceeding when they consider themselves to be disqualified on the grounds of personal bias, conflict of interest, or similar bases. In such event the Administrative Judge shall immediately notify the Commission and each of the parties of the withdrawal and of the basis for such action.

(b) *Upon the request of a party.* Any party may request an Administrative Judge to disqualify themselves on the grounds of personal bias, conflict of interest, or similar bases. Interlocutory review of an adverse ruling by the Administrative Judge may be sought without certification of the matter by the Administrative Judge only in accordance with the procedures set forth in § 12.309.

■ 29. In § 12.106, revise paragraph (a) to read as follows:

**§ 12.106 Final decision and order.**

(a) *When a final decision is required.* After all submissions of proof have been received, the Administrative Judge shall make the final decision. Upon its issuance, the final decision shall forthwith be filed with the Proceedings Clerk, and immediately served on the parties. The Proceedings Clerk shall also serve a notice, to accompany the final decision, of the effect of a failure by a party ordered to pay a reparation award to file the documents required by § 12.407(c).

* * * * *

■ 30. Revise § 12.200 to read as follows:

**§ 12.200 Scope and applicability of this subpart.**

The rules set forth in this subpart are applicable only to proceedings forwarded pursuant to § 12.26(b). The rules in subpart B of this part permitting discovery are applicable in a summary decisional proceeding. Unless specifically made applicable, the rules prescribed in subparts C and E of this part shall not apply to such proceedings. Parties to a proceeding forwarded pursuant to § 12.26(b) may, by signed agreement filed at any time prior to the issuance of the initial decision, or of any other order disposing of all issues in the proceeding, elect to have all of the issues in the proceeding decided pursuant to the voluntary decisional procedure. Upon receiving a timely filed stipulation signed by all parties evidencing such an election, the Administrative Judge shall conduct the proceeding and render a decision pursuant to subpart C of this part.

■ 31. In § 12.201, revise the section heading, the introductory text, and paragraphs (a) and (d) to read as follows:

**§ 12.201 Functions and responsibilities of the Administrative Judge.**

The Administrative Judge shall be responsible for the fair and orderly conduct of the proceeding and shall have the authority—

(a) In the Administrative Judge's discretion, to conduct pre-decision conferences in accordance with § 12.206;

* * * * *

(d) To take such action as is appropriate under § 12.35, if a party fails to comply with an order issued by the Administrative Judge pursuant to § 12.34;

* * * * *

■ 32. Revise § 12.202 to read as follows:

**§ 12.202 Disqualification of Administrative Judge.**

(a) *At their own request.* An Administrative Judge may withdraw from a summary decisional proceeding when they consider themselves to be disqualified on the grounds of personal bias, conflict of interest, or similar bases. In such event, the Administrative Judge shall immediately notify the Commission and each of the parties of the withdrawal and of the basis for such action.

(b) *Upon the request of a party.* Any party may request an Administrative Judge to disqualify themselves on the grounds of personal bias, conflict of interest, or similar bases. Interlocutory review of an order denying such a request may be sought without certification of the matter by the Administrative Judge only in accordance with the procedures set forth in § 12.309.

■ 33. In § 12.204, revise paragraphs (a) and (b) to read as follows:

**§ 12.204 Amended and supplemental pleadings.**

(a) *Amendments to pleadings.* At any time before the parties have concluded their submission of proof, the Administrative Judge may allow amendments of the pleadings either upon written consent of the parties, or for good cause shown, provided

however, that any pleading as amended shall not contain an allegation of damages in excess of $30,000. Any party may file a response to a motion to amend the pleadings within ten (10) days after the date of service upon that party of the motion.

(b) *Supplemental pleadings.* At any time before the parties have concluded their submissions of proof, and upon such terms as are just, the Administrative Judge may, upon motion by a party, permit a party to serve a supplemental pleading setting forth transactions, occurrences or events which have happened since the date of the pleadings sought to be supplemented and which are relevant to any of the issues in the proceeding: *Provided however,* that any pleading as supplemented may not contain an allegation of damages in excess of $30,000. Any party may file a response to a motion to supplement the pleadings within ten (10) days after the date of service upon that party of the motion.

* * * * *

■ 34. In § 12.205, revise paragraphs (a) and (b), republish the paragraph (c) heading, and revise paragraphs (c)(1) and (2) to read as follows:

**§ 12.205 Motions.**

(a) *In general.* Motions for relief not otherwise specifically provided for in this subpart (§§ 12.200 through 12.210), other than discovery-related motions and motions for extensions of time and similar procedural orders, shall not be allowed. Except as otherwise specifically provided in this subpart, all motions permitted under the provisions of this subpart shall be directed to the Administrative Judge prior to the filing of the initial decision, and to the Commission after the initial decision has been filed. Motions for extensions of time and similar procedural orders may be acted upon at any time, without awaiting a response thereto. Any party adversely affected by such action may request reconsideration, vacation or modification of such action.

(b) *Answer to motions.* Any party may serve and file a written response to a motion within ten (10) days after service of the motion, or within such longer or shorter period as is established by the provisions of this part, or as the Administrative Judge or the Commission may direct.

(c) *Dismissal*—(1) *By the Administrative Judge.* An Administrative Judge, acting upon their own motion, may:

(i) Dismiss the entire proceeding without prejudice to counterclaims, if the Administrative Judge finds that the matters alleged in the complaint fail to state a claim cognizable in reparations; or

(ii) Order dismissal of any claim, counterclaim, or party from the proceeding if the Administrative Judge finds, after review of the record, that such claim or counterclaim (by itself or as applied to any party) is not cognizable in reparations.

(2) *Motion for dismissal by a party.* Any party who believes that grounds exist for dismissal of the entire complaint, or of any claim therein, or of any counterclaim or party from the proceeding, may file a motion for dismissal specifying the claims or parties to be dismissed and the reasons therefor. Upon consideration of the whole record, the Administrative Judge may grant or deny such motion, in whole or in part.

* * * * *

■ 35. Amend § 12.206 as follows:

■ a. Redesignate paragraphs (a) through (g) as paragraphs (a)(1) through (7);

■ b. Designate the introductory text as paragraph (a) introductory text;

■ c. Revise newly designated paragraph (a) introductory text;

■ d. Designate the undesignated paragraph following newly redesignated paragraph (a)(7) as paragraph (b); and

■ e. Revise newly designated paragraph (b).

The revisions read as follows:

**§ 12.206 Pre-decision conferences.**

(a) At any time after a summary decisional proceeding has been commenced pursuant to § 12.26(b), the Administrative Judge may, in their discretion, conduct one or more pre-decision conferences to be held in Washington, DC, or by telephone, with all parties, for the purposes of:

* * * * *

(b) At or following the conclusion of such a conference, the Administrative Judge may serve a pre-decision memorandum and order setting forth the agreements, if any, reached by the parties, any procedural determinations made by the Administrative Judge, and the issues for resolution not disposed of by the admissions or agreements by the parties. Such order, when issued, shall control the subsequent course of the proceeding unless modified to prevent injustice.

■ 36. In § 12.207, revise paragraphs (a), (b), (c), and (d) to read as follows:

**§ 12.207 Summary disposition.**

(a) *Filing of motions, answers.* Any parties who believe that there is no genuine issue of material fact to be determined and that they are entitled to a decision as a matter of law concerning all issues of liability in the proceeding may file a motion for summary disposition at any time until the parties have concluded their submissions of proof. Any adverse party, within ten (10) days after service of the motion, may file and serve opposing papers or may countermove for summary disposition.

(b) *Supporting papers.* A motion for summary disposition shall include a statement of the material facts as to which the moving party contends there is no genuine issue, supported by the pleadings, and by affidavits, other verified statements, admissions, stipulations, and interrogatories. The motion may also be supported by briefs containing points and authorities in support of the contention of the party making the motion. When a motion is made and supported as provided in this section, unless otherwise ordered by the Administrative Judge, adverse parties may not rest upon the mere allegations, but shall serve and file in response a statement setting forth those material facts as to which they contend a genuine issue exists, supported by affidavits and other verified material. They may also submit a brief of points and authorities.

(c) *Summary disposition upon motion of the Administrative Judge.* If the Administrative Judge believes that there may be no genuine issue of material fact to be determined and that one of the parties may be entitled to a decision as a matter of law, the Administrative Judge may direct the parties to submit papers in support of and in opposition to summary disposition, substantially as provided in paragraphs (a) and (b) of this section.

(d) *Ruling on summary disposition.* The Administrative Judge may grant summary disposition if the undisputed pleaded facts, affidavits, other verified statements, admissions, stipulations, and matters of official notice show that:

(1) There is no genuine issue as to any material fact;

(2) There is no necessity that further facts be developed in the record; and

(3) A party is entitled to a decision in that party's favor as a matter of law.

* * * * *

■ 37. In § 12.208, revise paragraph (b) to read as follows:

**§ 12.208 Submissions of proof.**

* * * * *

(b) *Oral testimony and examination.* The Administrative Judge may order an oral hearing for the presentation of testimony and examination of the parties and their witnesses when appropriate and necessary for the

resolution of factual issues, upon motion by either a party or the Administrative Judge. An oral hearing held under this section will be convened by conference telephone call as provided in § 12.209(b), except that an in-person hearing may be held in Washington, DC, under the circumstances set forth in § 12.209(c).

■ 38. Revise § 12.209 to read as follows:

**§ 12.209 Oral testimony.**

(a) *Generally.* When the Administrative Judge determines that an oral hearing is necessary and appropriate, such oral hearing will be held either by telephone or in person in Washington, DC, as set forth in paragraphs (b) through (d) of this section. The Administrative Judge, in their discretion with consideration for the convenience of the parties and their witnesses, will determine the time and date of such hearing. During an oral hearing, in their discretion, the Administrative Judge may regulate appropriately the course and sequence of testimony and examination of the parties and their witnesses and limit the issues.

(b) *Telephonic hearings.* When an Administrative Judge has determined to hold an oral hearing by telephone, an order to that effect will be issued at least 15 days prior to the hearing notifying the parties of the date and time of the hearing. The order will direct the parties to confirm, at least 48 hours in advance of the hearing, that the correct telephone numbers for the parties and their witnesses are on file with the Office of Proceedings, and warn that failure to provide correct telephone numbers may be deemed waiver of that party's right to participate in the hearing, to present evidence, or to cross-examine other witnesses. If a party is unavailable by telephone at the appointed time, any other party in attendance may present testimony, and the Administrative Judge also may impose any appropriate sanction listed in § 12.35. All telephonic hearings will be recorded electronically but will be transcribed only upon direction of the Administrative Judge (if necessary) or in the event of Commission review. The parties may secure a copy of the recording of the hearing from the Proceedings Clerk upon written request and payment of the cost of the recording.

(c) *Washington, DC, hearings.* In exceptional circumstances and when an in-person hearing is determined to be necessary in resolving the issues, the Administrative Judge may order an in-person hearing in Washington, DC, upon written request by a party and the agreement of at least one opposing party. The Administrative Judge will issue notice of the time, date, and location of an in-person hearing to the parties at least 30 days in advance of the hearing. Except as otherwise provided in this section, an in-person hearing will be held and recorded in the manner prescribed in § 12.312(c) through (f). A party not agreeing to appear at the hearing in Washington, DC, may be ordered to participate by telephone. Any party not appearing in person or by telephone will be deemed to have waived the right to participate in the hearing, to present evidence, or to cross-examine other witnesses; further, that party may be subject to such action under § 12.35 as the Administrative Judge may find appropriate. The Administrative Judge may order any party who requests or agrees to appear at a hearing in Washington, DC, and fails to appear without good cause, to pay any reasonable costs unnecessarily incurred by parties appearing at such a hearing.

(d) *Compulsory process.* An application for a subpoena requiring a non-party to participate in a telephonic hearing or to appear at an in-person hearing in Washington, DC, may be made in writing to the Administrative Judge without notice to the other parties. The standards for issuance or denial of an application for a subpoena, the service and travel fee requirements, and the method for enforcing such subpoenas are set forth at § 12.313.

■ 39. In § 12.210, revise paragraphs (a), (b) introductory text, (b)(1), and (c) to read as follows:

**§ 12.210 Initial decision.**

(a) *In general.* Proposed findings of fact and conclusions of law briefs shall not be allowed. As soon as practicable after all submissions of proof have been received, the Administrative Judge shall make the initial decision, which will be filed forthwith with the Proceedings Clerk. Upon filing of an initial decision, the Proceedings Clerk shall immediately serve upon the parties a copy of the initial decision and a notification of the effect of a party's failure timely to appeal the initial decision to the Commission, as provided in paragraphs (d) and (e) of this section, as well as the effect of a failure by a party who has been ordered to pay a reparation award timely to file the documents required by § 12.407(c).

(b) *Content of initial decision.* In the initial decision in a summary decisional proceeding, the Administrative Judge shall:

(1) Include a brief statement of the findings as to the facts, with reference to those portions of the record which support those findings;

* * * * *

(c) *Costs; prejudgment interest.* The Administrative Judge may, in the initial decision, award costs (including the costs of instituting the proceeding, and if appropriate, reasonable attorneys' fees) and, if warranted as a matter of law under the circumstances of the particular case, prejudgment interest to the party in whose favor a judgment is entered.

* * * * *

■ 40. Amend § 12.303 as follows:

■ a. Redesignate paragraphs (a) through (g) as paragraphs (a)(1) through (7);

■ b. Designate the introductory text as paragraph (a) introductory text;

■ c. Revise newly designated paragraph (a) introductory text;

■ d. Designate the undesignated paragraph following newly redesignated paragraph (a)(7) as paragraph (b); and

■ e. Revise newly designated paragraph (b).

The revisions read as follows:

**§ 12.303 Pre-decision conferences.**

(a) During the time period permitted for discovery pursuant to § 12.30(d), and thereafter, Administrative Law Judges may, in their discretion, conduct one or more pre-decision conferences to be held in Washington, DC, or by telephone, with all parties for the purposes of:

* * * * *

(b) At or following the conclusion of a pre-decision conference, Administrative Law Judges may serve a pre-decision memorandum and order setting forth the agreements reached by the parties, any procedural determinations made by them, and the issues for resolution not disposed of by admissions or agreements by the parties. Such an order shall control the subsequent course of the proceeding unless modified to prevent injustice.

■ 41. In § 12.304, revise the introductory text and paragraph (e) to read as follows:

**§ 12.304 Functions and responsibilities of the Administrative Law Judge.**

Once an Administrative Law Judge has been assigned the case, the Administrative Law Judge shall be responsible for the fair and orderly conduct of a formal decisional proceeding and shall have the authority:

* * * * *

(e) In the Administrative Law Judge's discretion, to conduct pre-decision conferences, for the purposes prescribed in § 12.303, at any time after a

proceeding has commenced pursuant to § 12.26(c);

* * * * *

■ 42. Revise § 12.305 to read as follows:

**§ 12.305 Disqualification of Administrative Law Judge.**

(a) *At their own request.* An Administrative Law Judge may withdraw from a formal decisional proceeding when they consider themselves to be disqualified on the grounds of personal bias, conflict of interest, or similar bases. In such event, they shall immediately notify the Commission and each of the parties of the withdrawal and of the basis for such action.

(b) *Upon the request of a party.* Any party may request an Administrative Law Judge to disqualify themselves on the grounds of personal bias, conflict of interest, or similar bases. Interlocutory review of an order denying such a request may be sought without certification of the matter by an Administrative Law Judge, only in accordance with the procedures set forth in § 12.309.

■ 43. In § 12.307, revise paragraphs (a) and (b) to read as follows:

**§ 12.307 Amended and supplemental pleadings.**

(a) *Amendments to pleadings.* At any time before the parties have concluded their submissions of proof, the Administrative Law Judge may allow amendments of the pleadings either upon written consent of the parties or for good cause shown. Any party may file a response to a motion to amend the pleadings within ten (10) days after the date of service upon that party of the motion.

(b) *Supplemental pleadings.* At any time before the parties have concluded their submissions of proof, and upon such terms as are just, an Administrative Law Judge may, upon motion by a party, permit a party to serve a supplemental pleading setting forth transactions, occurrences or events which have happened since the date of the pleadings sought to be supplemented and which are relevant to the issues in the proceeding. Any party may file a response to a motion to supplement the pleadings within ten (10) days after the date of service upon that party of the motion.

* * * * *

■ 44. In § 12.308, revise paragraph (b), republish paragraph (c) heading, and revise paragraph (c)(1) to read as follows:

**§ 12.308 Motions.**

* * * * *

(b) *Answer to motions.* Any party may serve and file a written response to a motion within ten (10) days after service of the motion upon that party, or within such longer or shorter period as established by this part, or as the Administrative Law Judge or the Commission may direct.

(c) *Dismissal*—(1) *By the Administrative Law Judge.* The Administrative Law Judge, acting on their own motion, may, at any time after they have been assigned the case:

(i) Dismiss the entire proceeding, without prejudice to counterclaims, if they find that none of the matters alleged in the complaint state a claim that is cognizable in reparations; or

(ii) Order dismissal of any claim, counterclaim, or party from the proceeding if they find that such claim or counterclaim (by itself, or as applied to a party) is not cognizable in reparations.

* * * * *

■ 45. In § 12.309, revise paragraphs (a)(1), (d), and (e) to read as follows:

**§ 12.309 Interlocutory review by the Commission.**

* * * * *

(a) * * *

(1) The appeal is from a ruling pursuant to § 12.102, § 12.202, or § 12.305 refusing to grant a motion to disqualify an Administrative Judge or Administrative Law Judge;

* * * * *

(d) *Proceedings not stayed.* The filing of an application for interlocutory review and a grant of review shall not stay proceedings before an Administrative Law Judge (or an Administrative Judge, if applicable) unless that official or the Commission shall so order. The Commission will not consider a motion for a stay unless the motion shall have first been made to the Administrative Law Judge (or, if applicable, the Administrative Judge) and denied.

(e) *Interlocutory review by the Commission on its own motion.* Nothing in this section should be construed as restricting the Commission from acting on its own motion to review on an interlocutory basis any ruling of an Administrative Law Judge, Proceedings Officer or an Administrative Judge in any proceeding commenced pursuant to § 12.26.

■ 46. In § 12.310, revise paragraphs (a), (b), and (d) to read as follows:

**§ 12.310 Summary disposition.**

(a) *Filing of motions, answers.* Any parties who believe that there is no genuine issue of material fact to be determined and that they are entitled to a decision as a matter of law concerning all issues of liability in the proceeding may file a motion for summary disposition at any time before a determination is made by the Administrative Law Judge to order an oral hearing in the proceeding. Any adverse party, within ten (10) days after service of the motion, may file and serve opposing papers or may countermove for summary disposition.

(b) *Supporting papers.* A motion for summary disposition shall include a statement of all material facts as to which the moving party contends that there is no genuine issue, supported by the pleadings, and by affidavits, other verified statements, admissions, stipulations, and interrogatories. The motion may also be supported by briefs containing points and authorities in support of the contention of the party making the motion. When a motion is made and supported as provided in this section, unless otherwise ordered by the Administrative Law Judge, an adverse party may not rest upon the mere allegations, but shall serve and file in response a statement setting forth those material facts as to which the adverse party contends a genuine issue exists, supported by affidavits and other verified material. The adverse party may also submit a brief of points and authorities.

* * * * *

(d) *Summary disposition upon motion of the Administrative Law Judge.* If the Administrative Law Judge believes that there may be no genuine issue of material fact to be determined and that one of the parties may be entitled to a decision as a matter of law, the Administrative Law Judge may direct the parties to submit papers in support of and in opposition to summary disposition, and may hear oral argument, substantially as provided in paragraphs (a), (b), and (c) of this section.

* * * * *

■ 47. Revise § 12.311 to read as follows:

**§ 12.311 Disposing of proceeding or issues without oral hearing.**

If the Administrative Law Judge determines that the documentary proof and other tangible forms of proof submitted by the parties are sufficient to permit resolution of some or all of the factual issues in the proceeding without the need for oral testimony, the Administrative Law Judge may order that all proof relating to such issues be submitted in documentary and tangible form, and dispose of such issues without an oral hearing. In such an

event, proof in support of the complaint, answer, and reply, may be found in those verified documents, in depositions on written interrogatories, in admissible documents obtained through discovery, in other verified statements of fact, documents, and tangible evidence.

■ 48. In § 12.312, revise paragraphs (b) introductory text, (b)(2), (d)(1), (2), and (4), and (g) to read as follows:

**§ 12.312 Oral hearing.**

* * * * *

(b) *Location of hearing.* Unless the Director of the Office of Proceedings for reasons of administrative economy or practical necessity determines otherwise, and except as provided in this paragraph (b), the location of an oral hearing shall be in one of the following cities: Albuquerque, N.M.; Atlanta, Ga.; Boston, Mass.; Chicago, Ill.; Cincinnati, Ohio; Columbia, S.C.; Denver, Colo.; Houston, Tex.; Kansas City, Mo.; Los Angeles, Cal.; Minneapolis, Minn.; New Orleans, La.; New York, N.Y.; Oklahoma City, Okla.; Phoenix, Ariz.; San Diego, Cal.; San Francisco, Cal.; Seattle, Wash.; St. Petersburg, Fla.; and Washington, DC. The Administrative Law Judge may, in any case where a party avers, in an affidavit, that none of the foregoing cities is located within 300 miles of the party's principal residence, waive this paragraph (b) and, upon giving due regard for the convenience of all of the parties, order that the hearing be held in a more convenient locale.

* * * * *

(2) *Effect of failure to appear.* If any party to the proceeding fails to appear at the hearing, or at any part thereof, the non-appearing party shall to that extent be deemed to have waived the opportunity for an oral hearing in the proceeding. The Administrative Law Judge, for just cause, may take such action as is appropriate pursuant to § 12.35 against a party who fails to appear at the hearing. In the event that a party appears at the hearing and no party appears for the opposing side, the party who is present may present evidence, in whole or in part, in the form of affidavits or by oral testimony, before the Administrative Law Judge.

* * * * *

(d) * * *

(1) *Conduct direct and cross-examination of parties and witnesses.* All witnesses at a hearing for the purpose of taking evidence shall testify under oath or affirmation, which shall be administered by the Administrative Law Judge. Unless otherwise ordered by the Administrative Law Judge, parties shall be entitled to present oral direct testimony and other documentary proof, and to conduct direct examination and cross examine adverse parties and witnesses. To expedite the hearing, the Administrative Law Judge may, in their discretion, order that the direct testimony of the parties and their witnesses be presented in documentary form, by affidavit, interrogatory, and other documents. In any event, the Administrative Law Judge, in their discretion, may permit cross examination, without regard to the scope of direct testimony, as to any matter which is relevant to the issues in the proceeding;

(2) *Introduce exhibits.* The original of each exhibit introduced in evidence or marked for identification shall be filed unless the Administrative Law Judge permits the substitution of copies for the original documents. A copy of each exhibit introduced by a party or marked for identification shall be supplied by the introducing party to the Administrative Law Judge and to each other party to the proceeding. Exhibits shall be maintained by the reporter who shall serve as custodian of the exhibits until they are transmitted to the Proceedings Clerk pursuant to paragraph (f) of this section;

* * * * *

(4) *Make offers of proof.* When an objection to a question propounded to a witness is sustained, examiners may make a specific offer of what they expect to prove by the answer of the witness. Rejected exhibits, adequately marked for identification, shall be retained in the record so as to be available for consideration by any reviewing authority.

* * * * *

(g) *Proposed findings of fact and conclusions of law; briefs.* An Administrative Law Judge, upon their own motion or upon motion of a party, may permit the filing of post-hearing proposed findings of fact and conclusions of law. Absent an order permitting such findings and conclusions, none shall be allowed. Unless otherwise ordered by the Administrative Law Judge and for good cause shown, the proposed findings and conclusions (including briefs in support thereof), shall not exceed twenty-five (25) pages and shall be filed not later than forty-five (45) days after the close of the oral hearing.

■ 49. In § 12.313, revise paragraphs (a)(2) and (b)(3), republish paragraph (c) heading, and revise paragraphs (c)(1) and (2) and (c)(3)(ii) to read as follows:

**§ 12.313 Subpoenas for attendance at an oral hearing.**

(a) * * *

(2) *Standards for issuance or denial of subpoenas.* The Administrative Law Judge considering any application for a subpoena shall issue the subpoena if they are satisfied the application complies with this section and the request is not unreasonable, oppressive, excessive in scope or unduly burdensome. In the event they determine that a requested subpoena or any of its terms is unreasonable, oppressive, excessive in scope, or unduly burdensome, the Administrative Law Judge may refuse to issue the subpoena, or may issue it only upon such conditions as they determine fairness requires.

(b) * * *

(3) *Rulings.* The motion shall be decided by the Administrative Law Judge and the order shall provide such terms and conditions for the production of the material, the disclosure of the information, or the appearance of the witnesses as may appear necessary and appropriate for the protection of the public interest.

(c) *Service of subpoenas*—(1) *How effected.* Service of a subpoena upon a party shall be made in accordance with § 12.10. Service of a subpoena upon any other person shall be made by delivering a copy of the subpoena to them as provided in paragraph (c)(2) or (3) of this section, and by tendering to them the fees for one day's attendance and the mileage as specified in paragraph (e) of this section. When the subpoena is issued at the instance of any officer or agency of the United States, fees and mileage need not be tendered at the time of service.

(2) *Service upon a natural person.* Delivery of a copy of a subpoena and tender of fees and mileage to a natural person may be effected by:

(i) Handing them to the person;

(ii) Leaving them at the person's office with the person in charge thereof or, if there is no one in charge, by leaving the subpoena in a conspicuous place therein;

(iii) Leaving them at the person's dwelling place or usual place of abode with some person of suitable age and discretion then residing therein;

(iv) Mailing them by registered or certified mail to them at their last known address; or

(v) Any other method whereby actual notice is given to the person and the fees and mileage are timely made available.

(3) * * *

(ii) Mailing them by registered or certified mail to any such representative at the person's last known address; or

* * * * *

■ 50. In § 12.314, revise paragraphs (a) and (b)(1) to read as follows:

**§ 12.314 Initial decision.**

(a) *In general.* The Administrative Law Judge as soon as practicable after the parties have completed their submissions of proof, or after the conclusion of an oral hearing if one is held, shall render the initial decision, which shall forthwith be filed with the Proceedings Clerk, and a copy of which shall be served immediately by the Proceedings Clerk upon each of the parties. The Proceedings Clerk shall also serve a notice, to accompany the initial decision, of the effect of a party's failure timely to appeal to the Commission the initial decision, as provided in paragraphs (d) and (e) of this section, and the effect of a failure of a party who has been ordered to pay a reparation award timely to file the documents required by § 12.407(c).

(b) * * *

(1) Include a brief statement of findings as to the facts, with references to those portions of the record which support those findings;

* * * * *

■ 51. Revise § 12.402 to read as follows:

**§ 12.402 Appeal of disposition of less than all claims or parties in a proceeding.**

(a) *In general.* Where two or more different claims for relief are presented, or where multiple parties are involved, in a proceeding forwarded pursuant to § 12.26(b) or (c), the Administrative Judge or Administrative Law Judge, may upon the Judge's own motion or by motion of a party, direct that an initial decision or other order disposing of one or more, but fewer than all of the claims or parties, shall be final and immediately appealable to the Commission. Such a direction may be made only upon an express determination that there is no just reason for delay. When such a direction is made, a party may appeal the initial decision or order in accordance with the procedure prescribed by § 12.401.

(b) *When decision is not appealable.* In the absence of such a direction by the Administrative Judge or an Administrative Law Judge, an initial decision or order disposing of fewer than all of the claims or all of the parties shall be subject to revision by the decisionmaker at any time before a disposition is made of all remaining claims or parties, and no appeal may be taken to the Commission pursuant to this section.

■ 52. Revise § 12.405 to read as follows:

**§ 12.405 Leave to adduce additional evidence.**

Any time prior to issuance of its final decision pursuant to § 12.406, the Commission may, after notice to the parties and an opportunity for them to present their views, reopen the hearing to receive further evidence. The application shall show to the satisfaction of the Commission that the additional evidence is material, and that there were reasonable grounds for failure to adduce such evidence at the hearing. The Commission may receive the additional evidence or may remand the proceeding to the Administrative Judge or Administrative Law Judge to receive the additional evidence.

■ 53. In § 12.407, revise paragraphs (c) introductory text and (d) to read as follows:

**§ 12.407 Satisfaction of reparation award; enforcement; sanctions.**

* * * * *

(c) *Automatic suspension.* A person required to pay a reparation award shall be prohibited from trading on all contract markets and if such person is registered, the registration shall be suspended automatically, without further notice, unless such person shall, within fifteen (15) days after the time limit for satisfaction of an award (as prescribed in paragraph (a) or (b) of this section) expires, file with the Proceedings Clerk and serve on the other parties:

* * * * *

(d) *Reinstatement.* The sanctions imposed in accordance with paragraph (c) of this section shall remain in effect until the person required to pay the reparation award demonstrates to the satisfaction of the Commission that the amount required has been paid in full including prejudgment interest if awarded and post-judgment interest at the prevailing rate computed in accordance with 28 U.S.C. 1961 from the date directed in the final order to the date of payment, compounded annually. In the event an award of post-judgment interest is inadvertently omitted, such interest nevertheless shall run as calculated in accordance with 28 U.S.C. 1961 and the rules in this part.

* * * * *

■ 54. In § 12.408, revise the introductory text and paragraphs (a)(2) introductory text, (a)(2)(ii) and (iii), (a)(3), (4), and (6), and (b) to read as follows:

**§ 12.408 Delegation of authority to the General Counsel.**

Pursuant to the authority granted under section 2(a)(4) and 2(a)(11) of the Commodity Exchange Act, as amended, 7 U.S.C. 4a(c) and 4a(j), the Commission hereby delegates, until such time as it orders otherwise, the following functions to the General Counsel, to be performed by them, or such person or persons under their direction as they may designate from time to time:

(a) * * *

(2) Remand, with or without specific instructions, initial decisions or other orders disposing of the entire proceeding to the appropriate officer (Director of the Office of Proceedings, Administrative Judge, or Administrative Law Judge) in the following situations—

* * * * *

(ii) Where, in their judgment, clarification or supplementation of an initial decision or other order disposing of the entire proceeding prior to Commission review is appropriate; and

(iii) Where, in their judgment, a ministerial act necessary to the proper conduct of the proceeding has not been performed;

(3) Deny applications for interlocutory review by the Commission of a ruling of an Administrative Judge or Administrative Law Judge in cases in which the Administrative Judge or Administrative Law Judge has not certified the ruling to the Commission in the manner prescribed by § 12.309, and the ruling does not concern the disqualification of, or a motion to disqualify, an Administrative Judge or Administrative Law Judge, or the suspension of, or failure to suspend, an attorney from participating in reparation proceedings;

(4) Dismiss any appeal from an initial decision or other disposition of the entire proceeding by an Administrative Law Judge (or Administrative Judge), in a proceeding where such appeal is not filed or perfected in accordance with § 12.401, and deny any application for interlocutory review if it is not filed in accordance with § 12.309;

* * * * *

(6) Enter any order that, in their judgment, will facilitate or expedite Commission review of an initial decision or other order disposing of the entire proceeding.

(b) Notwithstanding the provisions of paragraph (a) of this section, in any case in which the General Counsel believes it appropriate, the General Counsel or their designee may submit the matter to the Commission for its consideration.

* * * * *

Issued in Washington, DC, on November 3, 2021, by the Commission.

**Christopher Kirkpatrick,**

*Secretary of the Commission.*

**Note:** The following appendix will not appear in the Code of Federal Regulations.

## Appendix to Changing Position Title of Judgment Officer to Administrative Judge—Commission Voting Summary

On this matter, Acting Chairman Behnam and Commissioners Stump and Berkovitz voted in the affirmative.* No Commissioner voted in the negative.

[FR Doc. 2021–24449 Filed 11–17–21; 8:45 am]

**BILLING CODE 6351–01–P**

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## DEPARTMENT OF JUSTICE

## Drug Enforcement Administration

## 21 CFR Part 1310

**[Docket No. DEA–678]**

## Designation of Methyl alpha-phenylacetoacetate, a Precursor Chemical Used in the Illicit Manufacture of Phenylacetone, Methamphetamine, and Amphetamine, as a List I Chemical

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Final rulemaking.

**SUMMARY:** The Drug Enforcement Administration is finalizing, without change, a March 30, 2021, notice of proposed rulemaking to designate the chemical methyl *alpha*-phenylacetoacetate (also known as MAPA; methyl 3-oxo-2-phenylbutanoate; methyl 2-phenylacetoacetate; α-acetyl-benzeneacetic acid, methyl ester; and CAS Number: 16648–44–5) and its optical isomers as a list I chemical under the Controlled Substances Act (CSA). Methyl *alpha*-phenylacetoacetate is used in clandestine laboratories to illicitly manufacture the schedule II controlled substances phenylacetone (also known as phenyl-2-propanone, P2P, or benzyl methyl ketone), methamphetamine, and amphetamine and is important to the manufacture of these controlled substances. This final rulemaking subjects handlers (manufacturers, distributors, importers, and exporters) of MAPA to the chemical regulatory provisions of the CSA and its implementing regulations.

**DATES:** Effective December 20, 2021.

**FOR FURTHER INFORMATION CONTACT:** Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

**SUPPLEMENTARY INFORMATION:** This final rule designates methyl *alpha*-phenylacetoacetate (MAPA; methyl 3-oxo-2-phenylbutanoate) and its optical isomers as a list I chemical. This action subjects handlers of MAPA to the chemical regulatory provisions of the Controlled Substances Act (CSA) and its implementing regulations. This rulemaking does not establish a threshold for domestic and international transactions of MAPA. As such, all MAPA transactions are regulated, regardless of transaction size, and are subject to control under the CSA. In addition, chemical mixtures containing MAPA are not exempt from regulatory requirements at any concentration. Therefore, all transactions of chemical mixtures containing any quantity of MAPA are regulated pursuant to the CSA.

### Legal Authority

The CSA and the Drug Enforcement Administration's (DEA) implementing regulations give the Attorney General, as delegated to the Administrator of DEA (Administrator), the authority to specify, by regulation, a chemical as a ''list I chemical.'' [1] This term refers to a chemical that is used in manufacturing a controlled substance in violation of subchapter I (Control and Enforcement) of the CSA and is important to the manufacture of the controlled substance.[2] The current list of all list I chemicals is available in 21 CFR 1310.02(a).

In addition, the United States is a Party to the 1988 United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988 Convention), December 20, 1988, 1582 U.N.T.S. 95. Under Article 12 of the 1988 Convention, when the United States receives notification that a chemical has been added to Table I or Table II of the 1988 Convention, the United States is required to take measures it deems appropriate to monitor the manufacture and distribution of that chemical within the United States and to prevent its diversion, including measures related to international trade.

### Background

In a letter dated May 7, 2020, the Secretary-General of the United Nations, in accordance with Article 12, paragraph 6 of the 1988 Convention, informed the United States Secretary of State that the Commission on Narcotic Drugs (CND) voted to place the chemical methyl *alpha*-phenylacetoacetate (MAPA), including its optical isomers, in Table I of the 1988 Convention (CND Decision 63/1) at its 63rd Session on March 4, 2020.

On March 30, 2021, DEA published a notice of proposed rulemaking (NPRM) [86 FR 16558] to designate methyl *alpha*-phenylacetoacetate (MAPA; methyl 3-oxo-2-phenylbutanoate) and its optical isomers as a list I chemical under the CSA. In the NPRM, the Acting Administrator found that MAPA is used in, and is important to, the manufacture of the schedule II substances phenylacetone (also known as phenyl-2-propanone, P2P, or benzyl methyl ketone), methamphetamine, and amphetamine. Clandestine laboratory operators have circumvented the schedule II controls on P2P by developing a variety of synthetic methods for producing P2P, which they then convert to methamphetamine and amphetamine.

MAPA is a close chemical relative of precursors controlled under the CSA and the 1988 Convention (*e.g., alpha*-phenylacetoacetonitrile (APAAN) and *alpha*-phenylacetoacetamide (APAA)) and the timing of its emergence suggests it is trafficked to circumvent these precursor controls, particularly the more recent control on APAA.[3] DEA has not identified any known legitimate use for MAPA, other than in small amounts for research, development, and laboratory analytical purposes. The International Narcotics Control Board (INCB) notes that MAPA does not have any legitimate use,[4] and despite this, the INCB highlighted an increase in the frequency of seizures and amounts seized reported through Precursors Incident Communication System (PICS) since November 2018.[5] This trend continued

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* Commissioner Berkovitz submitted his written vote on this matter prior to departing the Commission on October 15, 2021.

[1] 21 U.S.C. 802(34) and 871(b) and 21 CFR 1310.02(c).

[2] 21 U.S.C. 802(34) and 21 CFR 1300.02(b).

[3] The CND added APAAN and APAA to Table I of the 1988 Convention in March 2014 and March 2019, respectively. DEA designated APAAN and APAA as list I chemicals on July 14, 2017 (effective date: August 14, 2017) [82 FR 32457], and May 10, 2021 (effective date: June 9, 2021) [86 FR 24703], respectively, with a correction notice for APAA on June 7, 2021 [86 FR 30169].

[4] Statement by Mr. Cornelis de Joncheere, President, International Narcotics Control Board, Reconvened sixty-second session of the Commission on Narcotic Drugs, 13 December 2019, at 1.

[5] The Precursors Incident Communication System or PICS is a worldwide, real-time, on-line tool for communication and information sharing between

into 2020, with 37 incidents involving MAPA reported through PICS in the first 10 months of the year, totaling almost 21.5 metric tons.[6]

As noted in the NPRM, by DEA's designating MAPA as a list I chemical, the United States will fulfill its obligations under Article 12 of the 1988 Convention. The NPRM requested public comments on the proposed designation; however, DEA did not receive any comments.

**Designation of MAPA and Its Optical Isomers as a List I Chemical**

For the reasons discussed in the NPRM and reiterated in the above background section, the Administrator finds that MAPA is used in the manufacture of controlled substances in violation of the CSA and is important to the manufacture of these controlled substances. Therefore, the Administrator designates MAPA and its optical isomers as a list I chemical.

**Chemical Mixtures of MAPA**

Pursuant to this final rulemaking, chemical mixtures containing MAPA are subject to regulatory requirements at any concentration unless a manufacturer submits to DEA an application for exemption of a chemical mixture, DEA accepts the application for filing, and DEA exempts the chemical mixture in accordance with 21 CFR 1310.13 (Exemption of chemical mixtures by application). Since even a small amount of MAPA can potentially yield a significant amount of controlled substances, DEA believes that regulation of chemical mixtures containing any amount of MAPA is necessary to prevent its illicit extraction, isolation, and use. This rule modifies the ''Table of Concentration Limits'' in 21 CFR 1310.12(c) to reflect the fact that a chemical mixture containing any amount of MAPA is subject to CSA chemical control provisions, including 21 CFR parts 1309, 1310, 1313, and 1316.

**Application Process for Exemption of Chemical Mixtures**

DEA has implemented an application process to exempt certain chemical mixtures from the requirements of the CSA and its implementing regulations.[7] Manufacturers may submit an application for exemption for those mixtures that do not meet the criteria set forth in 21 CFR 1310.12(d) for an automatic exemption. Pursuant to 21 CFR 1310.13(a), DEA may grant an exemption of a chemical mixture, by publishing a final rule in the **Federal Register**, if DEA determines that: (1) The mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance, and (2) the listed chemical or chemicals cannot be readily recovered.

**Requirements for Handling List I Chemicals**

The designation of MAPA as a list I chemical subjects handlers (manufacturers, distributors, importers, and exporters) and proposed handlers to all of the regulatory controls and administrative, civil, and criminal actions applicable to the manufacture, distribution, importation, and exportation of a list I chemical. Upon the effective date of this final rulemaking, persons potentially handling MAPA, including regulated chemical mixtures containing MAPA, are required to comply with the following list I chemical regulations:

1. *Registration.* Any person who handles (manufactures, distributes, imports, or exports), or proposes to engage in such handling of, MAPA or a chemical mixture containing MAPA must obtain a registration pursuant to 21 U.S.C. 822, 823, 957, and 958. Regulations describing registration for list I chemical handlers are set forth in 21 CFR part 1309. DEA regulations require separate registrations for manufacturing, distributing, importing, and exporting of MAPA.[8] Further, a separate registration is required for each principal place of business at one general physical location where list I chemicals are manufactured, distributed, imported, or exported by a person.[9]

DEA notes that under the CSA, ''warehousemen'' are not required to register and may lawfully possess list I chemicals, if the possession of those chemicals is in the usual course of business or employment.[10] Under DEA implementing regulations, the warehouse in question must receive the list I chemical from a DEA registrant and shall only distribute the list I chemical back to the DEA registrant and registered location from which it was received.[11] A warehouse that distributes list I chemicals to persons other than the registrant and registered location from which they were obtained is conducting distribution activities and is required to register as such.

Upon the effective date of this final rulemaking, any person manufacturing, distributing, importing, or exporting MAPA or a chemical mixture containing MAPA will become subject to the registration requirement under the CSA. DEA recognizes, however, that it is not possible for persons who are subject to the registration requirements to immediately complete and submit an application for registration and for DEA to immediately issue registrations for those activities. Therefore, to allow any continued legitimate commerce in MAPA, DEA is establishing in 21 CFR 1310.09 a temporary exemption from the registration requirement for persons desiring to engage in activities with MAPA, provided that DEA receives a properly completed application for registration or application for exemption of chemical mixtures on or before December 20, 2021. The temporary exemption for such persons will remain in effect until DEA takes final action on their application for registration or application for exemption of a chemical mixture.

The temporary exemption applies solely to the registration requirement; all other chemical control requirements, including recordkeeping and reporting, will become effective on the effective date of the final rule. Therefore, all transactions of MAPA and chemical mixtures containing MAPA will be regulated while an application for registration or exemption is pending. This is necessary because failing to regulate these transactions could result in increased diversion of a chemical desirable to drug traffickers.

Additionally, the temporary exemption for registration does not suspend applicable Federal criminal laws relating to MAPA, nor does it supersede State or local laws or regulations. All handlers of MAPA must comply with applicable State and local requirements in addition to the CSA regulatory controls.

2. *Records and Reports.* Every DEA registrant must maintain records and submit reports to DEA with respect to MAPA pursuant to 21 U.S.C. 830(a) and (b)(1) and (2) and in accordance with 21 CFR 1310.04 and 1310.05. Pursuant to 21 CFR 1310.04, a record must be made and maintained for two years after the date of a transaction involving a listed chemical, provided the transaction is a regulated transaction.

Each regulated bulk manufacturer of a listed chemical must submit to DEA

national authorities on precursor incidents to include seizures, stopped shipments, diversion and diversion attempts, illicit laboratories and associated equipment.

[6] INCB Report on Precursors for 2020, 25 March 2021, at 17.

[7] 21 CFR 1310.13 specifies that this chemical mixture is a chemical mixture consisting of two or more chemical components, at least one of which is a list I or list II chemical.

[8] 21 CFR 1309.21.

[9] 21 CFR 1309.23(a). See also 21 U.S.C. 822(e)(1) with separate registration requirements pertaining to manufacturing or distributing a list I chemical.

[10] 21 U.S.C. 822(c)(2) and 21 U.S.C. 957(b)(1)(B).

[11] See 21 CFR 1309.23(b)(1).

manufacturing, inventory, and use data on an annual basis.[12] Existing standard industry reports containing the required information would be acceptable, provided the information is separate or readily retrievable from the report.

The CSA and its implementing regulations require that each regulated person must report to DEA any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of subchapter I of the CSA. In addition, regulated persons must report any proposed regulated transaction with a person whose description or other identifying characteristics DEA has previously furnished to the regulated person, any unusual or excessive loss or disappearance of a listed chemical under the control of the regulated person, and any in-transit loss in which the regulated person is the supplier.[13]

3. *Importation and Exportation.* All importation and exportation of MAPA must be done in compliance with 21 U.S.C. 957, 958, and 971 and in accordance with 21 CFR part 1313.

4. *Security.* All applicants and registrants must provide effective controls against theft and diversion in accordance with 21 CFR 1309.71–1309.73.

5. *Administrative Inspection.* Places, including factories, warehouses, or other establishments and conveyances, where registrants or other regulated persons may lawfully hold, manufacture, distribute, or otherwise dispose of a list I chemical or where records relating to those activities are maintained, are controlled premises as defined in 21 U.S.C. 880(a) and 21 CFR 1316.02(c). The CSA allows for administrative inspections of these controlled premises as provided in 21 CFR part 1316, subpart A.[14]

6. *Liability.* Any activity involving MAPA not authorized by, or in violation of, the CSA is unlawful, and may subject the person to administrative, civil, and/or criminal action.

## Finalization of Proposed Rule

DEA did not receive any comments on the NPRM proposing to designate the chemical methyl *alpha*-phenylacetoacetate (also known as MAPA; methyl 3-oxo-2-phenylbutanoate; methyl 2-phenylacetoacetate; α-acetyl-benzeneacetic acid, methyl ester; and CAS Number: 16648–44–5) and its optical isomers as a list I chemical under the CSA. For the reasons discussed in this rulemaking, DEA is finalizing the NPRM without any change.

## Regulatory Analyses

### *Executive Orders 12866 and 13563, Regulatory Planning and Review and Improving Regulation and Regulatory Review*

This rule was developed in accordance with the principles of Executive Orders (E.O.) 12866 and 13563. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866.

Section 3(f) of E.O. 12866 classifies a ''significant regulatory action,'' requiring review by the Office of Management and Budget (OMB), as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the E.O. As set forth below in the ''Costs'' discussion, this final rule will not have the economic effects described in E.O. 12866, section 3(f)(1). Since this rule merely designates MAPA and its optical isomers as a list I chemical, DEA believes that this rule does not create or cause the other effects described in section 3(f)(2)-(4). OMB has determined that this rule is not a ''significant regulatory action'' under E.O. 12866, section 3(f).

As finalized, MAPA is subject to all of the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, importing, and exporting of list I chemicals.

MAPA is a close chemical relative of precursors controlled under the 1988 Convention (*e.g.,* APAAN and APAA), as discussed in the above background section. MAPA is a precursor of methamphetamine and amphetamine, and it is highly suitable for the illicit manufacture of P2P, a precursor listed in Table I of the 1988 Convention. As noted earlier, incidents of illicit manufacture and trafficking of MAPA have been reported to the INCB with an increase in the frequency of seizures and amounts seized since November 2018.

DEA has searched information in the public domain for any legitimate uses of MAPA. Other than the small amounts for research, development, and laboratory analytical purposes, DEA has not documented any industrial use for MAPA except for it being a chemical intermediate in the production of the schedule II substances P2P, methamphetamine, and amphetamine. Legal conversion of MAPA to P2P in the United States, if it takes place at all, is limited to small, gram quantities. Therefore, DEA concludes the vast majority of, if not all, MAPA is used for the manufacturing of illicit P2P, methamphetamine, and amphetamine.

DEA cannot rule out the possibility that minimal quantities of MAPA are used for the manufacturing of legitimate P2P. However, DEA did not receive any public comments to that effect in response to the NPRM.

DEA evaluated the costs and benefits of this action.

### *Costs*

As stated above, the only use for MAPA of which DEA is aware is as a chemical intermediate for the manufacture of P2P, methamphetamine, and amphetamine. Any manufacturer, distributor, importer, or exporter of MAPA for the production of legitimate P2P, methamphetamine, and amphetamine, if they exist at all, will incur costs if they are not already registered for handling list I chemicals. The primary costs associated with this rule are the annual registration fees for manufacturers ($3,699) and for distributors, importers, and exporters ($1,850). Moreover, any manufacturer that uses MAPA for legitimate P2P, methamphetamine, and amphetamine production would already be registered with DEA and have all security and other handling processes established because of the controls already in place on P2P, methamphetamine, and amphetamine, resulting in minimal cost to those entities.

[12] 21 CFR 1310.05(d). See also 21 U.S.C. 830((b)(2).

[13] 21 U.S.C. 830(b) and 21 CFR 1310.05(a) and (b).

[14] 21 U.S.C. 880.

DEA has identified five domestic suppliers of MAPA, only one of which is registered with DEA to handle list I chemicals. The amount of MAPA distributed by these suppliers is unknown. It is common for chemical distributors to have items on their catalog while not actually having any material level of sales. Based on the discussion above, DEA believes any quantity of sales from these distributors for legitimate pharmaceutical purposes is minimal. As finalized, suppliers for the legitimate use of MAPA are expected to choose the least-cost option, which in many cases may lead them to stop selling the minimal quantities, if any, of MAPA, rather than incur the registration cost. Therefore, DEA estimates that the cost of foregone sales is minimal; and thus, the cost of this rule is minimal.

This analysis excludes consideration of any economic impact to those businesses that facilitate the manufacturing and distribution of MAPA for the illicit production of P2P, methamphetamine, and amphetamine.

*Benefits*

Controlling MAPA is expected to prevent, curtail, and limit the unlawful manufacture and distribution of the controlled substances P2P, methamphetamine, and amphetamine. This action is also expected to assist in preventing the possible theft or diversion of MAPA from any legitimate firms. DEA also believes control is necessary to prevent unscrupulous chemists from synthesizing MAPA and selling it (as an unregulated material) through the internet and other channels, to individuals who may wish to acquire an unregulated chemical intermediate for the purpose of manufacturing illicit P2P, methamphetamine, and amphetamine.

In summary, DEA conducted a qualitative analysis of costs and benefits. DEA believes this action will minimize the diversion of MAPA. DEA believes the legitimate market for MAPA for the legitimate manufacturing of P2P, methamphetamine, and amphetamine is minimal. Thus, any potential cost resulting from this regulation is minimal.

*Executive Order 12988, Civil Justice Reform*

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

*Executive Order 13132, Federalism*

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

*Executive Order 13175, Consultation and Coordination With Indian Tribal Governments*

This rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

*Regulatory Flexibility Act (RFA)*

The Administrator, in accordance with the RFA,[15] has reviewed this rule, and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities.

As discussed above, MAPA will now become subject to all of the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, importation, and exportation of list I chemicals. MAPA is used in, and is important to, the illicit manufacture of the schedule II-controlled substances P2P, methamphetamine, and amphetamine. DEA has not identified any legitimate industrial use for MAPA, other than its role as a chemical intermediate in the production of P2P, methamphetamine, and amphetamine. Legal conversion of MAPA to P2P in the United States, if it takes place at all, is limited to small, gram quantities. Therefore, DEA believes the vast majority, if not all, of MAPA is used for the illicit manufacturing of P2P, methamphetamine, and amphetamine. The primary costs associated with this rule are the annual registration fees ($3,699 for manufacturers and $1,850 for distributors, importers, and exporters), but only if they are not already registered to handle any list I chemicals.

DEA has identified five domestic suppliers of MAPA, only one of which is registered with DEA to handle list I chemicals. Based on Small Business Administration (SBA) size standards for chemical distributors and Statistics of U.S. Business data, each of the five suppliers are small entities because their revenues are below SBA's $150 million threshold. The quantity of MAPA distributed by these suppliers is unknown. It is common for chemical distributors to have items on their catalog while not actually having any material level of sales. Legal conversion of MAPA to P2P in the United States is limited to small, gram quantities. DEA believes any quantity of sales of MAPA from these distributors for legitimate P2P manufacturing is minimal. DEA did not receive any comments to the contrary in response to the NPRM. DEA estimates that this rule will not have a significant economic impact on a substantial number of small entities.

*Unfunded Mandates Reform Act of 1995 (UMRA)*

In accordance with the UMRA, 2 U.S.C. 1501 *et seq.,* DEA has determined and certifies that this rule will not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year * * *.'' Therefore, neither a Small Government Agency Plan nor any other action is required under the UMRA.

*Paperwork Reduction Act*

The action does not impose a new collection of information requirement under the Paperwork Reduction Act, 44 U.S.C. 3501–3521. This action will not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. 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.

*Congressional Review Act*

This final rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this final rule to both Houses of Congress and to the Comptroller General.

**List of Subjects 21 CFR Part 1310**

Administrative practice and procedure, Drug traffic control, Exports, Imports, Reporting and recordkeeping requirements.

Accordingly, for the reasons set forth in the preamble, DEA amends 21 CFR part 1310 as follows:

[15] 5 U.S.C. 601–612.

## PART 1310—RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES; IMPORTATION AND EXPORTATION OF CERTAIN MACHINES

■ 1. The authority citation for 21 CFR part 1310 continues to read as follows:

**Authority:** 21 U.S.C. 802, 827(h), 830, 871(b), 890.

■ 2. In § 1310.02, add paragraph (a)(37) to read as follows:

**§ 1310.02 Substances covered.**

* * * * *

(a) * * *

(37) methyl *alpha*-phenylacetoacetate (MAPA; methyl 3-oxo-2-phenylbutanoate) and its optical isomers 8795

* * * * *

■ 3. In § 1310.04:

■ a. Redesignate paragraphs (g)(1)(x) through (xvi) as paragraphs (g)(1)(xi) through (xvii), respectively; and

■ b. Add new paragraph (g)(1)(x).

The addition reads as follows:

**§ 1310.04 Maintenance of records.**

* * * * *

(g) * * *

(1) * * *

(x) methyl *alpha*-phenylacetoacetate (MAPA; methyl 3-oxo-2-phenylbutanoate) and its optical isomers

* * * * *

■ 4. In § 1310.09, add paragraph (r) to read as follows:

**§ 1310.09 Temporary exemption from registration.**

* * * * *

(r)(1) Each person required under 21 U.S.C. 822 and 957 to obtain a registration to manufacture, distribute, import, or export regulated forms of methyl *alpha*-phenylacetoacetate (MAPA; methyl 3-oxo-2-phenylbutanoate) and its optical isomers, including regulated chemical mixtures pursuant to § 1310.12, is temporarily exempted from the registration requirement, provided that DEA receives a properly completed application for registration or application for exemption for a chemical mixture containing regulated forms of MAPA pursuant to § 1310.13 on or before December 20, 2021. The exemption would remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in the Act and parts 1309, 1310, 1313, and 1316 of this chapter remain in full force and effect.

(2) Any person who manufactures, distributes, imports, or exports a chemical mixture containing regulated forms of methyl *alpha*-phenylacetoacetate (MAPA; methyl 3-oxo-2-phenylbutanoate) and its optical isomers whose application for exemption is subsequently denied by DEA must obtain a registration with DEA. A temporary exemption from the registration requirement would also be provided for those persons whose application for exemption is denied, provided that DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that the application for exemption has been denied. The temporary exemption for such persons would remain in effect until DEA takes final action on their registration application.

■ 5. In § 1310.12, in the Table of Concentration Limits under List I Chemicals in paragraph (c), add an entry for ''methyl *alpha*-phenylacetoacetate (MAPA; methyl 3-oxo-2-phenylbutanoate)'' in alphabetical order to read as follows:

**§ 1310.12 Exempt chemical mixtures.**

* * * * *

(c) * * *

TABLE OF CONCENTRATION LIMITS

| | DEA chemical code No. | Concentration | Special conditions |
|---|---|---|---|
| **List I Chemicals** | | | |
| * * * | * | * * | * * |
| methyl *alpha*-phenylacetoacetate (MAPA; methyl 3-oxo-2-phenylbutanoate) and its optical isomers. | 8795 | Not exempt at any concentration. | Chemical mixtures containing any amount of MAPA and its optical isomers are not exempt. |
| * * * | * | * * | * * |

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**Anne Milgram,**

*Administrator.*

[FR Doc. 2021–24952 Filed 11–17–21; 8:45 am]

**BILLING CODE 4410–09–P**

## DEPARTMENT OF LABOR

### Occupational Safety and Health Administration

### 29 CFR Parts 1910, 1915, 1917, 1918, 1926, and 1928

**[Docket No. OSHA–2021–007]**

### COVID–19 Vaccination and Testing; Emergency Temporary Standard; Ratification of Department's Actions

**AGENCY:** Occupational Safety and Health Administration, Department of Labor (DOL).

**ACTION:** Ratification.

**SUMMARY:** The Department of Labor is publishing notification of the Secretary of Labor's ratification of a rule.

**DATES:** The ratification was signed on November 12, 2021.

**FOR FURTHER INFORMATION CONTACT:**

*General information and press inquiries:* Contact Frank Meilinger, OSHA Office of Communications, U.S. Department of Labor; telephone (202) 693–1999; email: *OSHAComms@dol.gov.*

*For technical inquiries:* Contact Andrew Levinson, OSHA Directorate of Standards and Guidance, U.S. Department of Labor; telephone (202) 693–1950; email: *ETS@dol.gov.*

**SUPPLEMENTARY INFORMATION:** On November 12, 2021, the Secretary of Labor ratified an interim final rule codifying an emergency temporary standard to protect unvaccinated employees of large employers from the risk of contracting COVID–19. *See* Interim Final Rule, COVID–19 Vaccination and Testing; Emergency Temporary Standard, 86 FR 61402 (November 5, 2021) (the ''Interim Final Rule''). The Department is now publishing the ratification in the **Federal Register** out of an abundance of caution. Neither the ratification nor the publication is a statement that the ratified action would be invalid absent the ratification, whether published or otherwise.

## Appendix

### Ratification

By virtue of the authority vested in the Secretary of Labor by law, including 33 U.S.C. 941 and 29 U.S.C. 653, 655, 657, I am affirming and ratifying a prior action by Acting Assistant Secretary James S. Frederick. On November 5, 2021, the Occupational Safety and Health Administration published in the **Federal Register** an interim final rule codifying an emergency temporary standard to protect unvaccinated employees of large employers from the risk of contracting COVID–19. *See* Interim Final Rule, COVID–19 Vaccination and Testing; Emergency Temporary Standard, 86 FR 61402 (November 5, 2021) (the ''Interim Final Rule'').

The Interim Final Rule was signed by James S. Frederick, Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health, who was serving as Acting Assistant Secretary of Labor for Occupational Safety and Health before the current Assistant Secretary of Labor for Occupational Safety and Health assumed office. Questions have been raised in litigation, however, concerning Mr. Frederick's authority to sign the interim final rule.

Out of an abundance of caution, to avoid any doubt as to its validity, I have independently evaluated the Interim Final Rule and the basis for adopting it. I now affirm and ratify the Interim Final Rule, without deference to Mr. Frederick's prior decision. In my considered and independent judgment, the Interim Final Rule was and remains necessary to protect unvaccinated employees against the grave danger of exposure to the virus that causes COVID–19.

I have full and complete knowledge of the Interim Final Rule action taken by former Acting Assistant Secretary Frederick. I have also determined that the assessment of grave danger in the Interim Final Rule and the Rule's assessment of how best to respond to that danger remain valid based on my assessment of the situation at the time of this ratification. Pursuant to my authority as the Secretary of Labor, and based on my independent review of the action and the reasons for taking it, I hereby affirm and ratify the Interim Final Rule, as of October 26, 2021.

**Martin J. Walsh,**

*Secretary of Labor.*

[FR Doc. 2021–25167 Filed 11–15–21; 4:15 pm]

BILLING CODE 4510–HL–P

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## DEPARTMENT OF DEFENSE

### Office of the Secretary

### 32 CFR Part 310

**[Docket ID: DoD–2021–OS–0088]**

**RIN 0790–AL42**

## Protection of Privacy and Access to and Amendment of Individual Records Under the Privacy Act of 1974; Technical Amendment

**AGENCY:** Department of Defense (DoD).

**ACTION:** Final rule.

**SUMMARY:** DoD is making a technical amendment to reinstate an appendix to its Privacy Program regulation that was erroneously deleted when the regulation was previously revised. The appendix contained a list of blanket routine uses that are included by reference in many DoD Privacy Act systems of records notices (SORNs).

**DATES:** This rule is effective November 18, 2021.

**FOR FURTHER INFORMATION CONTACT:** Ms. Lyn Kirby, *OSD.DPCLTD@mail.mil;* (703) 571–0070.

**SUPPLEMENTARY INFORMATION:** This final rule amends 32 CFR part 310, ''Protection of Privacy and Access to and Amendment of Individual Records under the Privacy Act of 1974,'' to reinstate DoD's blanket routine uses. The appendix which enumerated DoD's blanket routine uses was erroneously removed when 32 CFR part 310 was revised on April 11, 2019 (84 FR 14728–14811).

A ''routine use'' is defined in the Privacy Act as ''with respect to the disclosure of a record, the use of such record for a purpose which is compatible with the purpose for which it was collected.'' *See* 5 U.S.C. 552a(a)(7). Routine uses are included in individual agency SORNs to allow the agency to disclose records from a particular system of records to individuals or entities in accordance with the terms of the routine use. Some agencies have established a set of routine uses that apply to a wide array of published agency SORNs, sometimes referred to as blanket routine uses. Their purpose is to provide consistent information sharing authority across the SORNs for common or non-controversial purposes. Examples of routine uses that are typically included in blanket routine uses are ones that allow agencies to share information with members of Congress inquiring on behalf of a constituent, with the Department of Justice when litigation arises, and with agency contractors for purposes outlined in the contract.

DoD had previously published a list of 14 blanket routine uses in an appendix to a prior publication of the DoD Privacy Program regulation on April 13, 2007 (72 FR 18758). In the 2019 update, all appendices to the prior regulation were removed; however, the appendix containing the DoD blanket routine uses (appendix C) should have remained because numerous DoD SORNs refer to and incorporate the blanket routine uses to support necessary information sharing. This technical amendment seeks to remedy this error by restoring the blanket routine uses as appendix A to part 310. This will provide clear public notice of the existence and ongoing use of the blanket routine uses at DoD. A list of DoD's blanket routine uses has also continued to be available on the DoD Privacy Program website since the DoD Privacy Program regulation was published in 2019.

## Regulatory Analysis

*Executive Order 12866, ''Regulatory Planning and Review'' and Executive Order 13563, ''Improving Regulation and Regulatory Review''*

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, distribute 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. It has been determined that this rule is not a significant regulatory action.

*Congressional Review Act*

This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

*Section 202, Public Law 104–4, ''Unfunded Mandates Reform Act''*

It has been determined that this rule does not involve a Federal mandate that may result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of

$100 million or more and that it will not significantly or uniquely affect small governments.

*Public Law 96–354, ''Regulatory Flexibility Act'' (5 U.S.C. Chapter 6)*

The Director of Administration and Management certified that this rule does not have a significant economic impact on a substantial number of small entities because it is concerned only with the administration of Privacy Act systems of records within the DoD.

*Public Law 96–511, ''Paperwork Reduction Act'' (44 U.S.C. Chapter 35)*

It has been determined that this rule does not impose information collection or record keeping requirements on the public under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

*Executive Order 13132, ''Federalism''*

It has been determined that this rule does not have federalism implications. This rule does 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.

*Executive Order 13175, ''Consultation and Coordination With Indian Tribal Governments''*

It has been determined that this rule does not have a substantial effect on Indian tribal governments. This rule does not impose substantial direct compliance costs on one or more Indian tribes, preempt tribal law, or effect the distribution of power and responsibilities between the Federal Government and Indian tribes.

**List of Subjects in 32 CFR Part 310**

Privacy.

Accordingly, 32 CFR part 310 is amended as follows:

## PART 310—PROTECTION OF PRIVACY AND ACCESS TO AND AMENDMENT OF INDIVIDUAL RECORDS UNDER THE PRIVACY ACT OF 1974

■ 1. The authority citation for 32 CFR part 310 continues to read as follows:

**Authority:** 5 U.S.C. 552a.

■ 2. Appendix A is added to read as follows:

### Appendix A to Part 310—DOD Blanket Routine Uses

**A. Routine Use—Law Enforcement**

If a system of records maintained by a DoD Component to carry out its functions indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or by regulation, rule, or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the agency concerned, whether Federal, State, local, or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, rule, regulation, or order issued pursuant thereto.

**B. Routine Use—Disclosure When Requesting Information**

A record from a system of records maintained by a Component may be disclosed as a routine use to a Federal, State, or local agency maintaining civil, criminal, or other relevant enforcement information or other pertinent information, such as current licenses, if necessary to obtain information relevant to a Component decision concerning the hiring or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant, or other benefit.

**C. Routine Use—Disclosure of Requested Information**

A record from a system of records maintained by a Component may be disclosed to a Federal agency, in response to its request, in connection with the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

**D. Routine Use—Congressional Inquiries**

Disclosure from a system of records maintained by a Component may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

**E. Routine Use—Private Relief Legislation**

Relevant information contained in all systems of records of the Department of Defense published on or before August 22, 1975, may be disclosed to the Office of Management and Budget (OMB) in connection with the review of private relief legislation as set forth in OMB Circular A–19 at any stage of the legislative coordination and clearance process as set forth in that circular.

**F. Routine Use—Disclosures Required by International Agreements**

A record from a system of records maintained by a Component may be disclosed to foreign law enforcement, security, investigatory, or administrative authorities to comply with requirements imposed by, or to claim rights conferred in, international agreements and arrangements, including those regulating the stationing and status in foreign countries of Department of Defense military and civilian personnel.

**G. Routine Use—Disclosure to State and Local Taxing Authorities**

Any information normally contained in Internal Revenue Service (IRS) Form W–2 which is maintained in a record from a system of records maintained by a Component may be disclosed to State and local taxing authorities with which the Secretary of the Treasury has entered into agreements under 5 U.S.C., sections 5516, 5517, 5520, and only to those State and local taxing authorities for which an employee or military member is or was subject to tax regardless of whether tax is or was withheld. This routine use is in accordance with Treasury Fiscal Requirements Manual Bulletin No. 76–07.

**H. Routine Use—Disclosure to the Office of Personnel Management**

A record from a system of records subject to the Privacy Act and maintained by a Component may be disclosed to the Office of Personnel Management (OPM) concerning information on pay and leave, benefits, retirement reductions, and any other information necessary for the OPM to carry out its legally authorized government-wide personnel management functions and studies.

**I. Routine Use—Disclosure to the Department of Justice for Litigation**

A record from a system of records maintained by a Component may be disclosed as a routine use to any component of the Department of Justice for the purpose of representing the Department of Defense, or any officer, employee or member of the Department in pending or potential litigation to which the record is pertinent.

**J. Routine Use—Disclosure to Military Banking Facilities**

Information as to current military addresses and assignments may be provided to military banking facilities who provide banking services overseas and who are reimbursed by the Government for certain checking and loan losses. For personnel separated, discharged, or retired from the Armed Forces, information as to last known residential or home of record address may be provided to the military banking facility upon certification by a banking facility officer that the facility has a returned or dishonored check negotiated by the individual or the individual has defaulted on a loan and that if restitution is not made by the individual, the U.S. Government will be liable for the losses the facility may incur.

**K. Routine Use—Disclosure of Information to the General Services Administration**

A record from a system of records maintained by a Component may be disclosed as a routine use to the General Services Administration (GSA) for the purpose of records management inspections conducted under authority of 44 U.S.C. 2904 and 2906.

**L. Routine Use—Disclosure of Information to the National Archives and Records Administration**

A record from a system of records maintained by a Component may be

disclosed as a routine use to the National Archives and Records Administration (NARA) for the purpose of records management inspections conducted under authority of 44 U.S.C. 2904 and 2906.

**M. Routine Use—Disclosure to the Merit Systems Protection Board**

A record from a system of records maintained by a Component may be disclosed as a routine use to the Merit Systems Protection Board, including the Office of the Special Counsel, for the purpose of litigation, including administrative proceedings, appeals, special studies of the civil service and other merit systems, review of OPM or Component rules and regulations, investigation of alleged or possible prohibited personnel practices, including administrative proceedings involving any individual subject of a DoD investigation, and such other functions, promulgated in 5 U.S.C. 1205 and 1206 or as may be authorized by law.

**N. Routine Use—Counterintelligence Purposes**

A record from a system of records maintained by a Component may be disclosed as a routine use outside the DoD or the U.S. Government for the purpose of counterintelligence activities authorized by U.S. law or Executive order or for the purpose of enforcing laws that protect the national security of the United States.

Dated: November 12, 2021.

**Aaron T. Siegel,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

[FR Doc. 2021–25067 Filed 11–17–21; 8:45 am]

BILLING CODE 5001–06–P

## DEPARTMENT OF HOMELAND SECURITY

## Coast Guard

## 33 CFR Part 100

**[Docket No. USCG–2021–0205]**

## Special Local Regulation: Seminole Hard Rock Winterfest Holiday Boat Parade

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of enforcement of regulation.

**SUMMARY:** The Coast Guard will enforce a special local regulation on December 11, 2021, from 2:30 p.m. through 11:30 p.m. to provide for the safety and security of certain navigable waterways during the Seminole Hard Rock Winterfest Holiday Boat Parade. All non-participant persons and vessels will be prohibited from entering, transiting, anchoring, or remaining within the regulated area during the enforcement period unless authorized by the Captain of the Port Miami or a designated representative. The operator of any vessel in the regulated area must comply with instructions from the Coast Guard or designated representative.

**DATES:** The regulation in 33 CFR 100.702, Table 1 to § 100.702, Line 11, will be enforced on December 11, 2021, from 2:30 p.m. through 11:30 p.m.

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this notice of enforcement, call or email Mr. Omar Beceiro, Sector Miami Waterways Management Division, U.S. Coast Guard: Telephone: 305–535–4317, Email: *Omar.Beceiro@uscg.mil.*

**SUPPLEMENTARY INFORMATION:** The Coast Guard will enforce a special local regulation for the Seminole Hard Rock Winterfest Holiday Boat Parade published in 33 CFR 100.702, Table 1 to § 100.702, Line 11 on December 11, 2021, from 2:30 p.m. through 11:30 p.m. This action is being taken to provide for the safety and security of certain navigable waters of the Intracoastal Waterway during this one-day event. Our regulation for marine events within the Seventh Coast Guard District, § 100.702, specifies the location of the special local regulation for the Seminole Hard Rock Winterfest Holiday Boat Parade, which includes a moving buffer zone of 50 yards around the parade as it travels along the New River and Intracoastal Waterway in Ft. Lauderdale, FL. Only event sponsor designated participants and official patrol vessels may enter the regulated area. Spectator vessels may contact the Coast Guard Patrol Commander to request permission to pass through the regulated area. If granted permission, vessels must pass directly through the regulated area at a safe speed without loitering.

In addition to this notice of enforcement in the **Federal Register.** the Coast Guard will inform the public through Local Notice to Mariners and marine information broadcasts at least 24 hours in advance of the enforcement of the special local regulation.

Dated: November 11, 2021.

**J.F. Burdian,**

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

[FR Doc. 2021–25149 Filed 11–17–21; 8:45 am]

BILLING CODE 9110–04–P

## DEPARTMENT OF HOMELAND SECURITY

## Coast Guard

## 33 CFR Part 165

**[Docket Number USCG–2021–0813]**

**RIN 1625–AA00**

## Safety Zone; Steak Restaurant Fireworks, San Francisco Bay, San Francisco, CA

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone on the navigable waters of the San Francisco Bay near Rincon Point in San Francisco in support of a fireworks display on December 18, 2021. The safety zone is necessary to protect personnel, vessels, and the marine environment from potential hazards created by pyrotechnics. Unauthorized persons or vessels are prohibited from entering into, transiting through, or remaining in the safety zone without the permission of the Captain of the Port San Francisco or a designated representative.

**DATES:** This rule is effective from 9 a.m. on December 18, 2021, until 12:45 a.m. on December 19, 2021.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2021–0813 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, call or email Lieutenant Anthony I. Solares, U.S. Coast Guard District 11, Sector San Francisco, at 415–399–3585, *SFWaterways@uscg.mil.*

**SUPPLEMENTARY INFORMATION:**

### I. Table of Abbreviations

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

### II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule

without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. The Coast Guard did not receive final details for this event until October 20, 2021. It is impracticable to go through the full notice and comment rule making process because the Coast Guard must establish this safety zone by December 18, 2021 and lacks sufficient time to provide a reasonable comment period and to consider those comments before issuing the rule.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to public interest because action is necessary to protect personnel, vessels, and the marine environment from the potential safety hazards associated with the fireworks display near Rincon Point in the San Francisco Bay on December 18, 2021.

## III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port San Francisco has determined that potential hazards associated with the Steak Restaurant Fireworks on December 18, 2021, will be a safety concern for anyone within a 100-foot radius of the fireworks vessel during loading and staging, and anyone within a 700-foot radius of the fireworks vessel starting 30 minutes before the fireworks display is scheduled to commence and ending 30 minutes after the conclusion of the fireworks display. For this reason, this temporary safety zone is needed to protect personnel, vessels, and the marine environment in the navigable waters around the fireworks vessel and during the fireworks display.

## IV. Discussion of the Rule

This rule establishes a temporary safety zone from 9 a.m. on December 18, 2021, until 12:45 a.m. on December 19, 2021, during the loading, staging, and transit of the fireworks vessel in San Francisco Bay from Pier 50 to 1,000 feet off Rincon Point, San Francisco, CA, and until 30 minutes after completion of the fireworks display. During the loading, staging, and transit of the fireworks vessel scheduled to take place between 9 a.m. and 11:15 p.m. on December 18, 2021, until 30 minutes prior to the start of the fireworks display, the safety zone will encompass the navigable waters around and under the fireworks vessel, from surface to bottom, within a circle formed by connection of all points 100 feet out from the fireworks vessel. The fireworks display is scheduled to start at 11:59 p.m. December 18, 2021, and end at approximately 12:15 a.m. on December 19, 2021, 1,000 feet from Rincon Point in San Francisco, CA.

The fireworks vessel will remain at Pier 50 until the start of its transit to the display location. Movement of the vessel from Pier 50 to the display location is scheduled to take place from 10 p.m. to 11:15 p.m. on December 18, 2021, where it will remain until the conclusion of the fireworks display.

At 11:29 p.m. on December 18, 2021, 30 minutes prior to the commencement of the 15-minute fireworks display, the safety zone will increase in size and encompass the navigable waters around and under the fireworks vessel, from surface to bottom, within a circle formed by all connecting points 700 feet from the circle center at approximate position 37 degrees 47′37.47″ N, 122 degrees 23′ 14.45″ W (NAD 83), or as announced via Broadcast Notice to Mariners. The safety zone will terminate at 12:45 a.m. on December 19, 2021.

This regulation is necessary to keep persons and vessels away from the immediate vicinity of the fireworks loading, staging, transit, and display site. Except for persons or vessels authorized by the COTP or the COTP's designated representative, no person or vessel may enter or remain in the restricted area. A ''designated representative'' means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel, or a Federal, State, or local officer designated by or assisting the Captain of the Port San Francisco (COTP) in the enforcement of the safety zone. This regulation is necessary to ensure the safety of participants, spectators, and transiting vessels.

## V. Regulatory Analyses

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

### *A. Regulatory Planning and Review*

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

This regulatory action determination is based on the limited duration and narrowly tailored geographic area of the safety zone. Although this rule restricts access to the waters encompassed by the safety zone, the effect of this rule will not be significant because the local waterways users will be notified to ensure the safety zone will result in minimum impact. The vessels desiring to transit through or around the temporary safety zone may do so upon express permission from the COTP or the COTP's designated representative.

### *B. Impact on Small Entities*

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

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

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

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's

responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

*C. Collection of Information*

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

*D. Federalism and Indian Tribal Governments*

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

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

*E. Unfunded Mandates Reform Act*

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

*F. Environment*

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a temporary safety zone in the navigable waters around the loading, staging, transit, and display of fireworks near Pier 50 and 1,000 ft off Rincon Bay in San Francisco Bay. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

*G. Protest Activities*

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

**List of Subjects in 33 CFR Part 165**

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

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

## PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

**Authority:** 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1. 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.2.

■ 2. Add § 165.T11–074 to read as follows:

### § 165.T11–074 Safety Zone; Steak Restaurant Fireworks, San Francisco Bay, San Francisco, CA.

(a) *Location.* The following area is a safety zone: All navigable waters of San Francisco Bay, from surface to bottom, within a circle formed by connecting all points 100 feet out from the fireworks vessel during loading and staging at Pier 50 in San Francisco, as well as transit and arrival 1,000 feet off of Rincon Point, San Francisco, CA. Between 11:29 p.m. December 18, 2021, and 12:45 a.m. on December 19, 2021, the safety zone will expand to all navigable waters, from surface to bottom, within a circle formed by connection all points 700 feet out from the fireworks vessel in approximate position 37 degrees 47′37.47″ N, 122 degrees 23′ 14.45″ W (NAD 83) or as announced via Broadcast Notice to Mariners.

(b) *Definitions.* As used in this section, ''designated representative'' means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel, or a Federal, State, or Local officer designated by or assisting the Captain of the Port San Francisco (COTP) in the enforcement of the safety zone.

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

(2) The safety zone is closed to all vessel traffic, except as may be permitted by the COTP or the COTP's designated representative.

(3) Vessel operators desiring to enter or operate within the safety zone must contact the COTP or the COTP's designated representative to obtain permission to do so. Vessel operators given permission to enter or operate in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative. Persons and vessels may request permission to enter the safety zone on VHF–23A or through the 24-hour Command Center at telephone (415) 399–3547.

(d) *Enforcement period.* This section will be enforced from 9 a.m. on December 18, 2021, until 12:45 a.m. on December 19, 2021.

(e) *Information broadcasts.* The COTP or the COTP's designated representative will notify the maritime community of periods during which this zone will be enforced, in accordance with 33 CFR 165.7.

Dated: November 10, 2021.

**Taylor Q. Lam,**

*Captain, U.S. Coast Guard, Captain of the Port, San Francisco.*

[FR Doc. 2021–25142 Filed 11–17–21; 8:45 am]

BILLING CODE 9110–04–P

**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

**33 CFR Part 165**

**[Docket Number USCG–2021–0872]**

**RIN 1625–AA00**

## Safety Zone; Haro Strait, San Juan County, WA

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

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary moving safety zone for navigable waters within a 500-yard radius around the ZIM KINGSTON. The safety zone is needed to protect personnel, vessels, and the marine environment from the potential hazards associated with the vessel transit. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sector Puget Sound.

**DATES:** This rule is effective without actual notice from November 18, 2021, until November 29, 2021. For the purposes of enforcement, actual notice will be used from November 15, 2021, until November 18, 2021.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2021–0872 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

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

**SUPPLEMENTARY INFORMATION:**

### I. Table of Abbreviations

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

### II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule, as the Coast Guard received initial notification on October 31, 2021, of an anticipated vessel transit from Victoria, BC, to Vancouver, BC, through U.S. Waters by the ZIM KINGSTON. On or around October 21, 2021, the ZIM KINGSTON lost containers overboard and two containers subsequently caught on fire and may contain toxic flammable gas or other hazardous materials. Immediate action is needed to respond to the potential safety hazards associated with the ZIM KINGSTON's transit. It is impracticable to publish an NPRM for this temporary rule because the safety zone must be established by November 15, 2021, to protect waterway users.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because immediate action is needed to protect personnel, vessels, and the marine environment from the potential hazards associated with the vessel transit of the ZIM KINGSTON.

### III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port (COTP) Puget Sound has determined that potential hazards associated with the transit of the ZIM KINGSTON will be a safety concern for anyone within a 500-yard radius of the vessel. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone during the transit.

### IV. Discussion of the Rule

This rule establishes a safety zone from 9:00 a.m.. November 15, 2021, through 9 a.m. November 29, 2021. The safety zone will cover all navigable waters within 500 yards of the ZIM KINGSTON. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters while the vessel is in transit. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

### V. Regulatory Analyses

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

#### *A. Regulatory Planning and Review*

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

This regulatory action determination is based on the fact that the safety zone created by this rule is limited in size and duration. Vessel traffic would be able to safely transit around this safety zone. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule would allow vessels to seek permission to enter the zone.

#### *B. Impact on Small Entities*

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

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

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

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

*C. Collection of Information*

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

*D. Federalism and Indian Tribal Governments*

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

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

*E. Unfunded Mandates Reform Act*

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

*F. Environment*

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone for navigable waters within a 500-yard radius around the ZIM KINGSTON between November 15, 2021, to November 29, 2021. The safety zone is needed to protect personnel, vessels, and the marine environment from the potential hazards associated with the vessel transit. It is categorically excluded from further review under paragraph L[60] of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1.

*G. Protest Activities*

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

**List of Subjects in 33 CFR Part 165**

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

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

## PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

**Authority:** 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.2.

■ 2. Add § 165.T13–0872 to read as follows:

**§ 165.T13–0872 Safety Zone; Haro Strait, San Juan County, WA.**

(a) *Location.* The following area is a moving safety zone: All navigable waters within a 500-yard radius around the ZIM KINGSTON.

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Puget Sound (COTP) in the enforcement of the safety zone.

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

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

(d) *Effective date.* This section is effective without actual notice from November 18, 2021, until November 29, 2021. For the purposes of enforcement, actual notice will be used from November 15, 2021, until November 18, 2021.

Dated: November 15, 2021.

**P.M. Hilbert,**

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

[FR Doc. 2021–25198 Filed 11–17–21; 8:45 am]

BILLING CODE 9110–04–P

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

### 33 CFR Part 165

**[Docket Number USCG–2021–0800]**

**RIN 1625–AA00**

## Safety Zone; Umbach Fireworks Scattering, Yellow Bluff San Francisco Bay, Sausalito, CA

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone on the navigable waters of the San Francisco Bay near Yellow Bluff in Sausalito, CA in support of a fireworks display on December 3, 2021. The safety zone is necessary to protect personnel, vessels, and the marine environment from potential hazards created by pyrotechnics. Unauthorized persons or vessels are prohibited from entering into, transiting through, or remaining in the safety zone without the permission of the Captain of the Port San Francisco or a designated representative.

**DATES:** This rule is effective from 4 p.m. until 6:15 p.m. on December 3, 2021.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2021–0800 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, call or email Lieutenant Anthony I. Solares, U.S. Coast Guard District 11, Sector San Francisco, at 415–399–3585, *SFWaterways@uscg.mil.*

**SUPPLEMENTARY INFORMATION:**

## I. Table of Abbreviations

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

## II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. The Coast Guard did not receive final details for this event until October 20, 2021. It is impracticable to go through the full notice and comment rule making process because the Coast Guard must establish this safety zone by December 3, 2021 and lacks sufficient time to provide a reasonable comment period and to consider those comments before issuing the rule.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to public interest because action is necessary to protect personnel, vessels, and the marine environment from the potential safety hazards associated with the fireworks display near Yellow Bluff the San Francisco Bay on December 3, 2021.

## III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port San Francisco has determined that potential hazards associated with the Umback Fireworks Scattering on December 3, 2021, will be a safety concern for anyone within a 100-foot radius of the fireworks vessel during loading and staging, and anyone within a 500-foot radius of the fireworks vessel starting 30 minutes before the fireworks display is scheduled to commence and ending 30 minutes after the conclusion of the fireworks display. For this reason, this temporary safety zone is needed to protect personnel, vessels, and the marine environment in the navigable waters around the fireworks vessel and during the fireworks display.

## IV. Discussion of the Rule

This rule establishes a temporary safety zone from 4 p.m. until 6:15 p.m. on December 3, 2021, during the loading, staging, and transit of the fireworks vessel in San Francisco Bay from Clipper Yacht Harbor to 500 yards off Yellow Bluff, Sausalito, CA, and until 30 minutes after completion of the fireworks display. During the loading, staging, and transit of the fireworks vessel scheduled to take place between 4 p.m. and 5 p.m. on December 3, 2021, until 30 minutes prior to the start of the fireworks display, the safety zone will encompass the navigable waters around and under the fireworks vessel, from surface to bottom, within a circle formed by connection of all points 100 feet out from the fireworks vessel. The fireworks display is scheduled to start from 5:30 p.m. and end at approximately 5:45 p.m. on December 3, 2021, 500 yards from Yellow Bluff in Sausalito, CA.

The fireworks vessel will remain at Clipper Yacht Harbor until the start of its transit to the display location. Movement of the vessel from Clipper Yacht Harbor to the display location is scheduled to take place from 5 p.m. to 5:30 p.m. on December 3, 2021, where it will remain until the conclusion of the fireworks display.

At 5 p.m. on December 3, 2021, 30 minutes prior to the commencement of the 15-minute fireworks display, the safety zone will increase in size and encompass the navigable waters around and under the fireworks vessel, from surface to bottom, within a circle formed by all connecting points 500 feet from the circle center at approximate position 50′ 12″ N 122 degrees 28′ 01″ W (NAD 83). The safety zone will terminate at 6:15 p.m. on December 3, 2021 or as announced via Broadcast Notice to Mariners.

This regulation is necessary to keep persons and vessels away from the immediate vicinity of the fireworks loading, staging, transit, and display site. Except for persons or vessels authorized by the COTP or the COTP's designated representative, no person or vessel may enter or remain in the restricted area. A ''designated representative'' means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel, or a Federal, State, or local officer designated by or assisting the Captain of the Port San Francisco (COTP) in the enforcement of the safety zone. This regulation is necessary to ensure the safety of participants, spectators, and transiting vessels.

## V. Regulatory Analyses

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

### *A. Regulatory Planning and Review*

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

This regulatory action determination is based on the limited duration and narrowly tailored geographic area of the safety zone. Although this rule restricts access to the waters encompassed by the safety zone, the effect of this rule will not be significant because the local waterways users will be notified to ensure the safety zone will result in minimum impact. The vessels desiring to transit through or around the temporary safety zone may do so upon express permission from the COTP or the COTP's designated representative.

### *B. Impact on Small Entities*

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C.

605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

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

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

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

*C. Collection of Information*

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

*D. Federalism and Indian Tribal Governments*

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

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

*E. Unfunded Mandates Reform Act*

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

*F. Environment*

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a temporary safety zone in the navigable waters around the loading, staging, transit, and display of fireworks near Clipper Yacht Harbor and 500 yards off Yellow Bluff in San Francisco Bay. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

*G. Protest Activities*

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

**List of Subjects in 33 CFR Part 165**

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

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

## PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

**Authority:** 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1. 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.2.

■ 2. Add § 165.T11–075 to read as follows:

### § 165.T11–075 Safety Zone; Umbach Fireworks Scattering, Yellow Bluff San Francisco Bay, Sausalito, CA.

(a) *Location.* The following area is a safety zone: All navigable waters of San Francisco Bay, from surface to bottom, within a circle formed by connecting all points 100 feet out from the fireworks vessel during loading and staging at Clipper Yacht Harbor in Sausalito, CA as well as transit and arrival 500 yards off of Yellow Bluff, Sausalito, CA. Between 5 p.m. and 6:15 p.m. on December 3, 2021, the safety zone will expand to all navigable waters, from surface to bottom, within a circle formed by connection all points 500 feet out from the fireworks vessel in approximate position 50′ 12″ N 122 degrees 28′ 01″ W (NAD 83) or as announced via Broadcast Notice to Mariners.

(b) *Definitions.* As used in this section, ''designated representative'' means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel, or a Federal, State, or Local officer designated by or assisting the Captain of the Port San Francisco (COTP) in the enforcement of the safety zone.

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

(2) The safety zone is closed to all vessel traffic, except as may be permitted by the COTP or the COTP's designated representative.

(3) Vessel operators desiring to enter or operate within the safety zone must contact the COTP or the COTP's designated representative to obtain permission to do so. Vessel operators given permission to enter or operate in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative. Persons and vessels may request permission to enter the safety zone on VHF–23A or through the 24-hour Command Center at telephone (415) 399–3547.

(d) *Enforcement period.* This section will be enforced from 4 p.m. until 6:15 p.m. on December 3, 2021.

(e) *Information broadcasts.* The COTP or the COTP's designated representative will notify the maritime community of periods during which this zone will be enforced, in accordance with 33 CFR 165.7.

Dated: November 10, 2021.

**Taylor Q. Lam,**

*Captain, U.S. Coast Guard,Captain of the Port, San Francisco.*

[FR Doc. 2021–25141 Filed 11–17–21; 8:45 am]

**BILLING CODE 9110–04–P**

## POSTAL SERVICE

## 39 CFR Part 111

## Domestic Competitive Products Pricing and Mailing Standards Changes

**AGENCY:** Postal Service™.

**ACTION:** Final rule.

**SUMMARY:** The Postal Service is amending *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM®), to reflect changes to prices and mailing standards for competitive products.

**DATES:** *Effective Date:* January 9, 2022.

**FOR FURTHER INFORMATION CONTACT:** Steven Jarboe at (202) 268–7690, Margaret Pepe (202) 268–3078, or Garry Rodriguez at (202) 268–7281.

**SUPPLEMENTARY INFORMATION:** This final rule describes new prices and product features for competitive products, by class of mail, established by the Governors of the United States Postal Service®. New prices are available under Docket Number CP2022–22 on the Postal Regulatory Commission PRC website at *http://www.prc.gov,* and on the Postal Explorer® website at *http://pe.usps.com.*

The Postal Service will revise *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM), to reflect changes to prices and mailing standards for the following competitive products:

- Priority Mail Express®.
- Priority Mail®.
- First-Class Package Service®.
- Parcel Select®.
- USPS Retail Ground®.
- Extra Services.
- Return Services.
- Mailer Services.
- Recipient Services.
- Other.

Competitive product prices and changes are identified by product as follows:

**Priority Mail Express**

*Prices*

Overall, Priority Mail Express prices will increase 3.1 percent. Priority Mail Express will continue to offer zoned and Flat Rate Retail, Commercial Base®, and Commercial Plus® pricing.

Retail prices will increase an average of 2.9 percent. The Flat Rate Envelope price will increase to $26.95, the Legal Flat Rate Envelope will increase to $27.10, and the Padded Flat Rate Envelope will increase to $27.50.

Commercial prices (Commercial Base and Commercial Plus) will increase an average of 4.3 percent.

*Dimensional Weight Pricing Dimension Standards*

The Postal Service is implementing a standard under dimensional weight pricing for commercial Priority Mail Express pieces to require Shipping Services file manifests or other approved electronic documentation include the accurate dimensions (length, width, height) of all pieces that exceed 1 cubic foot. This standard will assist the Postal Service with compliance in pricing. Shipping Services file manifests or other approved electronic documentation not meeting the requirement to include accurate dimensions will be assessed a dimension noncompliance fee.

**Priority Mail**

*Prices*

Overall, Priority Mail prices will increase 3.1 percent. Priority Mail will continue to offer zoned and Flat Rate Retail, Commercial Base, and Commercial Plus pricing.

Retail prices will increase an average of 4.5 percent. The Flat Rate Envelope price will increase to $8.95, the Legal Flat Rate Envelope will increase to $9.25, and the Padded Flat Rate Envelope will increase to $9.65. The Small Flat Rate Box price will increase to $9.45 and the Medium Flat Rate Boxes will increase to $16.10. The Large Flat Rate Box will decrease to $21.50 and the APO/FPO/DPO Large Flat Rate Box will decrease to $20.00.

Commercial prices (Commercial Base and Commercial Plus) will increase an average of 1.2 percent.

*Dimensional Weight Pricing Dimension Standards*

The Postal Service is implementing a standard under dimensional weight pricing for commercial Priority Mail pieces to require Shipping Services file manifests or other approved electronic documentation include the accurate dimensions (length, width, height) of all pieces that exceed 1 cubic foot. This standard will assist the Postal Service with compliance in pricing. Shipping Services file manifests or other approved electronic documentation not meeting the requirement to include accurate dimensions will be assessed a dimension noncompliance fee.

**First-Class Package Service**

*Prices*

Overall, First-Class Package Service prices will increase 8.8 percent.

Overall, First-Class Package Service—Retail prices will increase 9.0 percent.

Overall, First-Class Package Service—Commercial prices will increase 8.8 percent.

**Parcel Select**

*Prices*

The prices for Parcel Select Destination Entry will decrease an average of 11.1 percent. Parcel Select Ground prices will decrease an average of 12.1 percent. The prices for Parcel Select Lightweight® will increase an average of 7.4 percent.

*Dimensional Weight Pricing Dimension Standards*

The Postal Service is implementing a standard under dimensional weight pricing for Parcel Select Destination Entry and Parcel Select Ground pieces to require Shipping Services file manifests or other approved electronic documentation include the accurate dimensions (length, width, height) of all pieces that exceed 1 cubic foot. This standard will assist the Postal Service with compliance in pricing. Shipping Services file manifests or other approved electronic documentation not meeting the requirement to include accurate dimensions will be assessed a dimension noncompliance fee.

*Optional SCF Preparation for Parcel Select Destination Entry and Parcel Select Lightweight Machinable Parcels*

The Postal Service will implement an optional Sectional Center Facility (SCF) preparation level that will allow mailers to presort and dropship Parcel Select Destination Entry machinable parcels to an eligible destination SCF (DSCF) under Labeling List L051. The new SCF preparation level will follow the current Parcel Select Destination Entry standards for requirements, mail preparation, entry, and pricing.

The Postal will also implement an optional SCF preparation level that will allow mailers to presort and dropship Parcel Select Lightweight (PSLW) machinable parcels to an eligible DSCF under labeling List L051. The new SCF

preparation will follow the current PSLW standards for requirements, mail preparation, entry, and pricing.

As a result of the new SCF preparation level for PSLW machinable parcels, the Postal Service will delete Customer Support Ruling (CSR) PS–348, Parcel Select Lightweight Machinable Parcel Optional SCF Presort and Entry.

*USPS Connect Local*

USPS Connect Local™ is a new Parcel Select price category offering, designed to enhance access to our delivery network at the local level to deliver items the same-day or the next-day via a local Post Office to every address served by that delivery unit. Participation in the USPS Connect Local program requires agreement to program terms. Customers must contact a USPS Representative for details.

USPS Connect Local will offer three USPS-produced Flat Rate container prices (2 bags and a box), variable weight prices from 1 pound through 25 pounds that will not be subject to Dimensional (DIM) pricing, and an oversized (108 inches–130 inches) price.

USPS Click-N-Ship® will be the required payment method, providing both the shipping label and postage payment.

Certain additional mailing services such as Insurance and Signature Confirmation™ extra services and Pickup on Demand® and USPS Tracking Plus® will be available for USPS Connect Local.

USPS Connect Local will also offer Sunday delivery where available for a fee and has an automatic Sunday fee refund feature through USPS Click-N-Ship if the item is not delivered on Sunday or Sunday delivery was not attempted.

**USPS Retail Ground**

Overall, USPS Retail Ground prices will decrease an average of 7.4 percent.

*USPS Retail Ground Prices Zones 1 Through 4*

The Postal Service is eliminating the restriction that states USPS Retail Ground prices in Zones 1 through 4 are only available to items that require surface transportation. USPS Retail Ground prices will now be available for all eligible mailable items in Zones 1 through 9.

**Extra Services**

*Adult Signature Service*

Adult Signature Required and Adult Signature Restricted Delivery service prices are increasing 23.2 and 22.4 percent respectively. The price for Adult Signature Required will increase to $8.50 and Adult Signature Restricted Delivery will increase to $8.75.

**Return Services**

*Parcel Return Service*

Overall, Parcel Return Service prices will increase an average of 4.9 percent.

Return Sectional Center Facility (RSCF) prices will increase an average of 4.9 percent and Return Delivery Unit (RDU) prices will increase an average of 4.9 percent.

**Mailer Services**

*Pickup on Demand Service*

The Pickup on Demand® service fee will remain at $25.00.

*USPS Tracking Plus Service*

Overall, USPS Premium Tracking Service™ prices will decrease 51.5 percent.

*USPS Tracking Plus Service Expansion of Products*

The Postal Service is expanding the domestic product offering for USPS Tracking Plus™ to include Library Mail, Media Mail®, and Bound Printed Matter. The expansion will also include First-Class Mail® (Letters and Flats) with the purchase of a trackable extra service, USPS Marketing Mail® and Nonprofit USPS Marketing Mail parcels with the purchase of USPS Tracking®, and Nonprofit USPS Marketing Mail parcels with a trackable extra service.

The Postal Service is also expanding USPS Tracking Plus service to include some International outbound products. For further information see the International Mailing Services: Mailing Services Product and Price Changes **Federal Register** notice.

**Recipient Services**

*Post Office Box Service*

The competitive Post Office Box™ service prices will increase an average of 18.2 percent within the updated price ranges.

*Premium Forwarding Service*

Premium Forwarding Service® (PFS®) prices will increase between 4.8 and 5.3 percent depending on the specific price element. The enrollment fee paid at the retail counter for PFS-Residential will increase to $23.90 and the PFS-Residential, PFS-Commercial, and PFS-Local enrollment fee paid online will increase to $21.95 per application. The price of the weekly shipment charge for PFS-Residential and per container charge for PFS-Local will increase to $23.90.

*USPS Package Intercept*

The USPS Package Intercept® fee will increase 4.6 percent to $15.95.

**Other**

*Address Enhancement Service*

Address Enhancement Service competitive product prices will increase between 10.0 and 14.3 percent.

*Residential Delivery Indicator Application Program Interface (RDI–API) Eliminated*

The Postal Service is eliminating RDI–API due to low volume.

*Small Parcel Forwarding Fee*

The small parcel forwarding fee, an optional service first offered in January 2019, will increase 6.1 percent to $5.25.

*Nonstandard Fees*

The Postal Service is implementing Nonstandard Fees for domestic retail and commercial Priority Mail Express and Priority Mail pieces, First-Class Package Service-Retail, USPS Retail Ground (including USPS Retail Ground LOR), and Parcel Select (Destination Entry, Ground, PSLW, USPS Connect Local) pieces that are operationally considered nonstandard. The nonstandard fees will consist of two components, length and cube. The length component will consist of two fees, one fee for a piece that measures more than 22 inches up to 30 inches, and another fee for a piece that measures more than 30 inches in length. The cube component will consist of a fee for a piece that measures more than 2 cubic feet (3,456 cubic inches). Cube dimensions for rectangular pieces are determined by measuring the length, width, and height in inches (rounding off each measurement to the nearest whole inch) and multiplying the length by the width by the height. For nonrectangular pieces, calculate as stated above and multiply the result by an adjustment factor of 0.785. If either calculation exceeds 3,456 cubic inches, the piece is subject to the cube dimension nonstandard fee.

A piece may be subject to both a length and a cube dimension nonstandard fee. The nonstandard fees do not apply to Flat Rate products, Regional Rate products or returns (USPS Returns, PRS).

In addition, commercial Priority Mail Express and Priority Mail, and Parcel Select (Destination Entry, Ground, PSLW) will require the Shipping Services file manifests or other approved electronic documentation include the accurate dimensions

(length, width, height) of all pieces that exceed 22 inches.

* * * * *

*Dimension Noncompliance Fee*

The Postal Service is implementing a dimension noncompliance fee for commercial Priority Mail Express and Priority Mail, and Parcel Select (Destination Entry, Ground, PSLW, and USPS Connect Local) mailpieces. The dimension noncompliance fee will be assessed when dimensions (length, width, height) required by standard to be included in the Shipping Services file manifests or other approved electronic documentation, are omitted or are inaccurate. A mailpiece is only subject to one dimension noncompliance fee.

* * * * *

**Resources**

The Postal Service provides additional resources to assist customers with this price change for competitive products. These tools include price lists, downloadable price files, and **Federal Register** Notices, which may be found on the Postal Explorer® website at *http://pe.usps.com.*

The Postal Service adopts the following changes to *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM), incorporated by reference in the *Code of Federal Regulations.* See 39 CFR 111.1.

**List of Subjects in 39 CFR Part 111**

Administrative practice and procedure, Postal Service.

Accordingly, 39 CFR part 111 is amended as follows:

## PART 111—[AMENDED]

■ 1. The authority citation for 39 CFR part 111 continues to read as follows:

**Authority:** 5 U.S.C. 552(a); 13 U.S.C. 301–307; 18 U.S.C. 1692–1737; 39 U.S.C. 101, 401, 403, 404, 414, 416, 3001–3011, 3201–3219, 3403–3406, 3621, 3622, 3626, 3632, 3633, and 5001.

■ 2. Revise *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM) as follows:

**Mailing Standards of the United States Postal Service, Domestic Mail Manual (DMM)**

* * * * *

**100 Retail Mail Letters, Cards, Flats, and Parcels**

* * * * *

**110 Retail Mail Priority Mail Express**

**113 Prices and Eligibility**

**1.0 Prices and Fees**

* * * * *

*[Revise 1.0 by adding new 1.6 to read as follows:]*

**1.6 Nonstandard Fees**

A Priority Mail Express piece that measures more than 22 inches up to 30 inches or that measures more than 30 inches in length or that measures more than 2 cubic feet (3,456 cubic inches) is subject to a nonstandard fee (see Notice 123—Price List). Cube dimensions for rectangular pieces are determined by measuring the length, width, and height in inches (rounding off see 604.7.0) each measurement to the nearest whole inch) and multiplying the length by the width by the height. For nonrectangular, pieces calculate as stated above and multiply the result by an adjustment factor of 0.785. If either calculation exceeds 3,456 cubic inches, the piece is subject to the nonstandard fee. A piece may be subject to both a length and a cube nonstandard fee.

* * * * *

**120 Retail Mail Priority Mail**

**123 Prices and Eligibility**

**1.0 Prices and Fees**

* * * * *

*[Revise 1.0 by adding a new 1.7 to read as follows:]*

**1.7 Nonstandard Fees**

Except for Flat Rate and Regional Rate packaging, a Priority Mail piece that measures more than 22 inches up to 30 inches in length or that measures more than 30 inches or that measures more than 2 cubic feet (3,456 cubic inches) is subject to a nonstandard fee (see Notice 123—Price List). Cube dimensions for rectangular pieces are determined by measuring the length, width, and height in inches (rounding off see 604.7.0) each measurement to the nearest whole inch) and multiplying the length by the width by the height. For nonrectangular pieces, calculate as stated above and multiply the result by an adjustment factor of 0.785. If either calculation exceeds 3,456 cubic inches, the piece is subject to the nonstandard fee. A piece may be subject to both a length and a cube nonstandard fee.

* * * * *

**130 Retail Mail First-Class Mail and First-Class Package Service—Retail**

**133 Prices and Eligibility**

**1.0 Prices and Fees**

* * * * *

*[Revise 1.0 by adding new 1.6 to read as follows:]*

**1.6 Nonstandard Fees**

A First-Class Package Service—Retail piece that measures more than 22 inches up to 30 inches or that measures more than 30 inches in length or that measures more than 2 cubic feet (3,456 cubic inches) is subject to a nonstandard fee (see Notice 123—Price List). Cube dimensions for rectangular pieces are determined by measuring the length, width, and height in inches (rounding off see 604.7.0) each measurement to the nearest whole inch) and multiplying the length by the width by the height. For nonrectangular pieces, calculate as stated above and multiply the result by an adjustment factor of 0.785. If either calculation exceeds 3,456 cubic inches, the piece is subject to the nonstandard fee. A piece may be subject to both a length and a cube nonstandard fee.

* * * * *

**150 Retail Mail USPS Retail Ground**

**153 Prices and Eligibility**

**1.0 Prices and Fees**

**1.1 Price Eligibility**

USPS Retail Ground prices are calculated based on the zone to which the parcel is addressed and the weight of the parcel. USPS Retail Ground prices are available as follows:

*[Revise the text of item a to read as follows:]*

a. Except for items mailed under 1.3, USPS Retail Ground prices are available for eligible mailable items sent to Zones 1 through 9.

*[Delete item b and renumber items c and d as b and c.]*

* * * * *

**1.3 USPS Retail Ground—Limited Overland Routes Prices**

*[Revise the text of 1.3 to read as follows:]*

USPS Retail Ground—LOR retail prices are only available when mailing eligible items within the state of Alaska for pieces delivered to or from the eligible intra-Alaska ZIP Codes not connected by overland routes in Exhibit 1.3. USPS Retail Ground—LOR retail prices are not available through online or commercial postage payment.

* * * * *

*[Revise 1.0 by adding a new 1.5 to read as follows:]*

**1.5 Nonstandard Fees**

A USPS Retail Ground or USPS Retail Ground—Limited Overland Routes piece that measures more than 22 inches up to 30 inches in length or that

measures more than 30 inches or that measures more than 2 cubic feet (3,456 cubic inches) is subject to a nonstandard fee (see Notice 123—Price List). Cube dimensions for rectangular pieces are determined by measuring the length, width, and height in inches (rounding off see 604.7.0) each measurement to the nearest whole inch) and multiplying the length by the width by the height. For nonrectangular pieces, calculate as stated above and multiply the result by an adjustment factor of 0.785. If either calculation exceeds 3,456 cubic inches, the piece is subject to the nonstandard fee. A piece may be subject to both a length and a cube nonstandard fee.

* * * * *

**200 Commercial Letters, Flats, and Parcels**

**201 Physical Standards**

* * * * *

**8.0 Additional Physical Standards by Class of Mail**

* * * * *

**8.5 Parcel Select**

* * * * *

*[Revise 8.5 by adding a new 8.5.4 to read as follows:]*

**8.5.4 USPS Connect Local**

These standards apply to USPS Connect Local:

a. No piece may weigh more than 25 pounds.

b. USPS Connect Local pieces measuring over 108 inches in combined length and girth, but not more than 130 inches in combined length and girth, are mailable at the USPS Connect Local oversized price.

* * * * *

**202 Elements on the Face of a Mailpiece**

* * * * *

**3.0 Placement and Content of Mail Markings**

* * * * *

**3.7 Parcel Select, Bound Printed Matter, Media Mail, and Library Mail Markings**

**3.7.1 Basic Markings**

*[Revise the first sentence in the introductory text of 3.7.1 to read as follows:]*

The basic required marking (*i.e.,* ''Parcel Select'', ''Parcel Select Lightweight'', ''USPS Connect Local'', ''Bound Printed Matter'', ''Media Mail'', ''Library Mail'') must be printed on each piece claimed at the respective price.

* * *

* * * * *

**3.7.2 Parcel Select Markings**

* * * The following product markings are required:

* * * * *

*[Add new item d to read as follows:]*

d. USPS Connect Local—''USPS Connect Local''.

* * * * *

*[Renumber 3.7.3 through 3.7.5 as 3.7.4 through 3.7.6 and add new 3.7.3 to read as follows:]*

**3.7.3 USPS Connect Local**

In addition to the basic marking ''USPS Connect Local'' each piece of USPS Connect Local must bear the 5-digit ZIP Code of the local mailing Post Office (*i.e.,* USPS Connect Local—12345) additional price marking. For USPS Connect Local Sunday delivery, in addition to the 5-digit ZIP Code additional price marking, the piece must include the marking ''SUN'' (*i.e.,* USPS Connect Local—12345 SUN).

* * * * *

**210 Commercial Mail Priority Mail Express**

**213 Prices and Eligibility**

**1.0 Prices and Fees**

* * * * *

**1.5 Dimensional Weight Price for Low-Density Parcels to Zones 1–9**

* * * * *

*[Revise 1.5 by adding a new 1.5.3 to read as follows:]*

**1.5.3 Dimensional Weight Pricing Dimension Standard**

Shipping Services file manifests or other approved electronic documentation must include the accurate dimensions (length, width, height) of all pieces that exceed 1 cubic foot. Shipping Services file manifests or other approved electronic documentation not meeting the requirement to include accurate dimensions will be assessed a dimension noncompliance fee under 1.10.

* * * * *

*[Revise 1.0 by adding new 1.9 to read as follows:]*

**1.9 Nonstandard Fees**

A Priority Mail Express piece that measures more than 22 inches up to 30 inches or that measures more than 30 inches in length or that measures more than 2 cubic feet (3,456 cubic inches) is subject to a nonstandard fee (see Notice 123—Price List). Cube dimensions for rectangular pieces are determined by measuring the length, width, and height in inches (rounding off see 604.7.0) each measurement to the nearest whole inch) and multiplying the length by the width by the height. For nonrectangular pieces, calculate as stated above and multiply the result by an adjustment factor of 0.785. If either calculation exceeds 3,456 cubic inches, the piece is subject to the nonstandard fee. A piece may be subject to both a length and a cube nonstandard fee. Shipping Services file manifests or other approved electronic documentation must include the accurate dimensions (length, width, height) of all pieces that exceed 22 inches. Shipping Services file manifests or other approved electronic documentation not meeting the requirement to include accurate dimensions will be assessed a dimension noncompliance fee under 1.10.

* * * * *

*[Revise 1.0 by adding a new 1.10 to read as follows:]*

**1.10 Dimension Noncompliance Fee**

Priority Mail Express mailpieces required to include dimensions (length, width, height) in the Shipping Services file manifests or other approved electronic documentation under 1.5.3 or 1.9 and the dimensions are omitted or inaccurate are subject to the dimension noncompliance fee (see Notice 123—Price List). A mailpiece is only subject to one dimension noncompliance fee.

* * * * *

**220 Commercial Mail Priority Mail**

**223 Prices and Eligibility**

**1.0 Prices and Fees**

* * * * *

**1.5 Dimensional Weight Price for Low-Density Parcels to Zones 1–9**

* * * * *

*[Revise 1.5 by adding a new 1.5.3 to read as follows:]*

**1.5.3 Dimensional Weight Pricing Dimension Standard**

Shipping Services file manifests or other approved electronic documentation must include the accurate dimensions (length, width, height) of all pieces that exceed 1 cubic foot. Shipping Services file manifests or other approved electronic documentation not meeting the requirement to include accurate dimensions will be assessed a dimension noncompliance fee under 1.13.

* * * * *

*[Revise 1.0 by adding a new 1.12 to read as follows:]*

**1.12 Nonstandard Fees**

Except for Flat Rate and Regional Rate packaging and Priority Mail Return service packages, a Priority Mail piece that measures more than 22 inches up to 30 inches or that measures more than 30 inches in length or that measures more than 2 cubic feet (3,456 cubic inches) is subject to a nonstandard fee (see Notice 123—Price List). Cube dimensions for rectangular pieces are determined by measuring the length, width, and height in inches (rounding off see 604.7.0) each measurement to the nearest whole inch) and multiplying the length by the width by the height. For nonrectangular pieces, calculate as stated above and multiply the result by an adjustment factor of 0.785. If either calculation exceeds 3,456 cubic inches, the piece is subject to the nonstandard fee. A piece may be subject to both a length and a cube nonstandard fee. Shipping Services file manifests or other approved electronic documentation must include the accurate dimensions (length, width, height) of all pieces that exceed 22 inches. Shipping Services file manifests or other approved electronic documentation not meeting the requirement to include accurate dimensions will be assessed a dimension noncompliance fee under 1.13.

* * * * *

*[Revise 1.0 by adding a new 1.13 to read as follows:]*

**1.13 Dimension Noncompliance Fee**

Priority Mail mailpieces required to include dimensions (length, width, height) in the Shipping Services file manifests or other approved electronic documentation under 1.5.3 or 1.12 and the dimensions are omitted or inaccurate are subject to the dimension noncompliance fee (see Notice 123—Price List). A mailpiece is only subject to one dimension noncompliance fee.

* * * * *

**250 Commercial Mail Parcel Select**

**253 Prices and Eligibility**

**1.0 Prices and Fees**

**1.1 Price Application**

*[Revise the text of 1.1 to read as follows:]*

Postage is based on the price that applies to the weight increment of each addressed piece, and on the zone to which the piece is addressed, except for DDU and DSCF entered pieces and USPS Connect Local pieces. The price is charged per pound or fraction thereof; any fraction of a pound is considered a whole pound. Except for Parcel Select Lightweight, the minimum price per piece is the 1-pound price. For DDU, DSCF, and USPS Connect Local pieces, postage is based on the price that applies to the weight increment of each addressed piece. USPS Connect Local Flat Rate prices are not based on weight and zone but are charged a flat rate regardless of actual weight (up to 25 pounds) of the mailpiece and domestic destination. Parcel Select Lightweight postage is based on the price that applies to the weight increment of each addressed piece, charged per ounce or fraction thereof, with any fraction of an ounce being rounded to the next whole ounce. The price categories for Parcel Select are as follows:

a. Destination entry including destination entry network distribution center (DNDC), destination entry sectional center facility (DSCF), and destination entry delivery unit (DDU).
b. Ground.
c. Lightweight.
d. USPS Connect Local.

**1.2 Parcel Select Prices**

*[Revise the text of 1.2 to read as follows:]*

Pricing is available for all Parcel Select price categories under 1.1. For prices, see Notice 123–Price List.

**1.3 Dimensional Weight Price for Low-Density Parcels to Zones 1–9**

*[Revise the text of 1.3 to read as follows:]*

Postage for Destination Entry and Ground parcels addressed for delivery to Zones 1–9 and exceeding 1 cubic foot (1,728 cubic inches) is based on the actual weight or the dimensional weight (as calculated in 1.3.1 or 1.3.2), whichever is greater.

* * * * *

*[Revise 1.3 by adding a new 1.3.3 to read as follows:]*

**1.3.3 Dimensional Weight Dimension Standard**

Shipping Services file manifests or other approved electronic documentation must include the accurate dimensions (length, width, height) of all pieces that exceed 1 cubic foot. Shipping Services file manifests or other approved electronic documentation not meeting the requirement to include accurate dimensions will be assessed a dimension noncompliance fee under 1.9.

* * * * *

*[Revise 1.0 by adding a new 1.6 and 1.7 to read as follows:]*

**1.6 USPS Connect Local Flat Rate Packaging**

Only USPS-produced USPS Connect Local Flat Rate packaging is eligible for the USPS Connect Local Flat Rate prices and are charged a flat rate regardless of the actual weight (up to 70 pounds) of the mailpiece. Customers must only use USPS-produced USPS Connect Local Flat Rate containers at the applicable USPS Connect Local Flat Rate price. USPS-produced USPS Connect Local Flat Rate packaging is not eligible for shipping live animals.

**1.7 Sunday Delivery**

A USPS Connect Local mailer may request Sunday delivery where available for a fee (see Notice 123—Price List).

*[Revise 1.0 by adding new 1.8 to read as follows:]*

**1.8 Nonstandard Fees**

Except for Ground Return service, a Parcel Select Destination Entry, Ground, Parcel Select Lightweight, or USPS Connect Local, piece that measures more than 22 inches up to 30 inches or that measures more than 30 inches in length or that measures more than 2 cubic feet (3,456 cubic inches) is subject to a nonstandard fee (see Notice 123—Price List). Cube dimensions for rectangular pieces are determined by measuring the length, width, and height in inches (rounding off see 604.7.0) each measurement to the nearest whole inch) and multiplying the length by the width by the height. For nonrectangular pieces, calculate as stated above and multiply the result by an adjustment factor of 0.785. If either calculation exceeds 3,456 cubic inches, the piece is subject to the nonstandard fee. A piece may be subject to both a length and a cube nonstandard fee. Shipping Services file manifests or other approved electronic documentation must include the accurate dimensions (length, width, height) of all pieces that exceed 22 inches. Shipping Services file manifests or other approved electronic documentation not meeting the requirement to include accurate dimensions will be assessed a dimension noncompliance fee under 1.9.

* * * * *

*[Revise 1.0 by adding a new 1.9 to read as follows:]*

**1.9 Dimension Noncompliance Fee**

Parcel Select mailpieces required to include dimensions (length, width, height) in the Shipping Services file manifests or other approved electronic documentation under 1.3.3 or 1.8 and the dimensions are omitted or

inaccurate are subject to the dimension noncompliance fee (see Notice 123—Price List). A mailpiece is only subject to one dimension noncompliance fee.

* * * * *

**3.0 Basic Eligibility Standards for Parcel Select Parcels**

**3.1 Description of Service**

*[Revise the text of 3.1 to read as follows:]*

Parcel Select is a Shipping Services ground product. USPS Local Connect is a price category of Parcel Select with an expected same-day or next day delivery service. The USPS does not guarantee the delivery of Parcel Select mailpieces within a specified time. Certain Parcel Select mailpieces might receive deferred service.

* * * * *

*[Revise the heading of 4.0 to read as follows:]*

**4.0 Price Eligibility for Parcel Select and Parcel Select Lightweight**

**4.1 Destination Entry Price Eligibility**

**4.1.1 Definition**

* * * For this standard, the following destination facility definitions apply:

* * * * *

*[Revise the first sentence of item b to read as follows:]*

b. A destination sectional center facility (DSCF) includes all facilities in L005 or L051 for DSCF machinable parcels. * * *

* * * * *

**4.1.4 DSCF and DDU Prices**

For DSCF and DDU prices, pieces must meet the applicable standards in 3.0 and the following criteria:

*[Revise the first sentence of item a to read as follows:]*

a. For DSCF prices, be part of a Parcel Select destination entry mailing of parcels deposited at an SCF in L005, L051, or a USPS-designated facility. * * *

* * * * *

**4.3 Parcel Select Lightweight**

* * * * *

**4.3.3 Prices for Machinable Parcels**

The following prices apply to Parcel Select Lightweight machinable parcels:

* * * * *

*[Renumber items b and c as c and d and add new item b to read as follows:]*

*b. SCF Price;* the SCF price applies to machinable parcels that are dropshipped and presented to a DSCF:

1. In an SCF sack containing at least 10 pounds of parcels.

2. On an SCF pallet, according to 705.8.10.

* * * * *

*[Renumber 4.4 and 4.5 as 4.5 and 4.6 and add new 4.4 to read as follows:]*

**4.4 USPS Connect Local**

USPS Connect Local mailings are subject to the following criteria:

a. Participation in the USPS Connect Local program requires agreement to program terms. Customers must speak with a USPS Representative for details.

b. No minimum volume requirement.

c. Postage must be paid under 254.1.1.3.

d. Pieces are subject to specific marking requirements under 202.3.7.2 and 202.3.7.3.

e. Mailings must be addressed and entered at the local 5-digit Post Office by the designated critical entry time for same day delivery within the local 5-digit Post Office service area.

f. Only the following extra services are available with USPS Connect Local and must be purchased through the Click-N-Ship application:

1. Insurance.

2. Signature Confirmation.

3. Signature Confirmation Restricted Delivery.

g. Sunday delivery where available for a fee (see 1.8).

* * * * *

**254 Postage Payment and Documentation**

**1.0 Basic Standards for Postage Payment**

* * * * *

*[Revise 1.0 by adding a new 1.1.3 to read as follows:]*

**1.1.3 USPS Connect Local**

USPS Connect Local mailings must be paid with USPS Click-N-Ship.

* * * * *

**255 Mail Preparation**

**1.0 General Information for Mail Preparation**

*[Revise the text of 1.1 by renumbering the current text as 1.1.1 and adding new 1.1.2 to read as follows:]*

**1.1 Basic Standards**

**1.1.1 General**

All mailings at Parcel Select prices are subject to these general standards:

a. Each mailing must meet the applicable standards in 201, 202, 253, 255, and 256.

b. All pieces that are palletized must be prepared under 705.8.0.

**1.1.2 USPS Connect Local**

There are no sorting requirements for USPS Connect Local pieces.

* * * * *

**1.4 Terms for Presort Level**

Terms used for presort levels are defined as follows:

* * * * *

*[Renumber items c and d as d and e and add new item c to read as follows:]*

c. *SCF:* The separation includes pieces for two or more 3-digit areas served by the same sectional center facility (SCF) (see L002 and L051).

* * * * *

**4.0 Preparing Destination Entry Parcel Select**

* * * * *

**4.2 Preparing Destination SCF (DSCF) Parcel Select**

**4.2.1 Definition**

*[Revise the first sentence of 4.2.1 to read as follows:]*

A destination sectional center facility (DSCF) includes all facilities in L005 for 5-digit/scheme sacks, or L051 for SCF sorted machinable parcel sacks. * * *

**4.2.2 Basic Standards**

Pieces must meet the applicable standards in 4.0 and the following criteria:

* * * * *

*[Revise the text of item b to read as follows:]*

b. DSCF pieces must be for the same SCF area under L005 for 5-digit/scheme sacks or L051 for SCF sorted machinable parcel sacks.

*[Revise the first and second sentence of item c to read as follows:]*

c. Sorted to optional 5-digit scheme destinations under L606, Column B, 5-digit destinations, or SCF for machinable parcels under L051, either in sacks or directly on pallets or in pallet boxes. Mailers must enter the pieces at the designated SCF, under L605, that serves the 5-digit ZIP Code destinations of the pieces or designated SCF for machinable parcels under L051. * * *

* * * * *

**4.2.3 Sacking and Labeling**

Sacking requirements for DSCF entry:

*[Revise the text of item a to read as follows:]*

a. Only 5-digit scheme, 5-digit, and SCF, sacks are permitted.

* * * * *

*[Renumber items e and f as g and h and add new items e and f to read as follows:]*

e. Each SCF sack must contain a minimum of seven pieces. One overflow sack per SCF is permitted (no piece minimum).

f. SCF sack labeling: Line 1, use L051; for Line 2, ''PSVC PARCELS SCF.''

* * * * *

*[Revise the text of renumbered item h to read as follows:]*

h. See 705.8.0 for option to place 5-digit scheme and 5-digit DSCF sacks, SCF sacks, and 3-digit nonmachinable sacks on an SCF pallet.

* * * * *

**5.0 Preparing Machinable Parcels**

* * * * *

**5.3.1 Sack Preparation**

Sack size, preparation sequence, and Line 1 labeling:

* * * * *

*[Renumber items c through e as d through f and add new item c to read as follows:]*

c. SCF: Optional (minimum of 10 pieces or 20 pounds); for Line 1, use L051.

* * * * *

**5.3.2 Sack Line 2**

Line 2:

* * * * *

*[Renumber items c through e as d through f and add new item c to read as follows:]*

c. SCF: ''PSVC MACH SCF.''

* * * * *

**6.0 Preparing Parcel Select Lightweight**

* * * * *

**6.2 Preparing Machinable Parcels**

**6.2.1 Sacking**

*[Revise the text of 6.2.1 by adding a new second sentence to read as follows:]*

* * * Mailers may prepare SCF sacks only for parcels that will be dropshipped to a DSCF. * * *

**6.2.2 Sacking and Labeling**

* * * * *

*[Renumber items b through e as c through f and add new item b to read as follows:]*

b. SCF, allowed only for machinable parcels deposited at a DSCF to claim SCF price; 10-pound minimum; labeling:

1. For Line 1, L051.
2. For Line 2, ''PSLW MACH SCF.''

* * * * *

*[Add a new 7.0 to read as follows:]*

**7.0 Preparing USPS Connect Local**

**7.1 USPS Connect Local Flat Rate Packaging Provided by the USPS**

USPS Connect Local Flat Rate packaging provided by the USPS must be used only for USPS Connect Local.

**7.2 Sealing USPS Connect Local Flat Rate Packaging**

When sealing a USPS Connect Local Flat Rate Bag or Box, the container flaps must be able to close within the normal folds. Tape may be applied to the flaps and seams to reinforce the container; provided the design of the container is not enlarged by opening the sides and the container is not reconstructed in any way.

* * * * *

**256 Enter and Deposit**

**1.0 Verification**

* * * * *

**1.2 Office of Mailing**

*[Revise the text of 1.2 by renumbering the current text as 1.2.1 and adding a new 1.2.2 to read as follows:]*

**1.2.1 Parcel Select**

Parcel Select must be mailed at the Post Office from which the zone-based postage was computed, except under 1.3 and 1.4.

**1.2.2 USPS Connect Local**

USPS Connect Local pieces must be mailed at the local Post Office designated by the 5-digit ZIP Code destination.

* * * * *

**2.0 Deposit**

* * * * *

**2.2 Containers**

DNDC mailings (if not bedloaded), DDU mailings (if not bedloaded), and all DSCF mailings must be prepared as follows:

* * * * *

*[Revise the text of item d to read as follows:]*

d. For DSCF, 5-digit scheme, 5-digit, SCF, and 3-digit sacks may be bedloaded or be placed on SCF pallets that are labeled and otherwise prepared under 705.8.0.

* * * * *

**500 Additional Services**

**503 Extra Services**

**1.0 Basic Standards for All Extra Services**

* * * * *

**1.4 Eligibility for Extra Services**

* * * * *

**1.4.1 Eligibility—Domestic Mail**

* * * * *

**Exhibit 1.4.1 Eligibility—Domestic Mail**

* * * * *

| Extra service | Eligible mail | Additional combined extra services |
|---|---|---|
| * * * * * | | |
| **Insurance** | | |
| **Insurance Restricted Delivery** | *[Under the ''Insurance'' line item add ''USPS Connect Local'' under the ''Eligible Mail'' column with a footnote ''11'' notation to read as follows:]* | |
| USPS Connect Local [11] | | |
| * * * * * | | |
| | **Signature Confirmation** | |
| | *[Under the ''Signature Confirmation'' line item add ''USPS Connect Local'' under the ''Eligible Mail'' column.]* | |
| | * * * * * | |
| | **Signature Confirmation Restricted Delivery** | |
| | *[Under the ''Signature Confirmation Restricted Delivery'' line item add ''USPS Connect Local'' under the ''Eligible Mail'' column.]* | |
| | * * * * * | |
| | *[Add new footnote ''11'' to read as follows:]* | |
| | [11] Insurance Restricted Delivery not available for USPS Connect Local items. | |
| | * * * * * | |

**505 Return Services**

* * * * *

**4.0 Parcel Return Service**

**4.1 Prices and Fees**

* * * * *

*[Revise 4.1 by adding a new 4.1.4 to read as follows:]*

**4.1.4 Nonstandard Fee**

Parcel Return Service parcels are not subject to a nonstandard fee.

* * * * *

**507 Mailer Services**

* * * * *

**7.0 Pickup on Demand Service**

**7.1 Postage and Fees**

* * * * *

**7.1.2 Fee**

*[Revise the last sentence of 7.1.2 to read as follows:]*

* * * The Pickup on Demand fee must be paid online at *www.usps.com* or through USPS Click-N-Ship for USPS Connect Local.

* * * * *

**7.2 Basic Standards**

**7.2.1 Availability**

* * * Incidental amounts of other postage-affixed, full-price mail also may be collected when Pickup on Demand service is provided for:

* * * * *

*[Revise the text of 7.2.1 by renumbering items f through m as g through n and adding a new item f to read as follows:]*

f. USPS Connect Local

* * * * *

**7.2.3 Extra Services**

*[Revise the text of 7.2.3 to read as follows:]*

As applicable, Certified Mail, USPS Tracking, Adult Signature (not allowed for certain items under 503.8.0), insurance, Signature Confirmation, and return receipt, are the only extra postal services that may be used with pieces that are picked up.

* * * * *

**7.2.6 Requesting Pickup on Demand Service**

*[Revise the text of 7.2.6 to read as follows:]*

A customer can request Pickup on Demand service and schedule a pickup at *www.usps.com* or through USPS Click-N-Ship for USPS Connect Local. Pickup on Demand service allows a customer to have pickup on a specific date within a two-hour timeframe. Customers can schedule Pickup on Demand service up to one year in advance or for USPS Connect Local up to three days in advance. A same day request for pickup must be made before 5:00 a.m. local time on the requested day.

* * * * *

**7.3 Scheduled Service**

* * * * *

**7.3.4 Customer Changes**

*[Revise the last sentence of 7.3.4 to read as follows:]*

* * * Customers should make notifications of change to their requests through the *www.usps.com* Pickup on Demand application or through USPS Click-N-Ship for USPS Connect Local.

* * * * *

**11.0 USPS Tracking Plus Service**

*[Revise the text of 11.0 to read as follows:]*

**11.1 Description**

USPS Tracking Plus service allows customers to request the Postal Service retain scan data, or scan and signature data for their packages, beyond the Postal Service's standard data retention period, for up to 10 years for a fee (see Notice 123–Price List). Customers may request USPS Tracking Plus service online at *usps.com* or through a Shipping Services File.

**11.2 Scan Data Retention**

USPS Tracking Plus service is available for scan data retention on mailpieces shipped by the following products:

a. Priority Mail Express
b. Priority Mail
c. First-Class Mail (Letters and Flats) with a purchased trackable extra service
d. First-Class Package Service
e. Parcel Select
f. Library Mail and Media Mail
g. Bound Printed Matter
h. USPS Marketing Mail and Nonprofit USPS Marketing Mail parcels with purchased USPS Tracking and Nonprofit USPS Marketing Mail parcels with a trackable extra service

**11.3 Scan and Signature Data Retention**

USPS Tracking Plus service is available for Scan and Signature Retention on applicable products listed in 11.2. Except for Priority Mail Express, the customer must have purchased an underlying signature service (*e.g.,* Signature Confirmation service, Adult Signature service).

* * * * *

**509 Other Services**

**1.0 Address Information System Services**

* * * * *

**1.3 Address Matching System Application Program Interface**

* * * The following services require payment of separate additional fees:

* * * * *

*[Delete items c and d.]*

* * * * *

**600 Basic Standards for All Mailing Services**

* * * * *

**604 Postage Payment Methods and Refunds**

* * * * *

**9.0 Exchanges and Refunds**

* * * * *

**9.2 Postage and Fee Refunds**

* * * * *

**9.2.1 General Standards**

* * * * *

**Exhibit 9.2.1 Postage and Fees Refunds**

*[Revise the introductory text in Exhibit 9.2.1 to read as follows:]*

Except for USPS Connect Local under 9.2.5c, customers must apply for a refund within the time limits in the chart below.

* * * * *

**9.2.3 Full Refund**

A full refund (100%) may be made when:

* * * * *

*[Revise the text of 9.2.3 by adding a new item n to read as follows:]*

n. For USPS Connect Local, the USPS refunds the Sunday premium fee for an item not delivered or for an item which delivery was not attempted, on Sunday.

* * * * *

**9.2.5 Applying for Refund**

A customer may apply for refunds under 9.2, as follows:

* * * * *

*[Revise 9.2.5 by adding a new item c to read as follows:]*

c. *Automated:* A refund for the USPS Connect Local Sunday delivery fee under 9.2.3n is applied automatically through USPS Click-N-Ship.

* * * * *

**700 Special Standards**

* * * * *

**705 Advanced Preparation and Special Postage Payment Systems**

* * * * *

**8.0 Preparing Pallets**

* * * * *

**8.5 General Preparation**

* * * * *

**8.5.3 Minimum Load**

The following minimum load standards apply to mail prepared on pallets:

* * * * *

*[Revise the fourth sentence of item b to read as follows:]*

b. * * * There is no minimum weight requirement for an SCF pallet containing 5-digit scheme, 5-digit or SCF sacks prepared for the DSCF price. * * *

* * * * *

**8.10.7 Machinable Parcels—USPS Marketing Mail, Including Marketing Parcels 6 Ounces or More, and Parcel Select Lightweight**

* * * Label pallets under applicable standards in 8.6 and according to Line 1 and Line 2 information below:

* * * * *

*[Renumber items c through f as items d through g and add new item c to read as follows:]*

*c. SCF,* optional. Allowed only for mail deposited at a DSCF to claim SCF price; labeling:

1. For Line 1, L051.
2. For Line 2, ''PSLW MACH SCF.''

* * * * *

**8.18 Parcel Select DSCF Prices—Parcels on Pallets**

**8.18.1 Basic Preparation, Parcels on Pallets**

Unless prepared under 8.18.2, or in sacks, mail must be prepared for the DSCF price as follows:

*[Revise the first and third sentence of item a to read as follows:]*

*General.* Parcels for each SCF area must be sorted to 5-digit scheme, 5-digit, SCF (machinable parcels only), or 3-digit (nonmachinable) destinations on pallets. * * * * * * Except when prepared under 8.18.2, each 5-digit scheme, 5-digit, SCF, and 3-digit pallet must meet a minimum volume requirement under one of the criteria in 8.18.1. * * *

*[Revise the text of item b to read as follows:]*

b. *Minimum volume.* The minimum volume per 5-digit scheme, 5-digit, SCF, and 3-digit pallet can be met in one of the following ways:

1. Pieces may be placed on 5-digit scheme, 5-digit, SCF, and 3-digit pallets, each containing at least 50 pieces and 250 pounds.
2. Pieces may be placed on 5-digit scheme, 5-digit, SCF, and 3-digit pallets, each having a minimum height of 36 inches of mail (excluding the height of the pallet) (see 8.5.4).

*[Revise the text of items c, c1, and c2, to read as follows:]*

c. *Overflow.* After filling a pallet(s) to a 5-digit scheme, 5-digit, SCF, or 3-digit destination, any remaining pieces that do not meet the minimum pallet requirements may be prepared in one or both of the following ways:

1. Placed in 5-digit scheme, 5-digit, SCF, or 3-digit overflow sacks (no minimum number of pieces per sack) that are labeled in accordance with the 5-digit scheme, 5-digit, SCF, or 3-digit sacking requirements for the DSCF price in 255.4.2. Overflow pieces sacked in this manner are eligible for the DSCF prices.
2. Placed on a 5-digit scheme, 5-digit, SCF, or 3-digit pallet labeled under 8.18.1 that does not meet the minimums for the DSCF price. Overflow pieces palletized in this manner are not eligible for the DSCF prices but are eligible for the DNDC prices.

* * * * *

*[Renumber items f and g as items g and h and add new item f to read as follows:]*

*f. SCF.* Pallet labeling:

1. Line 1: Use L051.
2. Line 2: ''PSVC PARCELS SCF.''

* * * * *

**8.18.2 Alternate Preparation, Parcels on Pallets**

DSCF price mailings not prepared under 8.18.1 may be prepared as follows:

*[Revise the first sentence of item a to read as follows:]*

a. *General.* All DSCF price mail in the mailing must be sorted to 5-digit scheme, 5-digit, SCF (machinable parcels only), or 3-digit (nonmachinable) destinations under 8.18.2 (*i.e.,* mail prepared under 8.18.1 and mail sacked under 255.4.2 must not be included in a mailing prepared under 8.18.2). * * *

*[Revise the text of item b to read as follows:]*

b. *Minimum volume.* To qualify for the DSCF price, no pallet may contain fewer than 35 pieces and 200 pounds, and for the entire mailing the average number of DSCF price pieces per 5-digit scheme, 5-digit, SCF, or 3-digit destination must be at least 50.

* * * * *

*[Revise the text of items c, c1, and c2, to read as follows:]*

c. *Overflow.* After filling pallets to a 5-digit scheme, 5-digit, SCF, or 3-digit destination, any remaining pieces that do not meet the minimum pallet requirements may be prepared in one or both of the following ways:

1. Placed in 5-digit scheme, 5-digit, SCF, or 3-digit overflow sacks (no minimum number of pieces per sack) that are labeled in accordance with the DSCF sacking requirements in 255.4.2. Overflow pieces sacked in this manner are eligible for the DSCF prices.
2. Placed on a 5-digit scheme, 5-digit, SCF, or 3-digit pallet labeled under 8.18.2 that does not meet the minimums for the DSCF price. Overflow pieces palletized in this manner are not eligible for the DSCF prices but are eligible for the DNDC prices.

* * * * *

*[Renumber items f and g as items g and h and add new item f to read as follows:]*

*f. SCF.* Pallet labeling:

1. Line 1: Use L051.
2. Line 2: ''PSVC PARCELS SCF.''

* * * * *

*[Revise the first and fourth sentences of renumbered item h to read a follows:]*

h. *Documentation.* A list of each 5-digit scheme, 5-digit, SCF, and 3-digit pallet in the mailing that qualifies for the DSCF price must be submitted. * * * * * * For each pallet, the listing must show: The pallet identification number, the applicable 5-digit scheme, 5-digit, SCF, or 3-digit destination of the pallet, the total weight of pieces on the pallet, the total number of pieces on the pallet, and the running total of pieces (*i.e.,* the number equal to the number of pieces for that pallet plus the sum of the pieces on all pallets listed before it). * * *

* * * * *

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* * * * *

**U**

* * * * *

[Add ''USPS Connect Local, 253'' alphabetically under ''U''.]

* * * * *

**Notice 123 (Price List)**

*[Revise competitive prices as applicable.]*

* * * * *

We will publish an appropriate amendment to 39 CFR part 111 to reflect these changes.

**Joshua J. Hofer,**

*Attorney, Ethics & Legal Compliance.*

[FR Doc. 2021–25059 Filed 11–17–21; 8:45 am]

BILLING CODE P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 63**

**[EPA–HQ–OAR–2020–0572; FRL–7526–03–OAR]**

**RIN 2060–AU57**

# National Emission Standards for Hazardous Air Pollutants: Flexible Polyurethane Foam Fabrication Operations Residual Risk and Technology Review and Flexible Polyurethane Foam Production and Fabrication Area Source Technology Review

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This action finalizes the residual risk and technology review (RTR) conducted for the Flexible Polyurethane Foam Fabrication Operations source category regulated under national emission standards for hazardous air pollutants (NESHAP). This action also finalizes the NESHAP technology review for two area source categories, Flexible Polyurethane Foam Production and Flexible Polyurethane Foam Fabrication, which are combined in one subpart. In this action, the EPA is finalizing the proposed revisions to the Flexible Polyurethane Foam Fabrication Operations major source NESHAP, which include adding a numeric emission limit for existing flame lamination units, removing exemptions for periods of startup, shutdown, and malfunction (SSM) and specifying that the emissions standards always apply, requiring periodic performance tests, and requiring electronic reporting of performance test results and compliance reports. In this action, the EPA is also finalizing the proposed revisions to the NESHAP for Flexible Polyurethane Foam Production and Flexible Polyurethane Foam Fabrication area sources to remove references to the provisions of another NESHAP that has been revised and no longer contains the referenced provisions. Implementation of these final rules is not expected to result in significant changes to the hazardous air pollutant (HAP) emissions from affected facilities in these three source categories or to human health impacts or environmental impacts associated with those emissions. However, this action will result in improved monitoring, compliance, and implementation of the existing standards and codifies existing industry practices to prevent backsliding.

**DATES:** This final rule is effective on November 18, 2021.

**ADDRESSES:** The U.S. Environmental Protection Agency (EPA) has established a docket for this action under Docket ID No. EPA–HQ–OAR–2020–0572. All documents in the docket are listed on the *https://www.regulations.gov/* website. Although listed, some information is not publicly available, *e.g.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *https://www.regulations.gov/.* Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room was closed to public visitors on March 31, 2020, to reduce the risk of transmitting COVID–19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. There is a temporary suspension of mail delivery to the EPA, and no hand deliveries are currently accepted. For further information and updates on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets.*

**FOR FURTHER INFORMATION CONTACT:** For questions about this final action, contact Ms. Lisa Sutton, Sector Policies and Programs Division (D243–04), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–3450; fax number: (919) 541–4991; and email address: *sutton.lisa@epa.gov.* For specific information regarding the risk modeling methodology, contact Mr. Chris Sarsony, Health and Environmental Impacts Division (C539–02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–4843; fax number: (919) 541–0840; and email address: *sarsony.chris@epa.gov.*

**SUPPLEMENTARY INFORMATION:** *Preamble acronyms and abbreviations.* The Agency uses multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

CAA Clean Air Act
CDX Central Data Exchange
CEDRI Compliance and Emissions Data Reporting
CFR Code of Federal Regulations
CRA Congressional Review Act
EPA Environmental Protection Agency
ERT Electronic Reporting Tool
GACT generally available control technology
HAP hazardous air pollutants(s)
HCl hydrochloric acid
HQ hazard quotient
HQREL hazard quotient reference exposure level
ICR Information Collection Request
km kilometer
MACT maximum achievable control technology
MIR maximum individual risk
NAICS North American Industry Classification System
NESHAP national emission standards for hazardous air pollutants
NTTAA National Technology Transfer and Advancement Act
OAQPS Office of Air Quality Planning and Standards
OMB Office of Management and Budget
OSHA Occupational Safety and Health Administration
PB–HAP hazardous air pollutants known to be persistent and bio-accumulative in the environment
RATA relative accuracy test audit
REL reference exposure level
RFA Regulatory Flexibility Act
RIA Regulatory Impact Analysis
RIN Regulatory Information Number
RTR risk and technology review
SSM startup, shutdown, and malfunction
UMRA Unfunded Mandates Reform Act
TOSHI target organ-specific hazard index
tpy tons per year
UPL upper prediction limit
XML extensible markup language

Throughout this document, wherever ''we,'' ''us,'' or ''our'' is used, we mean the EPA.

*Background information.* On January 11, 2021, the EPA proposed revisions to the major source Flexible Polyurethane Foam Fabrication Operations NESHAP based on our RTR and to the NESHAP for Flexible Polyurethane Foam Production and Fabrication area sources based on our technology review. In this action, we are finalizing decisions and revisions for the rules. We summarize some of the more significant comments we timely received regarding the proposed rule and provide our responses in this preamble. A summary of all other public comments on the proposal and the EPA's responses to those comments is available in *Summary of Public Comments and Responses on the Proposed Rule for the Major Source Flexible Polyurethane Foam Fabrication NESHAP and the NESHAP for Flexible Polyurethane Foam Production and Fabrication Area Sources (86 FR 1868, January 11, 2021*), Docket ID No. EPA–HQ–OAR–2020–0572. A ''track changes'' version of the regulatory language that incorporates

the changes in this action is available in the docket.

*Organization of this document.* The information in this preamble is organized as follows:

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H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
I. National Technology Transfer and Advancement Act (NTTAA)
J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations
K. Congressional Review Act (CRA)

## I. General Information

### *A. Does this action apply to me?*

The source categories that are the subject of this final action are the Flexible Polyurethane Foam Fabrication Operations major source category regulated under 40 CFR part 63, subpart MMMMM, and the Flexible Polyurethane Foam Production and Flexible Polyurethane Foam Fabrication area source categories, regulated under 40 CFR part 63, subpart OOOOOO. The North American Industry Classification System (NAICS) code for fabricators of flexible polyurethane foam is 326150, ''Urethane and Other Foam Product (except Polystyrene) Manufacturing.'' This list of categories and NAICS codes is not intended to be exhaustive but rather provides a guide for readers regarding the entities that this final action is likely to affect. The final standards will be directly applicable to the affected sources. Federal, state, local, and tribal government entities would not be affected by this action.

The Flexible Polyurethane Foam Fabrication Operations major source category was added to the EPA's HAP source category list in 1996. (61 FR 28197, June 4, 1996.) The NESHAP for that major source category, 40 CFR part 63, subpart MMMMM, was promulgated in 2003. (68 FR 18062, April 14, 2003.) The Flexible Polyurethane Foam Fabrication area source category was added to the EPA's HAP source category list in 1999. (64 FR 38706, July 19, 1999.) The Flexible Polyurethane Foam Production area source category was added to the EPA's HAP source category list in 2002. (67 FR 70427, November 22, 2002.) The Flexible Polyurethane Foam Production major source category, Part 63, subpart III, was included on the EPA's initial HAP source category list. (57 FR 31576, July 16, 1992.) The maximum achievable control technology (MACT) standards for subpart III were initially promulgated in 1998. (63 FR 53980, October 7, 1998.) The EPA established one area source NESHAP at 40 CFR part 63, subpart OOOOOO, that applies to the two area source categories due to the similarity of their operations and because they are often collocated. (72 FR 38864, July 16, 2007.)

The Flexible Polyurethane Foam Fabrication Operations major source category and the Flexible Polyurethane Foam Fabrication area source category include facilities engaged in cutting, gluing, and/or laminating pieces of flexible polyurethane foam. These source categories include fabrication operations that are collocated with foam production plants as well as those located offsite from foam production plants. Emissions from foam fabrication primarily result from the lamination of polyurethane foam to adhere foam to other substrates and from the use of HAP-based adhesives in the gluing process. The Flexible Polyurethane Foam Production area source category includes facilities that manufacture foam made from a polymer containing a plurality of carbamate linkages in the chain backbone (polyurethane). Polyurethane is commonly made by reacting a polyisocyanate with an organic polyhydroxyl material in the presence of water. Application of blowing agents, catalysts, surfactants, and fillers transform the polyurethane into a foam with specialized properties.

This final action addresses the major source NESHAP that applies to the Flexible Polyurethane Foam Fabrication Operations major source category and addresses the area source NESHAP that applies to the Flexible Polyurethane Foam Production area source category and the Flexible Polyurethane Foam Fabrication area source category. If you have any questions regarding the applicability of any aspect of this NESHAP, please contact the appropriate person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section of this preamble.

### *B. Where can I get a copy of this document and other related information?*

In addition to being available in the docket, an electronic copy of this final action will also be available on the internet. Following signature by the

EPA Administrator, the EPA will post a copy of this final action at: *https://www.epa.gov/stationary-sources-air-pollution/flexible-polyurethane-foam-fabrication-operations-national-emission.* Following publication in the **Federal Register**, the EPA will post the **Federal Register** version and key technical documents at this same website.

Additional information is available on the RTR website at *https://www.epa.gov/stationary-sources-air-pollution/risk-and-technology-review-national-emissions-standards-hazardous.* This information includes an overview of the RTR program and links to project websites for the RTR source categories.

*C. Judicial Review and Administrative Reconsideration*

Under Clean Air Act (CAA) section 307(b)(1), judicial review of this final action is available only by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit by January 18, 2022. Under CAA section 307(b)(2), the requirements established by this final rule may not be challenged separately in any civil or criminal proceedings brought by the EPA to enforce the requirements.

Section 307(d)(7)(B) of the CAA further provides that only an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review. This section also provides a mechanism for the EPA to reconsider the rule if the person raising an objection can demonstrate to the Administrator that it was impracticable to raise such objection within the period for public comment or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule. Any person seeking to make such a demonstration should submit a Petition for Reconsideration to the Office of the Administrator, U.S. EPA, Room 3000, WJC South Building, 1200 Pennsylvania Ave. NW, Washington, DC 20460, with a copy to both the person(s) listed in the preceding **FOR FURTHER INFORMATION CONTACT** section, and the Associate General Counsel for the Air and Radiation Law Office, Office of General Counsel (Mail Code 2344A), U.S. EPA, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

## II. Background

*A. What is the statutory authority for this action?*

The statutory authority for this action is provided by sections 112 and 301 of the CAA, as amended (42 U.S.C. 7401 *et seq.*). Section 112 of the CAA establishes a two-stage regulatory process to address emissions of hazardous air pollutants (HAP) from stationary sources. In the first stage, we must identify categories of sources emitting one or more of the HAP listed in CAA section 112(b) and then promulgate technology-based NESHAP for those sources. ''Major sources'' are those that emit, or have the potential to emit, any single HAP at a rate of 10 tons per year (tpy) or more, or 25 tpy or more of any combination of HAP. All other sources are ''area sources.'' For major sources, these standards are commonly referred to as maximum achievable control technology (MACT) standards and must reflect the maximum degree of emission reductions of HAP achievable (after considering cost, energy requirements, and non-air quality health and environmental impacts). In developing MACT standards, CAA section 112(d)(2) directs the EPA to consider the application of measures, processes, methods, systems, or techniques, including, but not limited to, those that reduce the volume of or eliminate HAP emissions through process changes, substitution of materials, or other modifications; enclose systems or processes to eliminate emissions; collect, capture, or treat HAP when released from a process, stack, storage, or fugitive emissions point; are design, equipment, work practice, or operational standards; or any combination of the above.

For these MACT standards, the statute specifies certain minimum stringency requirements, which are referred to as MACT floor requirements, and which may not be based on cost considerations. See CAA section 112(d)(3). For new sources, the MACT floor cannot be less stringent than the emission control achieved in practice by the best-controlled similar source. The MACT standards for existing sources can be less stringent than floors for new sources, but they cannot be less stringent than the average emission limitation achieved by the best-performing 12 percent of existing sources in the category or subcategory (or the best-performing five sources for categories or subcategories with fewer than 30 sources). In developing MACT standards, we must also consider control options that are more stringent than the floor under CAA section 112(d)(2). We may establish standards more stringent than the floor, based on the consideration of the cost of achieving the emissions reductions, any non-air quality health and environmental impacts, and energy requirements. For area sources, CAA section 112(d)(5) gives the EPA discretion to set standards based on generally available control technologies or management practices (GACT standards) in lieu of MACT standards.

In the second stage of the NESHAP regulatory process, the CAA requires the EPA to undertake two different analyses, which we refer to as the technology review and the residual risk review. Under the technology review, which is applicable to both MACT and GACT standards, we must review the technology-based standards and revise them ''as necessary (taking into account developments in practices, processes, and control technologies)'' no less frequently than every 8 years, pursuant to CAA section 112(d)(6). Under the residual risk review, which is limited to the MACT standards, we must evaluate the risk to public health remaining after application of the technology-based standards and revise the standards, if necessary, to provide an ample margin of safety to protect public health or to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect. The residual risk review is required within 8 years after promulgation of the technology-based standards, pursuant to CAA section 112(f). In conducting the residual risk review, if the EPA determines that the current standards provide an ample margin of safety to protect public health, it is not necessary to revise the MACT standards pursuant to CAA section 112(f).[1] For more information on the statutory authority for this rule, see the proposal preamble (86 FR 1868, January 11, 2021) and the memorandum, *CAA Section 112 Risk and Technology Reviews: Statutory Authority and Methodology,* December 14, 2017, available in the docket for this action (Document ID EPA–HQ–OAR–2020–0572–0016).

*B. What are the source categories and how do the current NESHAPs regulate their HAP emissions?*

The EPA promulgated MACT standards for major source Flexible Polyurethane Foam Fabrication

[1] The court has affirmed this approach of implementing CAA section 112(f)(2)(A): *NRDC* v. *EPA,* 529 F.3d 1077, 1083 (D.C. Cir. 2008) (''If EPA determines that the existing technology-based standards provide an 'ample margin of safety,' then the Agency is free to readopt those standards during the residual risk rulemaking.'').

Operations facilities in 2003 under 40 CFR part 63, subpart MMMMM. The standards apply to major sources of HAP at existing and new flexible polyurethane foam fabrication facilities. Because of their potential to generate HAP emissions, the processing units of interest at foam fabrication facilities are loop slitters and flame lamination units. The 2003 MACT standards for Flexible Polyurethane Foam Fabrication Operations require HAP emissions reductions and control for new flame lamination units and prohibit use of HAP-based adhesives in new and existing loop slitting operations. For new flame lamination units, a 90 percent reduction in HAP emissions is required. For existing flame lamination units, the 2003 rule had no MACT emission limits. For new and existing loop slitters, the 2003 MACT standards prohibited use of any adhesive containing 5 percent or more (by weight) of total HAP. The EPA estimates that there are currently three facilities subject to subpart MMMMM.

In 2007, the EPA promulgated GACT standards for the Flexible Polyurethane Foam Production area source category and the Flexible Polyurethane Foam Fabrication area source category together under 40 CFR part 63, subpart OOOOOO. The GACT standards required that methylene chloride be significantly reduced or eliminated from slabstock foam production, molded foam release agents, equipment cleaning, rebond foam mold release agents, and foam fabrication adhesive use. Although both area source categories were listed for regulation due to emissions of the urban HAP methylene chloride, the EPA finds that methylene chloride is no longer used within either source category. The Flexible Polyurethane Foam Production area source category includes facilities that manufacture foam made from polyurethanes, which are in the class of compounds called ''reaction polymers.'' There are three types of polyurethane foam production facilities: Slabstock flexible polyurethane foam (slabstock foam), molded flexible polyurethane foam (molded foam), and rebond foam. Slabstock foam is produced in large continuous buns that are then cut in the desired size and shape. Molded foam is produced by ''shooting'' the foam mixture into a mold of the desired shape and size. Rebond foam is made from scrap foam that is converted into a material primarily used for carpet underlay. The EPA estimates that there are 32 facilities currently subject to the area source standards, of which approximately 20 are believed to be owned by small businesses.

For both the Flexible Polyurethane Foam Operations major source category and the Flexible Polyurethane Foam Fabrication area source category, operations involve cutting, bonding, and/or laminating pieces of flexible polyurethane foam together or to other substrates. Typical bonding techniques include gluing, taping, and flame lamination.

Both the Flexible Polyurethane Foam Production and Flexible Polyurethane Fabrication Operations area source categories were listed for regulation due to emissions of the urban HAP methylene chloride. At the time of the initial area source standards promulgation, methylene chloride was the only urban HAP used at foam production and foam fabrication facilities. Now, however, there are no known urban HAP used at foam production and foam fabrication facilities. In the past, slabstock foam production facilities sometimes used methylene chloride as an auxiliary blowing agent to control the density and other properties of the foam as it expanded during the pouring process. Methylene chloride was also sometimes used as an equipment cleaner, in particular for mix heads. A small number of molded and rebond foam facilities used methylene chloride in mold release agents, and some molded foam facilities used it as a mixhead cleaner. Foam fabricators used methylene chloride-based adhesives to adhere pieces of foam to one another. Flame laminators have never used methylene chloride and, as such, are not regulated by the area source standards.

*C. What changes did we propose for flexible polyurethane foam fabrication operations for major sources and flexible polyurethane foam production and fabrication area sources in our January 11, 2021, proposal?*

On January 11, 2021, the EPA published a proposed rule in the **Federal Register** (86 FR 1868) for the Flexible Polyurethane Foam Fabrication Operations NESHAP for major sources, 40 CFR part 63, subpart MMMMM, and the NESHAP for Flexible Polyurethane Foam Production and Flexible Polyurethane Foam Fabrication Area Sources, 40 CFR part 63, subpart OOOOOO, that took into consideration the RTR analyses for major sources and the technology review for area sources.

For the major source Flexible Polyurethane Foam Fabrication Operations NESHAP, we proposed that the health risks due to HAP emissions from the source category are acceptable, that the NESHAP provides an ample margin of safety to protect public health and that additional standards are not necessary to prevent an adverse environmental effect. To address emissions sources that do not have an emissions limit in the existing NESHAP, we proposed a numeric limit for HCl emissions from existing flame laminators under CAA section 112(d)(2) and (3). As a result of the technology review, we proposed to lower the amount of HAP that could be contained in an adhesive for that material to be considered a HAP-based adhesive. For this change, the definition of ''HAP-based adhesive'' was revised from adhesive with a HAP weight of 5 percent or more to adhesive with a HAP weight of 1 percent or more. In addition, we proposed to amend the NESHAP to list specific carcinogenic HAP that must be included in the adhesive HAP content calculation, rather than including references to other rules where these HAP were previously but are no longer listed. We also proposed revisions to the SSM provisions of this NESHAP to ensure it is consistent with the court decision in *Sierra Club* v. *EPA,* 551 F.3d 1019 (D.C. Cir. 2008). Finally, we proposed revisions to the recordkeeping and reporting requirements of the NESHAP to require the use of electronic reporting of performance test reports and semiannual reports and to require initial and periodic performance testing (every 5 years) for flame lamination units.

For the NESHAP for Flexible Polyurethane Foam Production and Flexible Polyurethane Foam Fabrication Area Sources, we proposed that no revisions to the NESHAP are necessary based on our technology review. Where subpart OOOOOO references the NESHAP for flexible polyurethane foam production major sources (40 CFR part 63, subpart III), we proposed to make conforming changes to reflect amendments made to subpart III. For additional information regarding the proposed rule, see the January 11, 2021, proposal (86 FR 1868).

## III. What is included in these final rules?

This action finalizes the EPA's determinations pursuant to the RTR provisions of CAA section 112 for the Flexible Polyurethane Foam Fabrication Operations major source category and the CAA technology review provisions for the Flexible Polyurethane Foam Production and Fabrication area source categories. This action amends the Flexible Polyurethane Foam Fabrication Operations major source NESHAP and the NESHAP for the Flexible

Polyurethane Foam Production and Fabrication area source categories based on those determinations. This action also finalizes other changes to the Flexible Polyurethane Foam Fabrication Operations major source NESHAP, including the proposed addition of a numeric emissions limit for existing flame lamination units under the authority of CAA section 112(d)(2) and (3), revisions to the SSM requirements, addition of electronic reporting requirements, and editorial corrections. For the Flexible Polyurethane Foam Production and Fabrication area sources NESHAP, this action finalizes the proposed revisions to the rule to eliminate references to another NESHAP (Subpart III, National Emission Standards for Hazardous Air Pollutants for Flexible Polyurethane Foam Production) that has been revised and no longer contains the referenced provisions.

*A. What are the final rule amendments based on the risk review for the major source Flexible Polyurethane Foam Fabrication Operations source category?*

The EPA proposed no changes to the Flexible Polyurethane Foam Fabrication Operations major source NESHAP based on the risk review conducted pursuant to CAA section 112(f). In this action, we are finalizing our proposed determination that risks from the Flexible Polyurethane Foam Fabrication Operations major source category are acceptable, the standards provide an ample margin of safety to protect public health, and more stringent standards are not necessary to prevent an adverse environmental effect. The EPA received no new data or other information during the public comment period that causes us to change that proposed determination. Therefore, we are not making any revisions to the existing standards under CAA section 112(f), and we are readopting the existing standards. Further information regarding these decisions is provided in section IV of this preamble.

*B. What are the final rule amendments based on the technology reviews for the major source Flexible Polyurethane Foam Fabrication Operations source category and the Flexible Polyurethane Foam Production and Fabrication area source categories?*

We determined that there are developments in practices, processes, and control technologies that warrant revisions to the MACT standards for the major source Flexible Polyurethane Foam Fabrication Operations source category. Therefore, to satisfy the requirements of CAA section 112(d)(6), consistent with the proposal, we are revising the MACT standards to include a revised definition of HAP-based adhesive. The analyses and rationale for these decisions are described in section IV.B of this preamble. As part of the technology review, we also identified a regulatory gap (a previously unregulated process) and are establishing a new standard to fill that gap as described in section III.C of this preamble.

*C. What are the final rule amendments pursuant to section 112(d)(2) and (3) for the major source Flexible Polyurethane Foam Fabrication Operations source category?*

During the technology review, we identified existing flame laminators as an unregulated process in the major source category. For major sources, the EPA is required to set technology-based standards for sources of HAP emissions that reflect the maximum reductions of HAP emissions achievable (after considering cost, energy requirements, and non-air health and environmental impacts). However, these standards must be no less stringent than the average emission performance of the best performing five sources for a source category with fewer than 30 sources, as is the case here. Therefore, to satisfy the requirements of CAA section 112(d)(2) and (3), consistent with the proposal, we are revising the major source Flexible Polyurethane Foam Fabrication Operations NESHAP to include a MACT standard for existing source flame laminators. The analyses and rationale for this standard are described in section IV.C of this preamble.

*D. What are the final rule amendments addressing emissions during periods of startup, shutdown, and malfunction?*

We are finalizing the proposed amendments to the major source Flexible Polyurethane Foam Fabrication Operations NESHAP to remove and revise provisions related to SSM. In its 2008 decision in *Sierra Club* v. *EPA,* 551 F.3d 1019 (D.C. Cir. 2008), the court vacated portions of two provisions in the EPA's CAA section 112 regulations governing the emissions of HAP during periods of SSM. Specifically, the court vacated the SSM exemption contained in 40 CFR 63.6(f)(1) and (h)(1), holding that under section 302(k) of the CAA, emissions standards or limitations must be continuous in nature and that the SSM exemption violates the CAA's requirement that some CAA section 112 standards apply continuously. Previously, the 2003 Flexible Polyurethane Foam Fabrication Operations NESHAP included exemptions for standards during SSM. As explained in section IV.E of the January 2021 proposal preamble (86 FR 1868 at 1885, January 11, 2021), the EPA proposed that the Flexible Polyurethane Foam Fabrication Operations NESHAP would require that the standards always apply, consistent with the court decision in *Sierra Club* v. *EPA,* 551 F.3d 1019 (D.C. Cir. 2008).

Table 7 to subpart MMMMM of 40 CFR part 63 (General Provisions applicability table) is being revised to change the specification of the requirements that apply during periods of SSM. We eliminated or revised certain recordkeeping and reporting requirements related to the eliminated SSM exemptions. The EPA also made other harmonizing changes to remove or modify inappropriate, unnecessary, or redundant language in the absence of the SSM exemptions. We proposed to remove the SSM exemptions such that the standards always apply because we determined that facilities in this source category can always meet the applicable emission standards in the NESHAP, including periods of startup and shutdown, without additional standards or work practices. We received no information to cause us to change our conclusion; therefore, the EPA is finalizing the removal of the SSM exemptions and is requiring that the standards always apply. The legal rationale and detailed changes for startup and shutdown periods that we are finalizing here are set forth in the January 11, 2021, preamble to the proposed rule. See 86 FR 1868 at 1885 and 1886.

Further, as proposed, the EPA is not including standards for malfunctions. As discussed in the proposal preamble, the EPA interprets CAA section 112 as not requiring emissions that occur during periods of malfunction to be factored into development of CAA section 112 standards, although the EPA has the discretion to set standards for malfunctions where feasible. See 86 FR 1868 at 1885 and 1886.

*E. What other changes have been made to the NESHAP?*

The EPA is requiring owners or operators of flexible polyurethane foam fabrication operations major sources to submit electronic copies of certain required performance test reports, performance evaluation reports, and semiannual reports through the EPA's Central Data Exchange using the Compliance and Emissions Data Reporting Interface (CEDRI). The final rule requires that performance test results and performance evaluation results be submitted using the Electronic Reporting Tool. For

semiannual reports, the final rule requires that owners or operators use the appropriate spreadsheet template to submit information to CEDRI. The final version of the templates for these reports are located on the CEDRI website.[2]

The electronic submittal of the reports addressed in this rulemaking will increase the usefulness of the data contained in those reports, is in keeping with current trends in data availability and transparency, will further assist in the protection of public health and the environment, will improve compliance by facilitating the ability of regulated facilities to demonstrate compliance with requirements and by facilitating the ability of delegated state, local, tribal, and territorial air agencies and the EPA to assess and determine compliance, and will ultimately reduce burden on regulated facilities, delegated air agencies, and the EPA. Electronic reporting also eliminates paper-based, manual processes, thereby saving time and resources, simplifying data entry, eliminating redundancies, minimizing data reporting errors, and providing data quickly and accurately to the affected facilities, air agencies, the EPA, and the public. For a more thorough discussion of electronic reporting, see the memorandum, *Electronic Reporting Requirements for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) Rules,* available in the docket for this action (Document ID EPA–HQ–OAR–2020–0572–0012).

*F. What are the effective and compliance dates of the standards?*

The revisions to the MACT standards being promulgated in this action are effective on November 18, 2021.

Affected sources that commenced construction or reconstruction on or before January 11, 2021, must comply with all amendments, except for the electronic format for submitting compliance reports, no later than 180 days after the effective date of the final rule, or upon startup, whichever is later. Affected sources that commence construction or reconstruction after January 11, 2021, must comply with all requirements of the subpart, including the amendments being finalized, except for the electronic format for submitting compliance reports, no later than the effective date of the final rule or upon startup, whichever is later. All affected sources must comply with the electronic compliance report requirements no later than either 180 days after the effective date of the final rule or once the report template for this subpart has been available on the CEDRI website for 1 year, whichever date is later. All affected facilities must continue to meet the current requirements of 40 CFR part 63, subpart MMMMM, until the applicable compliance date of the amended rule.

This final action is not a ''major rule'' as defined by 5 U.S.C. 804(2), so the effective date of the final rule is the promulgation date as specified in CAA section 112(d)(10). For existing sources, we are finalizing four changes that would impact ongoing compliance requirements for 40 CFR part 63, subpart MMMMM. As discussed elsewhere in this preamble, we are adding a numeric limit for HCl emissions from existing flame laminators. We are also adding a requirement that notifications, performance test results, and compliance reports be submitted electronically. Our experience with similar industries that are required to convert reporting mechanisms to install necessary hardware and software, become familiar with the process of submitting performance test results electronically through the EPA's CEDRI, test these new electronic submission capabilities, and reliably employ electronic reporting shows that a period of a minimum of 90 days, and, more typically, 180 days, is generally necessary to accomplish these revisions. For the final SSM revisions, we recognize that there are no facilities that are currently using the SSM provisions for new flame laminators, since there have not been any new sources since the standard was promulgated. As a result, we understand that no additional time is needed for compliance with the revised SSM provisions. Prior to proposal, we consulted with the regulated industry regarding the proposed limits for existing flame laminators and the requirement to conduct performance testing to demonstrate initial compliance within 180 days of the publication of the final rule and no less than every 5 years thereafter, to better understand the likely implications of the proposed revisions. Representatives of the company that owns the two impacted facilities indicated that performance testing could be done within the 180-day time frame for compliance. For the flame lamination unit existing sources that would be subject to the newly established emission limit, we understand that the facilities are able to meet the limit without add-on controls. However, we do recognize that facilities need time to conduct performance tests and demonstrate compliance with the emission limit.

To reduce the complication that different compliance dates for individual requirements would create and the additional burden such an assortment of dates would impose, considering our assessment of the timeframe needed for compliance with the entirety of the revised requirements, the EPA is finalizing a period of 180 days after the regulation's effective date within which all affected sources that commenced construction or reconstruction on or before January 11, 2021, must be in compliance with the regulation's revised requirements, with the exception of the electronic reporting requirements.

## IV. What is the rationale for our final decisions and amendments for the major source Flexible Polyurethane Foam Fabrication Operations source category and the Flexible Polyurethane Foam Production and Fabrication area source categories?

For each issue, this section provides a description of what we proposed and what we are finalizing for the issue, the EPA's rationale for the final decisions and amendments, and a summary of key comments and responses. For all comments not discussed in this preamble, comment summaries and the EPA's responses can be found in the comment summary and response document available in the docket.

*A. Residual Risk Review for the Major Source Flexible Polyurethane Foam Fabrication Operations Source Category*

1. What did we propose pursuant to CAA section 112(f) for the major source Flexible Polyurethane Foam Fabrication Operations source category?

We proposed that the health risks due to emissions of HAP from the major source Flexible Polyurethane Foam Fabrication Operations source category are acceptable and that the NESHAP provides an ample margin of safety to protect public health and that no additional standards are necessary to prevent an adverse environmental effect. Table 1 of this preamble provides a summary of the results of the inhalation risk assessment for the source category. More detailed information on the risk assessment can be found in the *Residual Risk Assessment for the Flexible Polyurethane Foam Fabrication Source Category in Support of the 2021*

[2] See *https://www.epa.gov/electronic-reporting-air-emissions/electronic-reporting-tool-ert.*

*Risk and Technology Review Final Rule* in the docket for this action.

TABLE 1—FLEXIBLE POLYURETHANE FOAM FABRICATION SOURCE CATEGORY INHALATION RISK ASSESSMENT RESULTS

| Risk assessment | Maximum individual cancer risk (in 1 million) | | Estimated population at increased risk of cancer ≥ 1-in-1 million | | Estimated annual cancer incidence (cases per year) | | Maximum chronic noncancer TOSHI [3] | | Maximum screening acute noncancer HQ [4] |
|---|---|---|---|---|---|---|---|---|---|
| | Based on actual emissions | Based on allowable emissions | Based on actual emissions | Based on allowable emissions | Based on actual emissions | Based on allowable emissions | Based on actual emissions | Based on allowable emissions | Based on actual emissions |
| Source Category | 0 | 0 | 0 | 0 | 0 | 0 | 0.002 | 0.002 | HQREL = <1 |
| Whole Facility | 0.1 | | 0 | | 0.00001 | | 0.2 | | |

The results of the inhalation risk assessment using actual emissions data, as shown in Table 1 of this preamble, indicate that no carcinogens are emitted by this category. Therefore, the cancer MIR based on actual emissions (lifetime) is zero and the total estimated annual cancer incidence (national) from these facilities based on actual emission levels is zero excess cancer cases per year. The maximum chronic noncancer target organ-specific hazard index (TOSHI) value based on actual emissions is 0.002 driven by HCl. The maximum screening acute noncancer HQREL value (off-facility site) is 0.003 driven by HCl. No persistent and bio-accumulative HAP (PB–HAP) are emitted from the Flexible Polyurethane Foam Fabrication Operations source category, therefore, a multipathway assessment was not conducted. A screening-level evaluation of the potential adverse environmental risk associated with emissions of HCl indicated that no ecological benchmarks were exceeded.

As shown in Table 1, the maximum facility-wide cancer MIR is 0.1-in-1 million, driven by 2,4/2,6-toluene diisocyanate mixture (TDI) emissions from a vertical non-category point source and a non-category fugitive point source. The total estimated cancer incidence from the whole facility is 0.00001 excess cancer cases per year, or one excess case in every 100,000 years. The maximum facility-wide TOSHI for the source category is estimated to be 0.2, mainly driven by 2,4/2,6-TDI emissions from a vertical non-category point source and a non-category fugitive point source. Considering all the health risk information and factors discussed above, the EPA proposed that the risks are acceptable.

No carcinogens are emitted by the Flexible Polyurethane Foam Fabrication Operations source category. Therefore, there are no individuals in the exposed population with lifetime cancer risks above 1-in-1 million as a result of actual or allowable emissions from this category. In addition, the maximum chronic noncancer TOSHI value based on actual and allowable emissions is well below 1 (0.002 and 0.2, respectively) and the maximum screening acute noncancer HQ value (off-facility site) is also well below 1 (0.003). Therefore, the EPA proposed that additional emissions controls for flexible polyurethane foam fabrication operations facilities are not necessary to provide an ample margin of safety to protect public health. In addition, based on our screening-level evaluation of the potential for adverse environmental effects, we concluded that more stringent standards were not necessary to prevent an adverse environmental effect. Considering all analyses, we did not propose any changes to the NESHAP based on the risk review. For more details regarding the risk review, see the proposal preamble (86 FR 1868 at 1876).

2. How did the risk review change for the major source Flexible Polyurethane Foam Fabrication Operations source category?

The EPA has not made any changes to either the risk assessments or our determinations regarding risk acceptability, ample margin of safety, or adverse environmental effects for the major source Flexible Polyurethane Foam Fabrication Operations source category since the proposal was published on January 11, 2021 (86 FR 1868). We are finalizing the risk review as proposed with no changes.

3. What key comments did we receive on the risk review, and what are our responses?

We received one comment in support of and one comment against the proposed residual risk review and our determination is that no revisions are warranted under CAA section 112(f)(2) for the source category. The comment in support of the determination noted that the residual risk review was reasonable and supported by the available data. The comment opposed to the determination was related to a concern that the EPA may not have included all HAP emitted from the source category, particularly from flame retardants. After review of these comments, and with no information from which to conclude that any HAP emissions are missing from the data or analyses performed, we determined that no changes are needed to the risk assessment. The comments and our specific responses can be found in the document, *Summary of Public Comments and Responses on the Proposed Rule for the Major Source Flexible Polyurethane Foam Fabrication NESHAP and the NESHAP for Flexible Polyurethane Foam Production and Fabrication Area Sources,* available in the docket for this rulemaking.

4. What is the rationale for our final approach and final decisions for the risk review?

As noted in our proposal, the EPA sets standards under CAA section 112(f)(2) using ''a two-step standard-setting approach, with an analytical first step to determine an 'acceptable risk' that considers all health information, including risk estimation uncertainty, and includes a presumptive limit on MIR of approximately 1-in-10 thousand'' (see 54 FR 38045, September 14, 1989). We weigh all health risk factors in our risk acceptability determination, including the cancer MIR, cancer incidence, the maximum chronic noncancer TOSHI, the maximum acute noncancer HQ, the extent of noncancer risks, the distribution of cancer and noncancer risks in the exposed population, and the risk estimation uncertainties.

In the second step of the approach, the EPA considers whether the emissions standards provide an ample margin of safety to protect public health ''in consideration of all health

[3] The TOSHI is the sum of the chronic noncancer HQ for substances that affect the same target organ or organ system.

[4] The maximum estimated acute exposure concentration was divided by available short-term threshold values to develop HQ values.

information, including the number of persons at risk levels higher than approximately 1-in-1 million, as well as other relevant factors, including costs and economic impacts, technological feasibility, and other factors relevant to each particular decision.'' *Id.*

For the Flexible Polyurethane Foam Fabrication Operations major source category, the risk analysis indicates that no carcinogens are emitted by the source category, and therefore, there is no cancer risk. In addition, the maximum chronic noncancer TOSHI value based on actual and allowable emissions is well below 1 and the maximum screening acute noncancer HQ value (off-facility site) is also well below 1. In addition, the screening-level evaluation of the potential for adverse environmental effects indicated that that no ecological benchmarks were exceeded.

We evaluated all comments on the risk review and determined that no changes to the review are needed. For the reasons explained in the proposal, we determined that the risks from the major source Flexible Polyurethane Foam Fabrication Operations source category are acceptable, the current standards provide an ample margin of safety to protect public health, and more stringent standards are not necessary to prevent an adverse environmental effect. Therefore, pursuant to CAA section 112(f)(2), we are finalizing our residual risk review as proposed and readopting the standards for the major source Flexible Polyurethane Foam Fabrication Operations source category.

*B. Technology Review for the Major Source Flexible Polyurethane Foam Fabrication Operations Source Category and the Flexible Polyurethane Foam Production and Fabrication Area Source Categories*

1. What did we propose pursuant to CAA section 112(d)(6) for the major source Flexible Polyurethane Foam Fabrication Operations Source Category and the Flexible Polyurethane Foam Production and Fabrication area source categories?

During the technology review, one development in a practice, process, or control technology was identified for loop slitter use in the Flexible Polyurethane Foam Fabrication Operations major source category. In addition, we identified existing flame laminators as an unregulated process in the major source category, and we proposed standards for those sources under CAA section 112(d)(2) and (3), as described in section IV.C of this preamble.

At the time of the development of the NESHAP, the EPA found that the foam fabrication industry had effectively discontinued the use of adhesives containing methylene chloride, which was the primary HAP in the adhesives used, and had switched to other adhesives that did not contain methylene chloride and contained only small amounts of other HAP. As a result, for both existing and new loop slitters, the definition of HAP-based adhesive included in the 2003 rule was an adhesive containing 5 percent (by weight) or greater of HAP. As part of the technology review, we reviewed other air toxics MACT standards and noted that several other NESHAP, developed both before and after the major source Flexible Polyurethane Foam Fabrication Operations NESHAP, include a definition of non-HAP adhesive or coating (where the coating definition included adhesives) with a lower percentage of HAP content than that of the definition included in the Flexible Polyurethane Foam Fabrication Operations rule. Additionally, through review of information provided by industry, we found that the current adhesives used in loop slitting operations are less than 1-percent HAP content by total weight. Based on the current industry standards of adhesive usage containing less than 1-percent HAP and the definition for HAP-based adhesive from similar source categories regulating adhesives, we proposed to revise the definition of ''HAP-based adhesive'' to read: ''an adhesive containing 1 percent (by weight) or more of HAP, according to EPA Method 311 (appendix A to 40 CFR part 63) or another approved alternative.''

We also proposed to amend 40 CFR 63.8802(a)(1)(i) and (a)(3)(i), which describe how to determine the mass fraction of HAP in each material used, to remove references to Occupational Safety and Health Administration (OSHA)-defined carcinogens as specified in 29 CFR 1910.1200(d)(4). The references to 29 CFR 1910.1200(d)(4) were intended to specify which compounds must be included in calculating the total HAP content of a coating material if the compounds are present at 0.1-percent or greater by mass; however, 29 CFR 1910.1200(d)(4) has been amended and no longer readily defines which compounds are carcinogens. We proposed to replace these references to OSHA-defined carcinogens and 29 CFR 1910.1200(d)(4) with a list (in a proposed new Table 8 to 40 CFR part 63, subpart MMMMM) of those HAP that must be included in calculating total HAP content of a coating material if they are present at 0.1 percent or greater by mass. We proposed to include HAP in this table if they were categorized in the EPA's *Prioritized Chronic Dose-Response Values for Screening Risk Assessments* (May 9, 2014), as a ''human carcinogen,'' ''probable human carcinogen,'' or ''possible human carcinogen'' according to *The Risk Assessment Guidelines of 1986* (EPA/600/8–87/045, August 1987),[5] or as ''carcinogenic to humans,'' ''likely to be carcinogenic to humans,'' or with ''suggestive evidence of carcinogenic potential'' according to the *Guidelines for Carcinogen Risk Assessment* (EPA/630/P–03/001F, March 2005).[6] Detailed information of the technology review can be found in the memorandum titled *Technology Review for the Flexible Polyurethane Foam Manufacturing Source Category,* which is available in the docket for this action (Document ID EPA–HQ–OAR–2020–0572–0003).

For the Flexible Polyurethane Foam Production and Flexible Polyurethane Foam Fabrication area source categories, we found the listed urban HAP methylene chloride is no longer used within either source category. Additionally, we did not find any advances in technologies during our review of the source categories. Detailed information of the technology review can be found in the memorandum titled *Technology Review for the Flexible Polyurethane Foam Production and Fabrication Area Source Categories,* which is available in the docket for this action (Document ID EPA–HQ–OAR–2020–0572–0004).

2. How did the technology review change for the major source Flexible Polyurethane Foam Fabrication Operations Source Category and the Flexible Polyurethane Foam Production and Fabrication area source categories?

The EPA has not made any changes to the technology review since the proposal was published on January 11, 2021. We are finalizing the technology review as proposed with no changes.

3. What key comments did we receive on the technology reviews, and what are our responses?

We received comments in support of the proposed technology reviews and the revisions we proposed to the definition of HAP-based adhesive resulting from the findings of the

[5] See *https://www.epa.gov/fera/dose-response-assessment-assessing-health-risks-associated-exposure-hazardous-air-pollutants.*

[6] See *https://www.epa.gov/risk/guidelinescarcinogen-risk-assessment.*

technology review. All commenters supported the proposed revision to the definition of HAP-based adhesive. One commenter noted that the proposed revision should not have an adverse impact on loop-slitting and that it is supported by the industry. Two commenters specifically supported this revision in its effect in limiting backsliding. After review of these comments, we determined that no changes are needed to the technology reviews or the proposed revised definition of HAP-based adhesive. The comments and our specific responses can be found in the document, *Summary of Public Comments and Responses on the Proposed Rule for the Major Source Flexible Polyurethane Foam Fabrication NESHAP and the NESHAP for Flexible Polyurethane Foam Production and Fabrication Area Sources,* available in the docket for this rulemaking.

4. What is the rationale for our final approach for the technology review?

We evaluated all comments on the technology reviews and determined that no changes to the reviews are needed. Commenters identified no developments in practices, processes, or control technologies advances in technologies to consider, beyond the technology-related development identified in the proposal (industry practice of using lower-HAP adhesive in loop-slitting operations). Therefore, pursuant to CAA section 112(d)(6), we are finalizing our technology reviews as proposed.

*C. Actions Taken Pursuant to CAA Sections 112(d)(2) and 112(d)(3)*

1. What did we propose for the major source Flexible Polyurethane Foam Fabrication Operations Source Category?

Pursuant to CAA section 112(d)(2) and (3), we proposed to establish a numeric limit in the Flexible Polyurethane Foam Fabrication Operations major source NESHAP for HCl emissions from existing flame laminators. Through the technology review, we identified these units as sources of HAP emissions that did not have MACT standards in the NESHAP. For the four existing source flame lamination units in the source category, HCl emissions data from only one of these units is available, and the proposed MACT floor was based on the HCl data for this unit. To determine the level of the MACT floor, the Upper Prediction Limit method was used to account for variability in flame laminator emissions performance, and the MACT floor was calculated at 1.45 pounds per hour of HCl.[7]

The EPA also evaluated whether a beyond-the-floor emissions limit would be appropriate; specifically, we evaluated whether the incremental emissions reduction achievable with a venturi scrubber would be cost effective. The venturi scrubber was the only control technology in use at flame lamination sources that was identified by the EPA with the initial promulgation of the NESHAP, and no other developments in control technologies were identified in the review of these standards. The EPA estimated that the average incremental cost per ton of HCl emissions reduced with this technology would be approximately $26,000 and found that this would not be cost effective for the control of HCl. Therefore, we proposed that floor-level MACT controls are appropriate for existing flame laminators.

2. What changed since proposal?

In the final rule, we have made revisions in several sections to clarify that the flame lamination emission limit applies to each flame lamination line individually. As 40 CFR 63.8784(b)(2) states that the flame lamination affected source is the collection of all flame lamination lines, these revisions will make it clear that the limit is for each flame lamination line within an affected source rather than the collection of all flame lamination lines of an affected source.

For existing flame lamination units, we have also revised the final rule to include a more appropriate method of calculating the HCl emissions rate. In the proposed rule, we proposed to require existing sources to use the same method of calculating the HCl emissions rate as that required for new and reconstructed sources. However, while that method is appropriate for determining compliance with an emissions limit that requires a certain emissions percentage reduction using a control device, it is not appropriate for the existing source emissions limit that requires emissions to be below a specified numeric value, regardless of the use of a control device. Therefore, to correct this deficiency in the final rule, we have added an HCl calculation method that is appropriate to the emissions limit format and is based on the concentration of HCl and the volumetric flow rate of the flame lamination line's outlet gas stream to the atmosphere.

3. What are the key comments and what are our responses?

*Comment:* Several commenters support the establishment of emission standards for HCl emissions from existing flame lamination units; however, one commenter states that the proposed limits need to be strengthened. The commenter observes that there are four existing flame lamination units and that due to data availability, the EPA used data from only one of these to set the proposed MACT floor. The commenter states the EPA should have required the other sources to provide the necessary data for analysis and that there is no indication that the one source for which the EPA has data represents the average emission limitation achieved by the best-performing sources. The commenter adds that the EPA used the upper prediction limit (UPL) approach, which moves the floor further from the average emissions limitation achieved by the best-performing sources. Due to these aspects of the proposed MACT floor, the commenter states that the EPA has not met the CAA requirements to set the limits at the maximum achievable degree.

The commenter also states that the EPA fails to meet the beyond-the-floor requirements by failing to assure the maximum achievable degree of emission limitation. According to the commenter, the EPA decided not to require additional reductions beyond the floor purely based on cost data from its analysis conducted for the proposal of the NESHAP in 2001. The commenter states that the EPA did not provide evidence to support its assumption that the cost effectiveness today would be similar to what it was in 2001 after adjusting for inflation and that the EPA provided no information to support its claim that nothing has substantially changed with the control technology of a venturi scrubber since that time. The commenter adds that the EPA did not consider the health benefits of the emissions reduction.

*Response:* In setting the MACT floor for these sources, we have used all data available to the Agency. As provided for by CAA section 112(d)(3)(B), this limit was set at the average emission limitation achieved by the best performing sources for which the Administrator has or could reasonably obtain emissions information. In this instance, one of the four flame lamination units in operation in the source category has been tested for HAP emissions. Therefore, this one emissions

[7] See *MACT Floor and Beyond-the-Floor Analysis for Existing Flame Laminators in the Flexible Polyurethane Foam Fabrication Source Category* (Document ID EPA–HQ–OAR–2020–0572–0002).

test, which represents performance of 25 percent of the flame lamination units in operation, represents the whole of the data available for these emissions sources and constitutes the basis for the MACT floor. Based on the information above, the EPA determined that the emissions information on which the MACT floor is based is representative of the source category. While it may have been possible for the EPA to require the facilities to conduct further HAP emissions testing to use in setting the MACT floor, due to several factors (including the additional time this would have added to the rulemaking process, the availability of at least one emissions test, and the expected types and levels of emissions expected from these units), the EPA determined, consistent with the Agency's discretion under the CAA, not to require additional emissions testing to be performed. Additionally, we note that while the commenter is concerned that the emissions limit set using the available data for one source may not be as stringent as the average of the best performing sources in the source category, the Administrator is required to set standards based on available data.

We disagree with the commenter that use of the UPL moves the floor further from the average emission limitation achieved by the best performing sources. To develop the proposed HCl MACT standard for existing flame lamination units, the EPA used the UPL statistical methodology, which the EPA has used in many rulemakings and which was upheld by the D.C. Circuit Court in *U.S. Sugar Corp.* v. *EPA,* 830 F.3d 579 (D.C. Cir. 2016). That is, the best performers, and their level of performance, are determined after accounting for sources' normal operating variability. The UPL represents the value below which one can expect the mean of a specified number of future observations (*e.g.,* 3-run average) to fall, for the specified level of confidence, based upon the results of an independent sample from the same population.

The UPL approach allows for the development of the average emissions value that the source is achieving, given that the MACT floor is derived from short-term emissions test data and such data are not representative of the range of operating conditions that the facility faces on a day-to-day basis. In statistical terms, each test produces a limited data sample, not a complete enumeration of the available data for performance of the unit over a long period of time. Therefore, the EPA needs to adjust the short-term data to account for these varying conditions to properly estimate the source's performance over time.

In calculating the UPL that we proposed as the MACT floor for existing flame lamination lines, we tested the dataset (three runs) for skewness and kurtosis to determine that the non-normal (lognormal) data distribution is the best representation of the sample set, and we used the UPL equation appropriate to that data distribution. Because the floor is based on the performance of a single unit, our evaluation of the data was limited to ensuring that the emission limit is a reasonable estimate of the performance of the unit based on our knowledge about the process and controls. The wide range in HCl emissions shown by the available data for this best-performing unit indicates that variability is significant, and we determined that the emission limit is representative of the actual performance of the unit upon which the limit is based, considering variability.

We note that after MACT standards are promulgated, we are required to review those standards periodically, and for such reviews, we typically have significant additional HAP emissions data from the intervening years of compliance with which to further assess the actual performance of the various emission sources. We anticipate that this will be the case for existing flame lamination lines.

As part of the technology review, a search for information on venturi scrubbers was undertaken and no new information on their performance or costs was found that would indicate that our previous cost analysis is not representative of current costs. No information was received during the comment period to suggest that these assumptions were incorrect.

We concluded in the residual risk assessment that risks from the source category are acceptable and that the standards provide an ample margin of safety. The addition of new MACT standards for HCl for existing sources will further reduce risks from the source category.

*Comment:* One commenter asserts that the EPA, in setting emission standards for uncontrolled HAP emissions for this source category, must include emission standards for 1-bromopropane (1–BP, also known as n-propyl bromide) as a ''necessary'' revision to satisfy its legal obligation in this rulemaking, citing *Louisiana Environmental Action Network* v. *EPA,* 955 F.3d 1088 (D.C. Cir. 2020) (*LEAN*). The commenter notes that the EPA has determined that 1–BP is an ''air pollutant'' that ''may reasonably be anticipated to cause adverse effects to human health'' and that it therefore qualifies as a HAP, and the commenter points out that the EPA, having granted 1–BP for listing as a HAP, has not yet completed that listing process.

Noting that at least one source reported using 1–BP, the commenter argues that the EPA should gather further information and ensure all sources meet emission standards for 1–BP that satisfy § 7412(d) and (f). The commenter cited a recent risk evaluation under TSCA, in which ''EPA has determined that risk from emissions to the ambient air of 1–BP could be eliminated or reduced to a sufficient extent by actions taken under the CAA.'' The commenter believes the EPA acted unlawfully and in an arbitrary manner by failing in this rulemaking to assess 1–BP emissions and propose emission standards for 1–BP.

*Response:* The EPA does not agree that the *LEAN* decision compels regulation of 1–BP for this sector, because that decision only goes to timing; the EPA must address any regulatory gaps (that is, any unregulated HAP emissions from the source category which the EPA is required to regulate) when it conducts a technology review for that category. For this source category, the EPA received information indicating that no major sources are using 1–BP and few to no area sources may be using 1–BP in small quantities as an equipment cleaner. At this time, there is no requirement to set standards for 1–BP as part of the review for major sources in this category during the CAA section 112(d)(6) technology review because 1–BP is not emitted by any major sources in this source category. As for the area sources, the EPA need only review the standards set for the urban HAP for which this area source category was listed under CAA section 112(c)(3), which is methylene chloride. We are not obligated to set standards for other listed HAP that are emitted from this area source category.[8] *See Desert Citizens Against Pollution* v. *EPA,* 699 F.3d 524, 525–26 (D.C. Cir. 2012).

4. What is the rationale for our final approach for the actions taken pursuant to CAA sections 112(d)(2) and 112(d)(3)?

We evaluated all comments received regarding the proposed standard for existing flame lamination units and determined that no changes to the level of the standard are needed. We conclude that the standard, which is based on the UPL and emissions data

[8] The EPA notes that while 1–BP is not yet a listed HAP, it soon will be.

from a single unit, represents the average emission limitation achieved by the best performing sources for which the Administrator has or could reasonably obtain emissions information. A more detailed explanation for this decision may be found in responses provided earlier in this document. Through further review of the proposed rule, we determined that clarifications are needed for the final rule language to ensure it is clear the flame lamination emissions limits apply to each individual flame lamination line, and we have revised the final rule accordingly. In addition, to correct a deficiency in the proposed rule's HCl emissions calculation method for existing source flame lamination units, we have added an appropriate calculation method in the final rule.

*D. Removal of the SSM Exemptions*

1. What did we propose for the major source Flexible Polyurethane Foam Fabrication Operations NESHAP?

The EPA proposed amendments to the major source Flexible Polyurethane Foam Fabrication Operations NESHAP to remove the provisions related to SSM to ensure that they are consistent with the court decision in *Sierra Club* v. *EPA,* 551 F.3d 1019 (D.C. Cir. 2008) that standards always apply. As detailed in the January 2021 proposal, we proposed to change the requirements for SSM by removing the exemption for new flame laminators from the requirements to meet the standard during SSM periods and by removing the requirement to develop and implement an SSM plan. The EPA proposed revisions to Table 7 of subpart MMMMM, The Applicability of General Provisions, to remove SSM exemptions and plan development for new flame lamination sources.

2. What changed since proposal?

We determined that no changes were necessary to the proposed revised requirements for SSM periods. Therefore, we are finalizing the revised provisions related to SSM periods as proposed (86 FR 1868 at 1885, January 11, 2021).

3. What are the key comments and what are our responses?

We received comments in support of the proposed revisions regarding SSM periods. Generally, commenters supported the proposed removal of the exemption for periods of SSM and the elimination of the requirement to develop an SSM plan, recognizing that these changes are consistent with court decisions requiring that the CAA standards always apply. After review of these comments, we determined that no changes are needed to the proposed revisions regarding SSM periods. The comments and our specific responses can be found in the document, *Summary of Public Comments and Responses on the Proposed Rule for the Major Source Flexible Polyurethane Foam Fabrication NESHAP and the NESHAP for Flexible Polyurethane Foam Production and Fabrication Area Sources,* available in the docket for this rulemaking.

4. What is the rationale for our final approach for the SSM provisions?

We evaluated all comments on the EPA's proposed amendments to remove the SSM provisions. For the reasons explained in the proposed rule, we determined that the proposed removal of the SSM exemptions is required to be consistent with the 2008 court decision that standards always apply. Therefore, we are finalizing our approach for removing the SSM exemptions as proposed.

*E. Electronic Reporting*

1. What did we propose?

We proposed amendments to the major source Flexible Polyurethane Foam Fabrication Operations NESHAP to require owners or operators to submit electronic copies of initial notifications, notifications of compliance status, performance test reports, performance evaluation reports, and semiannual reports through the EPA's Central Data Exchange (CDX) using CEDRI. Additionally, we proposed two broad circumstances in which electronic reporting extensions may be provided at the discretion of the Administrator. The EPA proposed these extensions to protect owners or operators from noncompliance in cases where they are unable to successfully submit a report by the reporting deadline for reasons outside of their control, including CDX and CEDRI outages and *force majeure* events, such as acts of nature, war, or terrorism.

2. What changed since proposal?

We determined that no changes were necessary to the proposed requirements for owners or operators of flexible polyurethane foam fabrication operations major sources to submit initial notifications, notifications of compliance status, performance test reports, performance evaluation reports, and semiannual reports electronically using CEDRI. Therefore, we are finalizing the electronic reporting provisions as proposed (86 FR 1886, January 11, 2021).

3. What are the key comments and what are our responses?

The EPA received one comment that generally supported the proposed amendment to require electronic reporting but was opposed to the *force majeure* provisions due to concern that those provision would allow for unreported exceedances to go unchecked. After review and consideration of this comment, we determined that no changes are needed to the electronic reporting requirements or their force majeure provisions. This comment and our specific response can be found in the document, *Summary of Public Comments and Responses on the Proposed Rule for the Major Source Flexible Polyurethane Foam Fabrication NESHAP and the NESHAP for Flexible Polyurethane Foam Production and Fabrication Area Sources,* available in the docket for this rulemaking.

4. What is the rationale for our final approach to electronic reporting?

We are finalizing as proposed a requirement in the major source NESHAP that owners or operators of flexible polyurethane foam fabrication operations submit electronic copies of notifications, performance evaluation reports, and semiannual compliance reports using CEDRI. We also are finalizing, as proposed, provisions that allow facility owners or operators a process to request extensions for submitting electronic reports for circumstances beyond the control of the facility (*i.e.,* for a possible outage in the CDX or CEDRI or for a *force majeure* event). Such extensions are intended to be available only in extraordinary circumstances; they are limited in duration and do not relieve owners or operators of their reporting obligations. The electronic reporting amendments will increase the ease and efficiency of data submittal for owners and operators of major source flexible polyurethane foam fabrication operations and will make the data more accessible to regulators and the public.

## V. Summary of Cost, Environmental, and Economic Impacts and Additional Analyses Conducted

*A. What are the affected facilities?*

Currently, there are three major sources operating in the United States that are subject to the major source Flexible Polyurethane Foam Fabrication Operations NESHAP. The affected sources under the NESHAP include flexible polyurethane foam fabrication plant sites that operate loop slitters and/or flame laminators. Facilities that use loop slitter adhesive processes would be

required to comply with a ban on the use of adhesives containing air toxics. However, the EPA estimates that current air toxic emissions from loop slitter adhesive users are essentially zero as the result of changes in adhesive composition required by OSHA's permissible exposure limit for methylene chloride that was enacted prior to the promulgation of the original MACT standard. Additionally, the EPA estimates that current air toxic emissions from flame laminators for the entire source category are less than 3.5 tpy.

Currently, there are approximately 32 area sources subject to the Flexible Polyurethane Foam Production and Fabrication NESHAP for area sources. The area source standard only regulates methylene chloride emissions, and, similar to the major source standards, emissions of methylene chloride are essentially zero, as required by OSHA's permissible exposure limit for methylene chloride that was enacted prior to the promulgation of the original GACT standards. Based on information provided by industry, there are no emissions of methylene chloride from these sources. For detailed information, please see the memorandum titled *Technology Review for Flexible Polyurethane Foam Production and Fabrication Area Sources,* available in the docket for this action (Document ID EPA–HQ–OAR–2020–0572–0004).

*B. What are the air quality impacts?*

Current estimated emissions from the Flexible Polyurethane Foam Fabrication Operations source category are approximately 3.5 tpy. We do not estimate any HAP emission reductions from the final amendment adding MACT limits for existing flame laminators nor from the final amendment revising the definition of HAP-based adhesives for loop slitters. Both revisions reflect current practices.

*C. What are the cost impacts?*

The final amendments to the Flexible Polyurethane Foam Fabrication Operations NESHAP for major sources are expected to have minimal cost impacts. The costs are associated with periodic emissions performance testing, recordkeeping and reporting, electronic reporting, and reviewing the proposed rule. Three major source facilities are affected by these costs, although only two of them are affected by the emissions performance testing requirement. The periodic performance test is required every 5 years, but only for major source facilities that perform flame lamination. Most of the information requirements in the final rule are unchanged from those of the proposed rule. However, after proposal of this action, the EPA revised its cost estimates to incorporate updated information about the costs associated with reporting and performance testing for sources in the flame lamination subcategory. The cost estimates are slightly higher than at proposal. The revised cost estimates reflect that a performance test is required for each flame lamination line at a facility, although the labor required for each test is estimated to be lower than at proposal. See the Economic Impact Analysis in the docket and the accompanying workbook for the updated assumptions and cost estimates (Docket ID No. EPA–HQ–OAR–2020–0572).

For the two affected facilities with flame lamination lines, the year 1 costs are estimated to be about $22,000 per facility, while the undiscounted costs related to reporting and recordkeeping in the following years are estimated at about $2,600 per facility per year except for year 6 when another emissions test is required. The undiscounted costs in year 6 are estimated to be about $17,000 per facility for the sources with flame laminators. For the major source that does not perform flame lamination and thus does not need to fulfill the testing requirement, the costs in year 1 are estimated to be about $6,000, while the undiscounted costs in the following years are estimated at about $2,600 per year.

Because the final amendments to the Flexible Polyurethane Foam Production and Fabrication Area Sources NESHAP impose no new requirements on area sources, there will be no cost impacts for area sources.

*D. What are the economic impacts?*

The final amendments to the Flexible Polyurethane Foam Fabrication Operations NESHAP for major sources and the Flexible Polyurethane Foam Production and Fabrication NESHAP for area sources are not expected to have market impacts. Over a 10-year timeframe from 2022 to 2031, the net present value of the estimated cost impacts is about $135,000 at a 3 percent discount rate and $121,000 at a 7 percent discount rate in 2019 dollars. The equivalent annualized value of the cost impacts is about $16,000 at a 3 percent discount rate and $17,000 at a 7 percent discount rate. Since there are no expected costs for area sources, and the estimated costs for major sources are minimal, no significant economic impacts are anticipated due to the final amendments. For more information regarding the facility-level cost estimates as well as the net present value and equivalent annualized value estimates, see the memorandum titled *Economic Impact Analysis for Final Residual Risk and Technology Review of the National Emission Standards for Hazardous Air Pollutants for Flexible Polyurethane Foam Fabrication Operations,* available in the docket for this action (Docket ID No. EPA–HQ–OAR–2020–0572).

*E. What are the benefits?*

This action will result in improvements to the rule and prevent backsliding. In general, backsliding is when a source uses a process, equipment, and/or ingredients that the industry in general has moved beyond in favor of processes, equipment, and/or ingredients with fewer potential adverse environmental impacts. Specifically, the final amendments codify existing industry practices both for existing flame laminators and for new and existing sources that use adhesives with loop slitters. The final amendments also revise the standards such that they always apply. Additionally, the final amendments requiring electronic submittal of initial notifications, performance test results, and semiannual reports will increase the usefulness of the data, are in keeping with current trends of data availability, will further assist in the protection of public health and the environment, and will ultimately result in less burden on the regulated community.

*F. What analysis of environmental justice did we conduct?*

Executive Order 12898 directs the EPA to identify the populations of concern who are most likely to experience unequal burdens from environmental harms—specifically, minority populations, low-income populations, and indigenous peoples (59 FR 7629, February 16, 1994). Additionally, Executive Order 13985 was signed to advance racial equity and support underserved communities through federal government actions (86 FR 7009, January 20, 2021). The EPA defines environmental justice as the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income, with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. The EPA further defines the term fair treatment to mean that ''no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and

commercial operations or programs and policies'' (*https://www.epa.gov/environmentaljustice*). In recognizing that minority and low-income populations often bear an unequal burden of environmental harms and risks, the EPA continues to consider ways of protecting them from adverse public health and environmental effects of air pollution.

Based on an analysis of exposed populations, the EPA determined that the source categories do not pose a disproportionately high adverse health impact on minority populations and/or low-income populations, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994) and referenced in Executive Order 13985 (86 FR 7009, January 20, 2021). The EPA remains committed to engaging with communities and stakeholders throughout the development of air pollution regulations.

To examine the potential for any environmental justice issues that might be associated with the major source category, we performed a demographic analysis, which is an assessment of risks to individual demographic groups of the populations living within 5 kilometers (km) and within 50 km of the facilities. In the analysis, we also evaluated the distribution of HAP-related cancer and noncancer risks from the major source Flexible Polyurethane Foam Fabrication Operations source category across different demographic groups within the populations living near facilities.

The results of the demographic analysis for the major source category indicate that the minority population (being the total population minus the white population) is slightly higher within 5 km of the three facilities than the national percentage (40 percent versus 38 percent). This difference is accounted for by the larger African American population around the facilities (17 percent versus 12 percent nationally). In addition, the percentage of the population living within 5 km of facilities in the source category is greater than the corresponding national percentage for the demographic groups, ''Ages 0 to 17'' and ''Below the Poverty Level.'' When examining the risk levels of those exposed to emissions from Flexible Polyurethane Foam Fabrication facilities, we find that no one is exposed to a cancer risk at or above 1-in-1 million or to a chronic noncancer TOSHI greater than 1. The methodology and the results of the demographic analysis are presented in a technical report, *Risk and Technology Review—Analysis of Demographic Factors for Populations Living Near Flexible Polyurethane Foam Fabrication Operations Source Category,* available in this docket for this action (Document ID EPA–HQ–OAR–2020–0572–0006).

*G. What analysis of children's environmental health did we conduct?*

The EPA determined that the environmental health or safety risks addressed by this action do not present a disproportionate risk to children. The health risk assessments for this action are contained in the document titled *Residual Risk Assessment for the Flexible Polyurethane Foam Fabrication Source Category in Support of the 2021 Risk and Technology Review Final Rule* available in the docket (Docket ID No. EPA–HQ–OAR–2020–0572).

## VI. Statutory and Executive Order Reviews

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

*A. Executive Orders 12866: Regulatory Planning and Review and 13563: Improving Regulation and Regulatory Review*

This action is not a significant regulatory action and was, therefore, not submitted to OMB for review.

*B. Paperwork Reduction Act (PRA)*

The information collection activities in rule have been submitted for approval to OMB under the PRA. The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 2027.09. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here. The information collection requirements are not enforceable until OMB approves them. The ICR is specific to information collection associated with the Flexible Polyurethane Foam Fabrication Operations source category, through amendments to 40 CFR part 63, subpart MMMMM. (The subject rulemaking imposes no new information collection associated with either the Flexible Polyurethane Foam Production area source category or the Flexible Polyurethane Foam Fabrication area source category.) We are finalizing changes to the recordkeeping and reporting requirements associated with 40 CFR part 63, subpart MMMMM, in the form of: Requiring periodic (every 5 years) performance tests at major sources that perform flame lamination; eliminating the SSM plan and reporting requirements; including reporting requirements for deviations in the semiannual (periodic) report; and including the requirement for electronic submittal of reports. In addition, the number of facilities subject to the standards has changed. The number of respondents was reduced from 20 to 3 based on consultation with industry representatives and state/local agencies.

*Respondents/affected entities:* The respondents to the recordkeeping and reporting requirements are owners or operators of flexible polyurethane foam fabrication operations subject to 40 CFR part 63, subpart MMMMM.

*Respondent's obligation to respond:* Mandatory (40 CFR part 63, subpart MMMMM).

*Estimated number of respondents:* 3 facilities.

*Frequency of response:* The frequency of responses varies depending on the burden item. Responses include one-time review of rule amendments, reports of periodic performance tests, and semiannual compliance reports.

*Total estimated burden:* The annual recordkeeping and reporting burden for responding facilities to comply with all requirements in the NESHAP, averaged over the 3 years of this ICR, is estimated to be 113 hours (per year). The average annual burden to the Agency over the 3 years after the amendments are final is estimated to be 51 hours (per year) for the Agency. Burden is defined at 5 CFR 1320.3(b).

*Total estimated cost:* The annual recordkeeping and reporting cost for responding facilities to comply with all requirements in the NESHAP, averaged over the 3 years of this ICR, is estimated to be $21,600 (rounded, per year). The total operation and maintenance costs associated with performance test requirements, averaged over the 3 years of this ICR, is estimated to be $10,100 per year. The total average annual Agency cost over the first 3 years after the amendments are final is estimated to be $2,500.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

*C. Regulatory Flexibility Act (RFA)*

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is

any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden, or otherwise has a positive economic effect on the small entities subject to the rule. As finalized, this action will impose new requirements only on major sources, and none of the major sources in the Flexible Polyurethane Foam Fabrication Operations source category are considered a small entity. Because this action imposes no new requirements on area sources, there will be no significant impact on any small entities among area sources. We have, therefore, concluded that this action will have no net regulatory burden for all directly regulated small entities.

*D. Unfunded Mandates Reform Act (UMRA)*

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. While this action creates an enforceable duty on the private sector, the cost does not exceed $100 million or more.

*E. Executive Order 13132: Federalism*

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

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

This action does not have tribal implications as specified in Executive Order 13175. No tribal facilities are known to be engaged in the industries that would be affected by this action nor are there any adverse health or environmental effects from this action. Thus, Executive Order 13175 does not apply to this action.

*G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks*

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This action's health and risk assessments are contained in sections IV.A of this preamble.

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

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

*I. National Technology Transfer and Advancement Act (NTTAA)*

This rulemaking does not involve technical standards.

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

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations, and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994).

The documentation for this decision is contained in the technical reports titled *Risk and Technology Review—Analysis of Demographic Factors for Populations Living Near Flexible Polyurethane Foam Fabrication Source Category Operations* and *Residual Risk Assessment for the Flexible Polyurethane Foam Fabrication Source Category in Support of the 2021 Risk and Technology Review Final Rule,* available in the docket for this action (Document ID EPA–HQ– OAR–2020–0572–0006).

*K. Congressional Review Act (CRA)*

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

**List of Subjects in 40 CFR Part 63**

Environmental protection, Administrative practice and procedures, Air pollution control, Hazardous substances, Intergovernmental relations, Reporting and recordkeeping requirements.

**Michael S. Regan,**

*Administrator.*

For the reasons set out in the preamble, 40 CFR part 63 is amended as follows:

## PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

■ 1. The authority citation for part 63 continues to read as follows:

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

### Subpart MMMMM—National Emission Standards for Hazardous Air Pollutants: Flexible Polyurethane Foam Fabrication Operations

■ 2. Section 63.8784 is amended by revising paragraphs (c)(2) and (e) to read as follows:

**§ 63.8784 What parts of my plant does this subpart cover?**

* * * * *

(c) * * *

(2) If you add one or more flame lamination lines at a plant site where flame lamination lines already exist, the added line(s) shall be a new affected source and meet new source requirements if the added line(s) are at a flexible polyurethane foam fabrication plant site that has the potential to emit 10 tons per year or more of any HAP or 25 tons or more per year of any combination of HAP.

* * * * *

(e) An affected source is existing if it commenced construction or reconstruction on or before August 8, 2001.

■ 3. Section 63.8786 is amended by revising paragraph (b) and adding paragraph (f) to read as follows:

**§ 63.8786 When do I have to comply with this subpart?**

* * * * *

(b) If you have an existing affected source, you must comply with this subpart according to paragraphs (b)(1) and (b)(2) of this section, as applicable.

(1) If you have an existing loop slitter affected source, you must comply with the emission standards for existing sources no later than April 14, 2004.

(2) If you have an existing flame lamination affected source, you must comply with the emission standards for existing sources no later than May 17, 2022.

* * * * *

(f) You must comply with the electronic reporting requirements according to paragraphs (f)(1) and (f)(2) of this section.

(1) You must comply with the performance test and CMS performance evaluation requirements of § 63.8818(j) on or before May 17, 2022.

(2) You must comply with the compliance report requirements of

§ 63.8818(k) on or before May 17, 2022 or once the report template for this subpart has been available on the CEDRI website for 1 year, whichever date is later.

■ 4. Section 63.8794 is amended by:
■ a. Revising paragraphs (b), (c) and (d);
■ b. Removing and reserving paragraph (e); and
■ c. Revising paragraph (f) introductory text.

The revisions read as follows:

**§ 63.8794 What are my general requirements for complying with this subpart?**

* * * * *

(b) For each flame lamination affected source, you must be in compliance with the requirements in this subpart at all times.

(c) At all times, you must operate and maintain any affected source, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. The general duty to minimize emissions does not require you to make any further efforts to reduce emissions if levels required by the applicable standard have been achieved. Determination of whether a source is operating in compliance with operation and maintenance requirements will be based on information available to the Administrator which may include, but is not limited to, monitoring results, review of operation and maintenance procedures, review of operation and maintenance records, and inspection of the source.

(d) For flame lamination affected sources in § 63.8786 using a control device to comply with the emission limitations in Table 1 to this subpart, you must maintain a log detailing the operation and maintenance of the process and emissions control equipment during the period between the compliance date specified for your flame lamination affected source in § 63.8786 and the date upon which continuous compliance monitoring systems required by § 63.8810(c) have been installed and verified and any applicable operating limits have been set.

* * * * *

(f) For each monitoring system required by § 63.8810(c) for flame lamination sources, you must develop and submit for approval a site-specific monitoring plan that addresses the requirements in paragraphs (f)(1) through (3) of this section.

* * * * *

■ 5. Section 63.8798 is amended by revising paragraph (b) and adding paragraph (c) to read as follows:

**§ 63.8798 By what date must I conduct performance tests or other initial compliance demonstrations?**

* * * * *

(b) For each flame lamination affected source, you must conduct performance tests by the compliance date that is specified for your source in § 63.8786 and according to the provisions in § 63.7(a)(2).

(c) You must conduct subsequent performance tests to demonstrate compliance with the flame lamination emissions limitations in Table 1 to this subpart no less frequently than every 5 years from the date of the last performance test.

■ 6. Section 63.8800 is amended by:
■ a. Revising paragraphs (b), (c) and (e) introductory text;
■ b. Redesignating paragraph (f) as (g);
■ c. Adding new paragraph (f); and
■ d. Revising newly redesignated paragraph (g) introductory text.

The revisions and additions read as follows:

**§ 63.8800 What performance tests and other procedures must I use to demonstrate compliance with the emission limit for flame lamination?**

* * * * *

(b) Each performance test must be conducted according to the requirements in paragraph (c) of this section and under the specific conditions in Table 3 to this subpart.

(c) You must conduct each performance test under conditions representative of normal operations. You may not conduct performance tests during periods of SSM. The owner or operator must record the process information that is necessary to document operating conditions during the test and include in such record an explanation to support that such conditions represent normal operation. Upon request, the owner or operator shall make available to the Administrator such records as may be necessary to determine the conditions of performance tests.

* * * * *

(e) For new and reconstructed affected sources, you must determine the percent reduction of HAP emissions during the performance test according to paragraphs (e)(1) through (3) of this section.

* * * * *

(f) For existing affected sources, you must determine the HCl emissions rate according to paragraphs (f)(1) through (3) of this section.

(1) Calculate the concentration of HCl in the vent outlet to the atmosphere or at the control device outlet, if a control device is used, using the procedures in the specified test method.

(2) Determine the vent outlet gas stream volumetric flow rate or if a control device is used, the control device outlet gas stream volumetric flow rate, using the procedures in the specified test method.

(3) Calculate the HCl emission rate for the period of the performance test using Equation 2 of this section:

$$E_{HCl} = C \; x \; AOF \quad \text{Eq.2}$$

Where:

$E_{HCl}$ = Emission rate of HCl, lbs/hr.
C= average HCl concentration of vent or control device outlet stream for all test runs, lb/dscft.
AOF = average outlet volumetric flow rate of gas stream, dry basis, dscft/hr.

(g) You must also meet the requirements in paragraphs (g)(1) and (2) of this section.

* * * * *

■ 7. Section 63.8802 is amended by revising paragraphs (a)(1)(i) and (3)(i) to read as follows:

**§ 63.8802 What methods must I use to demonstrate compliance with the emission limitation for loop slitter adhesive use?**

(a) * * *

(1) * * *

(i) Include in the HAP total each HAP in Table 8 of this subpart that is measured at 0.1 percent by weight or more and any other HAP that is measured at 1.0 percent by weight or more. Express the weight fraction of each HAP you measure as a value truncated to four places after the decimal point (for example, 0.1234).

* * * * *

(3) * * *

(i) Include in the HAP total each HAP in Table 8 of this subpart that is present at 0.1 percent by weight or more and any other HAP that is present at 1.0 percent by weight or more.

* * * * *

■ 8. Section 63.8810 is amended by revising paragraphs (b) introductory text, (c) introductory text and (c)(1) to read as follows:

**§ 63.8810 How do I monitor and collect data to demonstrate continuous compliance?**

* * * * *

(b) If you own or operate a flame lamination affected source, you must meet the requirements in paragraphs (b)(1) through (3) of this section if you use a scrubber, or paragraph (b)(4) of this section if you use any other control device.

* * * * *

(c) If you own or operate a control device to meet the emissions limitations for a flame lamination affected source, you must meet the requirements in paragraphs (c)(1) through (4) of this section.

(1) Except for periods of monitoring-associated repairs and required quality assurance or control activities (including, as applicable, calibration checks and required zero and span adjustments), you must monitor continuously (or collect data at all required intervals) at all times that the affected source is operating.

* * * * *

■ 9. Section 63.8812 is amended by:

■ a. Revising paragraph (b);

■ b. Removing and reserving paragraph (d); and

■ c. Revising paragraph (e) introductory text.

The revisions read as follows:

**§ 63.8812 How do I demonstrate continuous compliance with the emission limitations?**

* * * * *

(b) You must report each instance in which you did not meet each emission limit and each operating limit in Tables 1 and 2 to this subpart that applies to you. These instances are deviations from the operating limits in this subpart. These deviations must be reported according to the requirements in § 63.8818.

* * * * *

(e) You must meet the following requirements if you are complying with the adhesive use ban for loop slitter adhesive use described in § 63.8790(a).

* * * * *

■ 10. Section 63.8816 is amended by revising paragraphs (d), (f), (g) introductory text, and (h)(1) to read as follows:

**§ 63.8816 What notifications must I submit and when?**

* * * * *

(d) If you own or operate a flame lamination affected source, submit a notification of intent to conduct a performance test at least 60 calendar days before the performance test is scheduled to begin, as required in § 63.7(b)(1).

* * * * *

(f) If you own or operate a flame lamination affected source, submit a Notification of Compliance Status according to § 63.9(h)(2)(ii) that includes the results of the performance test conducted according to the requirements in Table 3 to this subpart. You must submit the notification before the close of business on the 60th calendar day following the completion of the performance test according to § 63.10(d)(2).

(g) For each flame lamination affected source, the Notification of Compliance Status must also include the information in paragraphs (g)(1) and (2) that applies to you.

* * * * *

(h) * * *

(1) A list of each adhesive used at the affected source, its HAP content (percent by weight), and the manufacturer or supplier of each.

* * * * *

■ 11. Section 63.8818 is amended by:

■ a. Revising paragraphs (b) introductory text and (f);

■ b. Removing and reserving paragraph (i); and

■ c. Adding paragraphs (j) through (m).

The revisions and additions read as follows:

**§ 63.8818 What reports must I submit and when?**

* * * * *

(b) Unless the Administrator has approved a different schedule for submission of reports under § 63.10(a), you must submit each compliance report for flame lamination affected sources semiannually according to paragraphs (b)(1) through (4) of this section.

* * * * *

(f) The compliance report for flame lamination affected sources required by § 63.8810(c) to conduct continuous monitoring must also contain the following information in paragraphs (f)(1) and (2) of this section.

(1) If there were no periods during which the CPMS was out-of-control in accordance with the monitoring plan, a statement that there were no periods during which the CPMS was out-of-control during the reporting period.

(2) If there were periods during which the CPMS was out-of-control in accordance with the monitoring plan, the date, time, and duration of each out-of-control period.

* * * * *

(j) For Performance Test and CMS Performance Evaluation Reports, beginning on May 17, 2022, within 60 days after the date of completing each performance test or CMS performance evaluation (as defined in § 63.2) required by this subpart, the owner or operator must submit the results of the performance test or CMS performance evaluation following the procedures specified in paragraphs (j)(1) through (3) of this section.

(1) *Data collected using test methods supported by the EPA's Electronic Reporting Tool (ERT) as listed on the EPA's ERT website (https://www.epa.gov/electronic-reporting-air-emissions/electronic-reporting-tool-ert) at the time of the test.* Submit the results of the performance test or the performance evaluation of CMS measuring relative accuracy test audit (RATA) pollutants to the EPA via the Compliance and Emissions Data Reporting Interface (CEDRI), which can be accessed through the EPA's Central Data Exchange (CDX) *(https://cdx.epa.gov/).* The data must be submitted in a file format generated using the EPA's ERT. Alternatively, you may submit an electronic file consistent with the extensible markup language (XML) schema listed on the EPA's ERT website.

(2) *Data collected using test methods that are not supported by the EPA's ERT as listed on the EPA's ERT website at the time of the test.* The results of the performance test or the performance evaluation of CMS measuring RATA pollutants by methods that are not supported by the ERT, must be included as an attachment in the ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website. Submit the ERT generated package or alternative file to the EPA via CEDRI.

(3) *Confidential business information (CBI).* Do not use CEDRI to submit information you claim as CBI. Anything submitted using CEDRI cannot later be claimed CBI. Although we do not expect persons to assert a claim of CBI, if you wish to assert a CBI claim for some of the information submitted under paragraph (a)(1) or (2) of this section, you must submit a complete file, including information claimed to be CBI, to the EPA. The file must be generated using the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website. Submit the file on a compact disc, flash drive, or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium to U.S. EPA/OAQPS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described in paragraphs (a)(1) and (2) of this section. All CBI claims must be asserted at the time of submission. Furthermore, under CAA section 114(c), emissions data is not entitled to confidential treatment, and the EPA is required to make emissions data available to the public. Thus, emissions

data will not be protected as CBI and will be made publicly available.

(k) When submitting reports electronically, on and after the date specified in § 63.8786(f)(2), you must submit reports to the EPA via CEDRI, which can be accessed through the EPA's CDX (*https://cdx.epa.gov/*). The EPA will make all the information submitted through CEDRI available to the public without further notice to you. Do not use CEDRI to submit information you claim as confidential business information (CBI). Anything submitted using CEDRI cannot later be claimed CBI. You must use the appropriate electronic report template on the CEDRI website (*https://www.epa.gov/electronic-reporting-air-emissions/cedri*) for this subpart. The date report templates become available will be listed on the CEDRI website. Unless the Administrator or delegated state agency or other authority has approved a different schedule for submission of reports, the report must be submitted by the deadline specified in this subpart, regardless of the method in which the report is submitted. Although we do not expect persons to assert a claim of CBI, if you wish to assert a CBI claim, submit a complete report, including information claimed to be CBI, to the EPA. The report must be generated using the appropriate form on the CEDRI website. Submit the file on a compact disc, flash drive, or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium to U.S. EPA/OAQPS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described earlier in this paragraph (k). All CBI claims must be asserted at the time of submission. Furthermore, under CAA section 114(c), emissions data is not entitled to confidential treatment, and the EPA is required to make emissions data available to the public. Thus, emissions data will not be protected as CBI and will be made publicly available.

(l) For claims of EPA system outage, when you are required to electronically submit a report through CEDRI in the EPA's CDX, you may assert a claim of EPA system outage for failure to timely comply with the reporting requirement. To assert a claim of EPA system outage, you must meet the requirements outlined in paragraphs (l)(1) through (7) of this section.

(1) You must have been or will be precluded from accessing CEDRI and submitting a required report within the time prescribed due to an outage of either the EPA's CEDRI or CDX systems.

(2) The outage must have occurred within the period of time beginning five business days prior to the date that the submission is due.

(3) The outage may be planned or unplanned.

(4) You must submit notification to the Administrator in writing as soon as possible following the date you first knew, or through due diligence should have known, that the event may cause or has caused a delay in reporting.

(5) You must provide to the Administrator a written description identifying:

(i) The date(s) and time(s) when CDX or CEDRI was accessed and the system was unavailable;

(ii) A rationale for attributing the delay in reporting beyond the regulatory deadline to EPA system outage;

(iii) Measures taken or to be taken to minimize the delay in reporting; and

(iv) The date by which you propose to report, or if you have already met the reporting requirement at the time of the notification, the date you reported.

(6) The decision to accept the claim of EPA system outage and allow an extension to the reporting deadline is solely within the discretion of the Administrator.

(7) In any circumstance, the report must be submitted electronically as soon as possible after the outage is resolved.

(m) For claims of force majeure, when you are required to electronically submit a report through CEDRI in the EPA's CDX, you may assert a claim of force majeure for failure to timely comply with the reporting requirement. To assert a claim of force majeure, you must meet the requirements outlined in paragraphs (m)(1) through (5) of this section.

(1) You may submit a claim if a force majeure event is about to occur, occurs, or has occurred or there are lingering effects from such an event within the period of time beginning five business days prior to the date the submission is due. For the purposes of this section, a force majeure event is defined as an event that will be or has been caused by circumstances beyond the control of the affected facility, its contractors, or any entity controlled by the affected facility that prevents you from complying with the requirement to submit a report electronically within the time period prescribed. Examples of such events are acts of nature (*e.g.,* hurricanes, earthquakes, or floods), acts of war or terrorism, or equipment failure or safety hazard beyond the control of the affected facility (*e.g.,* large scale power outage).

(2) You must submit notification to the Administrator in writing as soon as possible following the date you first knew, or through due diligence should have known, that the event may cause or has caused a delay in reporting.

(3) You must provide to the Administrator:

(i) A written description of the force majeure event;

(ii) A rationale for attributing the delay in reporting beyond the regulatory deadline to the force majeure event;

(iii) Measures taken or to be taken to minimize the delay in reporting; and

(iv) The date by which you propose to report, or if you have already met the reporting requirement at the time of the notification, the date you reported.

(4) The decision to accept the claim of force majeure and allow an extension to the reporting deadline is solely within the discretion of the Administrator.

(5) In any circumstance, the reporting must occur as soon as possible after the force majeure event occurs.

■ 12. Section 63.8820 is amended by revising paragraph (b) to read as follows:

**§ 63.8820 What records must I keep?**

* * * * *

(b) For each flame lamination affected source, you must also keep the following records specified in paragraphs (b)(1) through (3) of this section.

(1) Records of performance tests, as required in § 63.10(b)(2)(viii).

(2) Records of the operating parameter values required in § 63.8810(b).

(3) The records specified in paragraphs (b)(3)(i) through (iii) of this section.

(i) The number of deviations. For each deviation, record the date, time, cause, and duration of the deviation.

(ii) For each deviation, record and retain a list of the affected sources or equipment, an estimate of the quantity of each regulated pollutant emitted over any emission limit and a description of the method used to estimate the emissions.

(iii) Record actions taken to minimize emissions in accordance with § 63.8794(c), and any corrective actions taken to return the affected unit to its normal or usual manner of operation.

* * * * *

■ 13. Section 63.8830 is amended by revising the definitions of ''Deviation'' and ''HAP-based adhesive'' to read as follows:

**§ 63.8830 What definitions apply to this subpart?**

* * * * *

*Deviation* means any instance in which an affected source subject to this subpart, or an owner or operator of such a source:

(1) Fails to meet any requirement or obligation established by this subpart, including but not limited to any emission limitation (including any operating limit); or

(2) Fails to meet any term or condition that is adopted to implement an applicable requirement in this subpart and that is included in the operating permit for any affected source required to obtain such a permit; or

(3) Fails to meet any emission limitation (including any operating limit) in this subpart, regardless of whether such failure is permitted by this subpart.

* * * * *

*HAP-based adhesive* means an adhesive containing 1.0 percent by weight or more of any individual or combination HAP listed in Table 8 to this subpart or 1.0 percent by weight or more of any other individual HAP, according to information from the supplier or manufacturer of the material, EPA Method 311 (appendix A to 40 CFR part 63) or another approved alternative.

* * * * *

■ 14. Table 1 to subpart MMMMM is amended by revising entry 3 to read as follows:

TABLE 1 TO SUBPART MMMMM OF PART 63—EMISSION LIMITS

As stated in § 63.8790(a), you must comply with the emission limits in the following table:

| For . . . | You must . . . |
|---|---|
| * * * | * * * * |
| 3. Each existing flame lamination affected source | Emit no more than 1.45 pounds per hour of HCl per flame lamination line. |

■ 15. Table 2 to subpart MMMMM is amended by revising the table title and introductory text to read as follows:

TABLE 2 TO SUBPART MMMMM OF PART 63—OPERATING LIMITS FOR EXISTING, NEW, OR RECONSTRUCTED FLAME LAMINATION AFFECTED SOURCES

As stated in § 63.8790(b), you must comply with the applicable operating limits in the following table:

* * * * *

■ 16. Table 3 to subpart MMMMM is revised to read as follows:

TABLE 3 TO SUBPART MMMMM OF PART 63—PERFORMANCE TEST REQUIREMENTS FOR EXISTING, NEW, OR RECONSTRUCTED FLAME LAMINATION AFFECTED SOURCES

As stated in § 63.8800, you must comply with the requirements for performance tests for flame lamination affected sources in the following table using the requirements in rows 1 through 5 of the table if you are measuring HCl and using a scrubber, row 6 for new or reconstructed sources measuring HCN and using a scrubber, and row 7 if you are using any other control device. For existing sources not using a control device, you must comply with row 8 and rows 1 through 4 of the table.

| For each existing, new, or reconstructed flame lamination affected source, you must . . . | Using . . . | According to the following requirements . . . |
|---|---|---|
| 1. Select sampling port's location and the number of traverse ports. | Method 1 or 1A in appendix A to part 60 of this chapter. | Sampling sites must be located at the inlet and outlet of the scrubber and prior to any releases to the atmosphere. |
| 2. Determine velocity | Method 2, 2A, 2C, 2D, 2F, or 2G in appendix A to part 60 of this chapter.. | |
| 3. Determine gas molecular weight | Not applicable | Assume a molecular weight of 29 (after moisture correction) for calculation purposes. |
| 4. Measure moisture content of the stack gas. | Method 4 in appendix A to part 60 of this chapter.. | |
| 5. Measure HCl concentration | Method 26A in appendix A to part 60 of this chapter. | i. For new or reconstructed sources, determine the HCl reduction efficiency of the control device using Method 26A and the procedures specified in § 63.8800(e).<br>ii. For existing sources, determine the HCl emission rate using Method 26A and the procedures specified in § 63.8800(f).<br>iii. Collect scrubber liquid flow rate, scrubber effluent pH, and pressure drop (pressure drop data only required for venturi scrubbers) every 15 minutes during the entire duration of each 1-hour test run, and determine the average scrubber liquid flow rate, scrubber effluent pH, and pressure drop (pressure drop data only required for venturi scrubbers) over the period of the performance test by computing the average of all 15-minute readings. |
| 6. Measure HCN concentration | A method approved by the Administrator. | i. Conduct the performance test according to the site-specific test plan submitted according to § 63.7(c)(2)(i). Measure total HCN emissions and determine the reduction efficiency of the control device. Any performance test which measures HCN concentrations must be submitted for the administrator's approval prior to testing. You must use EPA Method 301 (40 CFR part 63, Appendix A) to validate your method. |

TABLE 3 TO SUBPART MMMMM OF PART 63—PERFORMANCE TEST REQUIREMENTS FOR EXISTING, NEW, OR RECONSTRUCTED FLAME LAMINATION AFFECTED SOURCES—Continued

As stated in § 63.8800, you must comply with the requirements for performance tests for flame lamination affected sources in the following table using the requirements in rows 1 through 5 of the table if you are measuring HCl and using a scrubber, row 6 for new or reconstructed sources measuring HCN and using a scrubber, and row 7 if you are using any other control device. For existing sources not using a control device, you must comply with row 8 and rows 1 through 4 of the table.

| For each existing, new, or reconstructed flame lamination affected source, you must . . . | Using . . . | According to the following requirements . . . |
|---|---|---|
| | | ii. Collect scrubber liquid flow rate, scrubber effluent pH, and pressure drop (pressure drop data only required for venturi scrubbers) every 15 minutes during the entire duration of each 1-hour test run, and determine the average scrubber liquid flow rate, scrubber effluent pH, and pressure drop (pressure drop data only required for venturi scrubbers) over the period of the performance test by computing the average of all 15-minute readings. |
| 7. If you use any control device other than a scrubber, establish operating parameter limits with which you will demonstrate continuous compliance with the emission limit that applies to the source. | EPA-approved methods and data from the continuous parameter monitoring system. | i. Conduct the performance test according to the site-specific test plan submitted according to § 63.7(c)(2)(i). |
| | | ii. For new or reconstructed sources, determine the HCl or HCN reduction efficiency of the control device using the EPA-approved method and the procedures specified in § 63.8800(e). |
| | | iii. For existing sources, determine the HCl emission rate using the EPA-approved method and the procedures specified in § 63.8800(f). |
| | | iv. Collect operating parameter data as specified in the site-specific test plan. |
| 8. Measure HCl concentration ..... | Method 26A in appendix A to part 60 of this chapter. | Determine the HCl emission rate using the appropriate test methods and the procedures specified in § 63.8800(f). |

■ 17. Table 4 to subpart MMMMM is amended by adding entry 4 to read as follows:

TABLE 4 TO SUBPART MMMMM OF PART 63—INITIAL COMPLIANCE WITH EMISSION LIMITS

* * * * * * *

| For . . . | For the following emission limit . . . | You have demonstrated initial compliance if . . . |
|---|---|---|
| * * * * * * * | | |
| 4. Each existing flame lamination affected source ..... | Emit no more than 1.45 pounds per hour of HCl per flame lamination line. | The average HCl emissions, measured over the period of the performance test(s) do not exceed 1.45 pounds per hour per flame lamination line. |

■ 18. Table 5 to subpart MMMMM is amended by revising entries 2 and 3 to read as follows:

TABLE 5 TO SUBPART MMMMM OF PART 63—CONTINUOUS COMPLIANCE WITH EMISSION LIMITS AND OPERATING LIMITS

* * * * * * *

| For . . . | For the following emission limits or operating limits . . . | You must demonstrate continuous compliance by . . . |
|---|---|---|
| * * * * * * * | | |
| 2. Each existing, new, or reconstructed flame lamination affected source using a scrubber. | * * * | * * * |
| 3. Each existing, new, or reconstructed flame lamination affected source using any other control device. | * * * | * * * |

■ 19. Table 6 to subpart MMMMM is amended by revising table introductory text and entry 4 and removing entry 5 to read as follows:

TABLE 6 TO SUBPART MMMMM OF PART 63—REQUIREMENTS FOR REPORTS

You must submit a compliance report that includes the information in § 63.8818(e) through (g) as well as the information in the following table, as applicable. Rows 1 and 3 of the following table apply to loop slitter affected sources. Rows 1 through 4 apply to flame lamination affected sources.

| If . . . | Then you must submit a report or statement that . . . |
|---|---|
| * * * * * * * | |
| 4. There were periods during which the operating parameter monitoring systems were out-of-control in information in accordance with the monitoring plan. | Contains the information in § 63.8818(f)(2). |

■ 20. Table 7 to subpart MMMMM is revised to read as follows:

TABLE 7 TO SUBPART MMMMM OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART MMMMM

As stated in § 63.8826, you must comply with the applicable General Provisions requirements according to the following table:

| Citation | Requirement | Applies to subpart MMMMM | Explanation |
|---|---|---|---|
| § 63.1 | Initial applicability determination; applicability after standard established; permit requirements; extensions; notifications. | Yes. | |
| § 63.2 | Definitions | Yes | Additional definitions are found in § 63.8830. |
| § 63.3 | Units and abbreviations | Yes. | |
| § 63.4 | Prohibited activities; compliance date; circumvention, severability. | Yes. | |
| § 63.5 | Construction/reconstruction applicability; applications; approvals. | Yes. | |
| § 63.6(a) | Compliance with standards and maintenance requirements-applicability. | Yes. | |
| § 63.6(b)(1)–(4) | Compliance dates for new or reconstructed sources | Yes | § 63.8786 specifies compliance dates. |
| § 63.6(b)(5) | Notification if commenced construction or reconstruction after proposal. | Yes. | |
| § 63.6(b)(6) | [Reserved] | Yes. | |
| § 63.6(b)(7) | Compliance dates for new or reconstructed area sources that become major. | Yes | § 63.8786 specifies compliance dates. |
| § 63.6(c)(1)–(2) | Compliance dates for existing sources | Yes | § 63.8786 specifies compliance dates. |
| § 63.6(c)(3)–(4) | [Reserved] | Yes. | |
| § 63.6(c)(5) | Compliance dates for existing area sources that become major. | Yes | § 63.8786 specifies compliance dates. |
| § 63.6(d) | [Reserved] | Yes. | |
| § 63.6(e)(1)(i) | General duty to minimize emissions | No | § 63.8794(c) specifies general duty requirements. |
| § 63.6(e)(1)(ii) | Requirement to correct malfunctions as soon as possible | No. | |
| § 63.6(e)(1)(iii) | Enforceability of requirements independent of other regulations. | Yes. | |
| § 63.6(e)(2) | [Reserved] | Yes. | |
| § 63.6(e)(3) | SSM plans | No. | |
| § 63.6(f)(1) | Compliance except during SSM | No. | |
| § 63.6(f)(2)–(3) | Methods for determining compliance | Yes. | |
| § 63.6(g) | Use of an alternative nonopacity emission standard | Yes. | |
| § 63.6(h) | Compliance with opacity/visible emission standards | No | Subpart MMMMM does not specify opacity or visible emission standards. |
| § 63.6(i) | Extension of compliance with emission standards | Yes. | |
| § 63.6(j) | Presidential compliance exemption | Yes. | |
| § 63.7(a)(1)–(2) | Performance test dates | Yes | Except for loop slitter affected sources as specified in § 63.8798(a). |
| § 63.7(a)(3) | Administrator's section 114 authority to require a performance test. | Yes. | |
| § 63.7(b) | Notification of performance test and rescheduling | Yes. | |
| § 63.7(c) | Quality assurance program and site-specific test plans | Yes. | |
| § 63.7(d) | Performance testing facilities | Yes. | |
| § 63.7(e)(1) | Conditions for conducting performance tests | No | Requirements for performance test conditions are found in § 63.8800(b) and (c). |
| § 63.7(e)(2)–(3) | Performance test data reduction and number of test runs | Yes. | |
| § 63.7(f) | Use of an alternative test method | Yes. | |
| § 63.7(g) | Performance test data analysis, recordkeeping, and reporting. | Yes. | |
| § 63.7(h) | Waiver of performance tests | Yes. | |
| § 63.8(a)(1)–(2) | Applicability of monitoring requirements | Yes | Unless otherwise specified, all of § 63.8 applies only to new or reconstructed flame lamination sources. Additional monitoring requirements for these sources are found in §§ 63.8794(f) and (g) and 63.8804. |
| § 63.8(a)(3) | [Reserved] | Yes. | |
| § 63.8(a)(4) | Monitoring with flares | No | Subpart MMMMM does not refer directly or indirectly to § 63.11. |
| § 63.8(b) | Conduct of monitoring and procedures when there are multiple effluents and multiple monitoring systems. | Yes. | |
| § 63.8(c)(1)–(3) | Continuous monitoring system (CMS) operation and maintenance. | No | CMS requirements are found in § 63.8794(f) and (g). |

TABLE 7 TO SUBPART MMMMM OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART MMMMM—Continued

As stated in § 63.8826, you must comply with the applicable General Provisions requirements according to the following table:

| Citation | Requirement | Applies to subpart MMMMM | Explanation |
|---|---|---|---|
| § 63.8(c)(4) | Continuous monitoring system requirements during breakdown, out-of-control, repair, maintenance, and high-level calibration drifts. | Yes | Applies as modified by § 63.8794(g). |
| § 63.8(c)(5) | Continuous opacity monitoring system (COMS) minimum procedures. | No | Subpart MMMMM does not have opacity or visible emission standards. |
| § 63.8(c)(6) | Zero and high-level calibration checks | Yes | Applies as modified by § 63.8794(f). |
| § 63.8(c)(7)–(8) | Out-of-control periods, including reporting | Yes. | |
| § 63.8(d)–(e) | Quality control program and CMS performance evaluation | No | CMS requirements are found in § 63.8794(f) and (g). |
| § 63.8(f)(1)–(5) | Use of an alternative monitoring method | Yes. | |
| § 63.8(f)(6) | Alternative to relative accuracy test | No | Only applies to sources that use continuous emissions monitoring systems (CEMS). |
| § 63.8(g) | Data reduction | Yes | Applies as modified by § 63.8794(g). |
| § 63.9(a) | Notification requirements—applicability | Yes. | |
| § 63.9(b) | Initial notifications | Yes | Except § 63.8816(c) requires new or reconstructed affected sources to submit the application for construction or reconstruction required by § 63.9(b)(1)(iii) in lieu of the initial notification. |
| § 63.9(c) | Request for compliance extension | Yes. | |
| § 63.9(d) | Notification that a new source is subject to special compliance requirements. | Yes. | |
| § 63.9(e) | Notification of performance test | Yes. | |
| § 63.9(f) | Notification of visible emissions/opacity test | No | Subpart MMMMM does not have opacity or visible emission standards. |
| § 63.9(g)(1) | Additional CMS notifications—date of CMS performance evaluation. | Yes. | |
| § 63.9(g)(2) | Use of COMS data | No | Subpart MMMMM does not require the use of COMS. |
| § 63.9(g)(3) | Alternative to relative accuracy testing | No | Applies only to sources with CEMS. |
| § 63.9(h) | Notification of compliance status | Yes. | |
| § 63.9(i) | Adjustment of submittal deadlines | Yes. | |
| § 63.9(j) | Change in previous information | Yes. | |
| § 63.9(k) | Electronic reporting procedures | Yes | Only as specified in § 63.9(j). |
| § 63.10(a) | Recordkeeping/reporting applicability | Yes. | |
| § 63.10(b)(1) | General recordkeeping requirements | Yes | §§ 63.8820 and 63.8822 specify additional recordkeeping requirements. |
| § 63.10(b)(2)(i) and (ii) | Records related to SSM periods and CMS | No | See § 63.8820 for recordkeeping of (1) date, time, and duration; (2) listing of affected source or equipment, and an estimate of the quantity of each regulated pollutant emitted over the standard; and (3) actions to minimize emissions and correct the failure. |
| § 63.10(b)(2)(iii) | Records of maintenance on air pollution control equipment.. | Yes. | |
| § 63.10(b)(2)(iv) and (v) | Records related to SSM | No. | |
| § 63.10(b)(2)(vi)–(xi) | Records of CMS and other compliance records | Yes. | |
| § 63.10(b)(2)(xii) | Records when under waiver | Yes. | |
| § 63.10(b)(2)(xiii) | Records when using alternative to relative accuracy test | No | Applies only to sources with CEMS. |
| § 63.10(b)(2)(xiv) | All documentation supporting initial notification and notification of compliance status. | Yes. | |
| § 63.10(b)(3) | Recordkeeping requirements for applicability determinations. | Yes. | |
| § 63.10(c) | Additional recordkeeping requirements for sources with CMS. | Yes | Applies as modified by § 63.8794(g). |
| § 63.10(d)(1) | General reporting requirements | Yes | § 63.8818 specifies additional reporting requirements. |
| § 63.10(d)(2) | Performance test results | Yes. | |
| § 63.10(d)(3) | Opacity or visible emissions observations | No | Subpart MMMMM does not specify opacity or visible emission standards. |
| § 63.10(d)(4) | Progress reports for sources with compliance extensions | Yes. | |
| § 63.10(d)(5) | SSM reports | No. | |
| § 63.10(e)(1) | Additional CMS reports—general | Yes | Applies as modified by § 63.8794(g). |
| § 63.10(e)(2)(i) | Results of CMS performance evaluations | Yes | Applies as modified by § 63.8794(g). |
| § 63.10(e)(2) | Results of continuous opacity monitoring systems performance evaluations. | No | Subpart MMMMM does require the use of COMS. |
| § 63.10(e)(3) | Excess emissions/CMS performance reports | Yes | Only applies to new or reconstructed flame lamination affected sources. |
| § 63.10(e)(4) | Continuous opacity monitoring system data reports | No | Subpart MMMMM does not require the use of COMS. |
| § 63.10(f) | Recordkeeping/reporting waiver | Yes. | |
| § 63.11 | Control device requirements—applicability | No | Facilities subject to subpart MMMMM do not use flares as control devices. |
| § 63.12 | State authority and delegations | Yes | § 63.8828 lists those sections of subparts MMMMM and A that are not delegated. |
| § 63.13 | Addresses | Yes. | |
| § 63.14 | Incorporation by reference | Yes | Subpart MMMMM does not incorporate any material by reference. |
| § 63.15 | Availability of information/confidentiality. | Yes. | |

■ 21. Table 8 to Subpart MMMMM of Part 63 is added to read as follows:

TABLE 8 TO SUBPART MMMMM OF PART 63—LIST OF HAZARDOUS AIR POLLUTANTS THAT MUST BE COUNTED TOWARD TOTAL HAP CONTENT IF PRESENT AT 0.1 PERCENT OR MORE BY WEIGHT

| Chemical name | CAS No. |
|---|---|
| 1,1,2,2-Tetrachloroethane | 79–34–5 |
| 1,1,2-Trichloroethane | 79–00–5 |
| 1,1-Dimethylhydrazine | 57–14–7 |
| 1,2-Dibromo-3-chloropropane | 96–12–8 |
| 1,2-Diphenylhydrazine | 122–66–7 |
| 1,3-Butadiene | 106–99–0 |
| 1,3-Dichloropropene | 542–75–6 |
| 1,4-Dioxane | 123–91–1 |
| 2,4,6-Trichlorophenol | 88–06–2 |
| 2,4/2,6-Dinitrotoluene (mixture) | 25321–14–6 |
| 2,4-Dinitrotoluene | 121–14–2 |
| 2,4-Toluene diamine | 95–80–7 |
| 2-Nitropropane | 79–46–9 |
| 3,3′-Dichlorobenzidine | 91–94–1 |
| 3,3′-Dimethoxybenzidine | 119–90–4 |
| 3,3′-Dimethylbenzidine | 119–93–7 |
| 4,4′-Methylene bis(2-chloroaniline) | 101–14–4 |
| Acetaldehyde | 75–07–0 |
| Acrylamide | 79–06–1 |
| Acrylonitrile | 107–13–1 |
| Allyl chloride | 107–05–1 |
| alpha-Hexachlorocyclohexane (a-HCH) | 319–84–6 |
| Aniline | 62–53–3 |
| Benzene | 71–43–2 |
| Benzidine | 92–87–5 |
| Benzotrichloride | 98–07–7 |
| Benzyl chloride | 100–44–7 |
| beta-Hexachlorocyclohexane (b-HCH) | 319–85–7 |
| Bis(2-ethylhexyl)phthalate | 117–81–7 |
| Bis(chloromethyl)ether | 542–88–1 |
| Bromoform | 75–25–2 |
| Captan | 133–06–2 |
| Carbon tetrachloride | 56–23–5 |
| Chlordane | 57–74–9 |
| Chlorobenzilate | 510–15–6 |
| Chloroform | 67–66–3 |
| Chloroprene | 126–99–8 |
| Cresols (mixed) | 1319–77–3 |
| DDE | 3547–04–4 |
| Dichloroethyl ether | 111–44–4 |
| Dichlorvos | 62–73–7 |
| Epichlorohydrin | 106–89–8 |
| Ethyl acrylate | 140–88–5 |
| Ethylene dibromide | 106–93–4 |
| Ethylene dichloride | 107–06–2 |
| Ethylene oxide | 75–21–8 |
| Ethylene thiourea | 96–45–7 |
| Ethylidene dichloride (1,1-Dichloroethane) | 75–34–3 |
| Formaldehyde | 50–00–0 |
| Heptachlor | 76–44–8 |
| Hexachlorobenzene | 118–74–1 |
| Hexachlorobutadiene | 87–68–3 |
| Hexachloroethane | 67–72–1 |
| Hydrazine | 302–01–2 |
| Isophorone | 78–59–1 |
| Lindane (hexachlorocyclohexane, all isomers) | 58–89–9 |
| m-Cresol | 108–39–4 |
| Methylene chloride | 75–09–2 |
| Naphthalene | 91–20–3 |
| Nitrobenzene | 98–95–3 |
| Nitrosodimethylamine | 62–75–9 |
| o-Cresol | 95–48–7 |
| o-Toluidine | 95–53–4 |
| Parathion | 56–38–2 |
| p-Cresol | 106–44–5 |
| p-Dichlorobenzene | 106–46–7 |
| Pentachloronitrobenzene | 82–68–8 |
| Pentachlorophenol | 87–86–5 |

TABLE 8 TO SUBPART MMMMM OF PART 63—LIST OF HAZARDOUS AIR POLLUTANTS THAT MUST BE COUNTED TOWARD TOTAL HAP CONTENT IF PRESENT AT 0.1 PERCENT OR MORE BY WEIGHT—Continued

| Chemical name | CAS No. |
|---|---|
| Propoxur | 114–26–1 |
| Propylene dichloride | 78–87–5 |
| Propylene oxide | 75–56–9 |
| Quinoline | 91–22–5 |
| Tetrachloroethene | 127–18–4 |
| Toxaphene | 8001–35–2 |
| Trichloroethylene | 79–01–6 |
| Trifluralin | 1582–09–8 |
| Vinyl bromide | 593–60–2 |
| Vinyl chloride | 75–01–4 |
| Vinylidene chloride | 75–35–4 |

## Subpart OOOOOO—National Emission Standards for Hazardous Air Pollutants for Flexible Polyurethane Foam Production and Fabrication Area Sources

■ 22. Section 63.11416 is amended by revising paragraphs (b) and (f) to read as follows:

### § 63.11416 What are the standards for new and existing sources?

* * * * *

(b) If you own or operate a new or existing slabstock polyurethane foam production affected source, you must not use any material containing methylene chloride for any purpose in any slabstock flexible foam production process.

* * * * *

(f) You may demonstrate compliance with the requirements in paragraphs (b) through (e) of this section using adhesive usage records, Material Safety Data Sheets, and engineering calculations.

■ 23. Section 63.11417 is amended by:

■ a. Revising paragraph (b) introductory text;

■ b. Removing and reserving paragraph (b)(1); and

■ c. Revising paragraph (b)(2) to read as follows:

### § 63.11417 What are the compliance requirements for new and existing sources?

* * * * *

(b) Each owner or operator of a new or existing slabstock flexible polyurethane foam production affected source must comply with paragraphs (b)(2) and (3) of this section.

(1) [Reserved]

(2) You must submit a notification of compliance status report no later than 180 days after your compliance date. The report must contain this certification of compliance, signed by a responsible official, for the standards in § 63.11416(b): ''This facility uses no material containing methylene chloride for any purpose on any slabstock flexible foam process.''

* * * * *

■ 24. Section 63.11418 is revised to read as follows:

### § 63.11418 What General Provisions apply to this subpart?

The provisions in 40 CFR part 63, subpart A, do not apply to sources subject to this subpart.

■ 25. Remove Table 1 to Subpart OOOOOO of Part 63—Applicability of General Provisions to Subpart OOOOOO.

[FR Doc. 2021–24019 Filed 11–17–21; 8:45 am]

BILLING CODE 6560–50–P

## DEPARTMENT OF DEFENSE

## GENERAL SERVICES ADMINISTRATION

## NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

## 48 CFR Parts 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 18, 19, 22, 23, 25, 26, 27, 28, 29, 30, 31, 32, 37, 38, 39, 42, 43, 44, 46, 47, 49, 52, and 53

**[FAC 2022–01; FAR Case 2018–018; Item I; Docket No. FAR–2018–0018, Sequence No. 1]**

**RIN 9000–AN76**

## Federal Acquisition Regulation: Revision of Definition of ''Commercial Item''; Correction

**AGENCY:** Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

**ACTION:** Final rule; correction.

**SUMMARY:** DoD, GSA, and NASA published a final rule amending the Federal Acquisition Regulation (FAR) to implement a section of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 to change the definition of ''commercial item.'' This document corrects an erroneous weblink in that rule.

**DATES:** Effective December 6, 2021.

**FOR FURTHER INFORMATION CONTACT:** Ms. Zenaida Delgado, Procurement Analyst, at 202–969–7207 or by email at *zenaida.delgado@gsa.gov,* for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755 or *GSARegSec@gsa.gov.* Please cite FAC 2022–01, FAR Case 2018–018.

**SUPPLEMENTARY INFORMATION:** DoD, GSA, and NASA are correcting an erroneous weblink under the Background section of the rule.

In FR Doc. 2021–22144 appearing on pages 61017–61038 in the issue of November 4, 2021, make the following correction:

### I. Background [Corrected]

1. On page 61017, in the second column, correct the weblink ''*https://section809panel.org/wp-content/uploads/2018/04/Sec809Panel_Vol1-Report_Jan18_REVISED_2018-03-14.pdf*'' to read ''*https://discover.dtic.mil/wp-content/uploads/809-Panel-2019/Volume1/Sec809Panel_Vol1-Report_Jan2018.pdf.*''

**William F. Clark,**

*Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.*

[FR Doc. 2021–25028 Filed 11–17–21; 8:45 am]

BILLING CODE 6820–EP–P

# Proposed Rules

Federal Register
Vol. 86, No. 220
Thursday, November 18, 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 AGRICULTURE

### Agricultural Marketing Service

### 7 CFR Part 906

**[Doc. No. AMS–SC–21–0065; SC21–906–1 PR]**

## Increased Assessment Rate for Texas Oranges and Grapefruit

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would implement a recommendation from the Texas Valley Citrus Committee (Committee) to increase the assessment rate established for the 2021–22 and subsequent fiscal periods. The proposed assessment rate would remain in effect indefinitely unless modified, suspended, or terminated.

**DATES:** Comments must be received by December 20, 2021.

**ADDRESSES:** Interested persons are invited to submit written comments concerning this proposed rule. Comments must be sent to the Docket Clerk, Market Development Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Fax: (202) 720–8938; or internet: *http://www.regulations.gov.* Comments should reference the document number and the date and page number of this issue of the **Federal Register** and will be available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: *http://www.regulations.gov.* All comments submitted in response to this proposed rule will be included in the record and will be made available to the public. Please be advised that the identity of individuals or entities submitting comments will be made public on the internet at the address provided above.

**FOR FURTHER INFORMATION CONTACT:** Abigail Campos, Marketing Specialist, or Christian D. Nissen, Regional Director, Southeast Marketing Field Office, Market Development Division, Specialty Crops Program, AMS, USDA; Telephone: (863) 324–3375, Fax: (863) 291–8614, or Email: *Abigail.Campos@usda.gov* or *Christian.Nissen@usda.gov.*

Small businesses may request information on complying with this regulation by contacting Richard Lower, Market Development Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: *Richard.Lower@usda.gov.*

**SUPPLEMENTARY INFORMATION:** This action, pursuant to 5 U.S.C. 553, proposes to amend regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This proposed rule is issued under Marketing Agreement No. 121 and Marketing Order No. 906, both as amended (7 CFR part 906), regulating the handling of oranges and grapefruit grown in the Lower Rio Grande Valley in Texas. Part 906, (referred to as ''the Order'') is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.'' The Committee locally administers the Order and comprises producers and handlers of oranges and grapefruit operating within the production area.

The Department of Agriculture (USDA) is issuing this proposed rule in conformance with Executive Orders 12866 and 13563. 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, reducing costs, harmonizing rules, and promoting flexibility. This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review.

This proposed rule has been reviewed under Executive Order 13175—Consultation and Coordination with Indian Tribal Governments, which requires agencies to consider whether their rulemaking actions would have tribal implications. AMS has determined that this proposed rule is unlikely to have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the Order now in effect, Texas citrus handlers are subject to assessments. Funds to administer the Order are derived from such assessments. It is intended that the assessment rate would be applicable to all assessable oranges and grapefruit for the 2021–22 fiscal period and continue until amended, suspended, or terminated.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This proposed rule would increase the assessment rate from $0.01 per 7/10-bushel carton or equivalent, the rate that was established for the 2018–19 and subsequent fiscal periods, to $0.05 per 7/10-bushel carton or equivalent of oranges and grapefruit handled for the 2021–22 and subsequent fiscal periods.

The Order authorizes the Committee, with the approval of USDA, to formulate an annual budget of expenses and collect assessments from handlers to administer the program. Members are familiar with the Committee's needs and with costs for goods and services in their local area and are in a position to formulate an appropriate budget and assessment rate. The assessment rate is

formulated and discussed in a public meeting. Thus, all directly affected persons have had an opportunity to participate and provide input.

For the 2018–19 and subsequent fiscal periods, the Committee recommended, and USDA approved, an assessment rate of $.01 per 7/10-bushel carton or equivalent of oranges and grapefruit handled. That assessment rate continues to be in effect unless modified, suspended, or terminated by USDA upon recommendation and information submitted by the Committee or other information available to USDA.

The Committee met on July 14, 2021, and recommended 2021–22 expenditures of $43,900 and an assessment rate of $0.05 per 7/10-bushel carton or equivalent. In comparison, the previous fiscal period's budgeted expenditures were $155,720. The assessment rate of $0.05 is $0.04 higher than the rate currently in effect. The Committee unanimously voted to increase the assessment rate due to the extensive tree damage from a freeze experienced in Texas occurring in February 2021. This February freeze decreased the 2020–21 production from an expected 7.5 million 7/10-bushel cartons to 3.1 million 7/10-bushel cartons. The Committee discussed how freeze damages caused a depletion of financial reserves for the 2020–21 fiscal period due to assessment income being lower than expected. Production will be further reduced during the upcoming fiscal period because of freeze damage to trees. Estimated production for the 2021–22 fiscal period has been reduced from 7.5 million 7/10-bushel cartons or equivalents to 1 million. At the current assessment rate, assessment income would equal $10,000, an amount insufficient to cover the Committee's anticipated expenses of $43,900. By increasing the assessment rate by $0.04, assessment income would be $50,000. This amount should provide sufficient funds to meet fiscal period 2021–22 anticipated expenses.

Major expenditures recommended by the Committee for the 2021–22 fiscal period include $20,000 for management expenses, $13,900 for administrative expenses, and $10,000 for compliance. Budgeted expenses for these items in the 2020–21 fiscal period were $79,220, $26,500, and $50,000, respectively.

The Committee derived the recommended assessment rate by considering anticipated expenses and expected shipments of Texas oranges and grapefruit. Orange and grapefruit shipments for the 2021–22 fiscal period are estimated at 1,000,000 7/10-bushel cartons or equivalents, which should provide $50,000 in assessment income (1,000,000 cartons multiplied by $0.05). Income derived from handler assessments at the proposed rate, along with interest income, should be adequate to cover estimated program expenses of $43,900. Funds in the reserve (currently about $43,000) would be kept within the maximum permitted by § 906.35 of the Order (approximately one fiscal period's expenses).

The proposed assessment rate would continue in effect indefinitely unless modified, suspended, or terminated by USDA upon recommendation and information submitted by the Committee or other available information.

Although this assessment rate would be in effect for an indefinite period, the Committee will continue to meet prior to or during each fiscal period to recommend a budget of expenses and consider recommendations for modification of the assessment rate. Dates and times of Committee meetings are available from the Committee or USDA. Committee meetings are open to the public and interested persons may express their views at these meetings. USDA would evaluate Committee recommendations and other available information to determine whether modification of the assessment rate is needed. Further rulemaking would be undertaken as necessary. The Committee's 2021–22 budget and those for subsequent fiscal periods would be reviewed and, as appropriate, approved by USDA.

**Initial Regulatory Flexibility Analysis**

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this proposed rule on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 119 producers of oranges and grapefruit in the production area and 14 handlers subject to regulation under the Order. Small agricultural producers are defined by the Small Business Administration (SBA) as those having annual receipts of less than $1,000,000, and small agricultural service firms are defined as those whose annual receipts are less than $30,000,000 (13 CFR 121.201).

According to data from the National Agricultural Statistics Service (NASS), the industry, and the Committee, the weighted average free-on-board price for Texas citrus for the 2019–20 fiscal period was approximately $16.20 per carton, with total shipments of around 8.2 million cartons. Based on this information, total annual receipts of Texas citrus handlers in the 2019–20 fiscal period was approximately $132,840,000 ($16.20 multiplied by 8.2 million cartons equals $132,840,000). Dividing by the number of citrus handlers infers average annual receipts of less than $30 million ($132,840,000 divided by 14 handlers equals $9.5 million).

In addition, based on NASS data, the weighted average producer price for the 2019–20 fiscal period was around $5.65 per carton of Texas citrus. Based on producer price, shipment data, and the total number of Texas citrus producers, the average annual producer revenue is below $1,000,0000 ($5.65 multiplied by 8.2 million cartons equals $46,330,000 divided by 119 producers equals approximately $389,328).

This proposal would increase the assessment rate and collected from handlers for the 2021–22 and subsequent fiscal periods from $0.01 per 7/10-bushel carton or equivalent to $0.05 per 7/10-bushel carton or equivalent of oranges and grapefruit grown in the Lower Rio Grande Valley in Texas. The Committee recommended 2021–22 expenditures of $43,900 and an assessment rate of $0.05 per 7/10-bushel carton. The proposed assessment rate of $0.05 is $0.04 higher than the current rate. The quantity of assessable Texas Citrus for the 2021–22 fiscal period is estimated at 1,000,000 7/10-bushel cartons. Thus, the $0.05 rate should provide $50,000 in assessment income ($0.05 multiplied by 1,000,000 cartons), which should be adequate to cover budgeted expenses for the 2021–22 season.

Major expenditures recommended by the Committee for the 2021–22 fiscal period include $20,000 for management expenses, $13,900 for administrative expenses, and $10,000 for compliance. Budgeted expenses for these items in 2020–21 were $79,220, $26,500, and $50,000, respectively.

The Committee recommended increasing the assessment rate because of the extensive tree damage from the freeze in February 2021. At the current assessment rate of $0.01 and with the 2021–22 crop estimated to be 1,000,000 7/10-bushel cartons, assessment income would equal $10,000 ($0.01 multiplied

by 1,000,000 cartons), an amount insufficient to cover the Committee's anticipated expenditures of $43,900. By increasing the assessment rate by $0.04, assessment income would be approximately $50,000 ($0.05 multiplied by 1,000,000 cartons). This amount should provide sufficient funds to meet 2021–22 anticipated expenses.

Prior to arriving at this budget and assessment rate, the Committee considered maintaining the current assessment rate of $0.01. However, leaving the assessment unchanged would not generate sufficient revenue to meet the Committee's expenses for the 2021–22 budget of $43,900 and would diminish reserves. Therefore, the alternative was rejected.

A review of historical information and preliminary information pertaining to the upcoming fiscal period indicates that the producer price for 2021–22 should be approximately $5.42 per 7/10-bushel carton or equivalent of oranges and grapefruit. Therefore, the estimated assessment revenue for the 2021–22 fiscal period as a percentage of total producer revenue would be approximately 0.9 percent ($50,000 divided by $5.42 × 1,000,000 cartons).

This action would increase the assessment obligation imposed on handlers. While assessments impose additional costs on handlers, costs are minimal and uniform on all handlers, and some portion of additional costs may be passed through to producers. However, these costs are expected to be offset by benefits derived by the operation of the Order.

The Committee's meeting was widely publicized throughout the Texas citrus industry. All interested persons were invited to attend the meeting and participate in Committee deliberations on all issues. Like all Committee meetings, the July 14, 2021, meeting was a public meeting and all entities, both large and small, were able to express views on this issue. Finally, interested persons are invited to submit comments on this proposed rule, including the regulatory and informational impacts of this action on small businesses.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Order's information collection requirements have been previously approved by the OMB and assigned OMB No. 0581–0189 Fruit Crops. No changes in these requirements would be necessary as a result of this proposed rule. Should any changes become necessary, they would be submitted to OMB for approval.

This proposed rule would not impose any additional reporting or recordkeeping requirements on either small or large Texas orange and grapefruit handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act, promoting the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services.

USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this proposed rule.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *http://www.ams.usda.gov/rules-regulations/moa/small-businesses.* Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

A 30-day comment period is provided to allow interested persons to respond to this proposed rule. All written comments timely received will be considered before a final determination is made on this matter.

**List of Subjects in 7 CFR Part 906**

Grapefruit, Marketing agreements, Oranges, Reporting and recordkeeping requirements.

For reasons set forth in the preamble, 7 CFR part 906 is proposed to be amended as follows:

## PART 906—ORANGES AND GRAPEFRUIT GROWN IN LOWER RIO GRANDE VALLEY IN TEXAS

■ 1. The authority citation for 7 CFR part 906 continues to read as follows:

**Authority:** 7 U.S.C. 601–674.

■ 2. Section 906.235 is revised to read as follows:

**§ 906.235 Assessment rate.**

On and after August 1, 2021, an assessment rate of $0.05 per 7/10-bushel carton or equivalent is established for oranges and grapefruit grown in the Lower Rio Grande Valley in Texas.

**Erin Morris,**

*Associate Administrator, Agricultural Marketing Service.*

[FR Doc. 2021–25116 Filed 11–17–21; 8:45 am]

BILLING CODE P

## SMALL BUSINESS ADMINISTRATION

## 13 CFR Part 125

**RIN 3245–AH71**

## Past Performance Ratings for Small Business Joint Venture Members and Small Business First-Tier Subcontractors

**AGENCY:** U.S. Small Business Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Small Business Administration is proposing to amend its regulations to implement new provisions of the National Defense Authorization Act (NDAA) Fiscal Year 2021 (FY 2021). The proposed rule would provide new methods for small business government contractors to obtain past performance ratings to be used with offers on prime contracts with the Federal Government. A small business contractor may use a past performance rating for work performed as a member of a joint venture or for work performed as a first-tier subcontractor. This proposed rule updates the requirements for small business subcontracting plans to add a requirement for prime contractors to report past performance to a first-tier, small business subcontractor when requested by the small business that was a first-tier subcontractor.

**DATES:** Comments must be received on or before January 18, 2022.

**ADDRESSES:** You may submit comments, identified by RIN: 3245–AH71, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email:* Donna Fudge, Procurement Analyst, Office of Policy Planning and Liaison, Small Business Administration, at *Donna.Fudge@sba.gov.*

SBA will post all comments on *https://www.regulations.gov.* If you wish to submit confidential business information (CBI), as defined in the User Notice at *https://www.regulations.gov,* please submit the information to Donna Fudge, Small Business Administration at *Donna.Fudge@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:** Donna Fudge, Procurement Analyst, Office of Policy Planning and Liaison, Small Business Administration, at *Donna.Fudge@sba.gov,* (202) 205–6363.

**SUPPLEMENTARY INFORMATION:**

## I. Background Information

Section 868 of NDAA FY21, Public Law 116–283, addresses a common obstacle that small businesses may face when competing for prime Federal Government contracts: Possessing qualifying past performance. The proposed rule implements section 868 by providing small businesses with two new methods for obtaining qualifying past performance. First, a small business may use the past performance of a joint venture of which it is a member, provided that the small business worked on the joint venture's contract or contracts. Second, a small business may use past performance it obtained as a first-tier subcontractor on a prime contract with a subcontracting plan. For this latter method, section 868 authorizes the small business to seek a past performance rating from the prime contractor and submit the rating with the small business' offer on a new prime contract.

Section 868 added a new section 15(e)(5) to the Small Business Act, 15 U.S.C. 644(e)(5), to address past performance ratings of joint ventures for small business concerns. A small business concern that previously participated in a joint venture with another business concern (whether or not the other concern was small) may use the past performance of the joint venture with the small business' offer on a prime contract. Section 15(e)(5) directs SBA to establish regulations to allow the small business to elect to use the joint venture's past performance if the small business has no relevant past performance of its own. The small business must: (i) Identify to the contracting officer the joint venture of which the small business was a member; (ii) the contract(s) of the joint venture the small business elects to use; and (iii) inform the contracting officer what duties and responsibilities the small business carried out as part of the joint venture. In turn, the contracting officer shall consider the past performance of the joint venture when evaluating the past performance of the small business concern, giving due consideration to the information submitted about the duties and responsibilities that the small business carried out.

To address first-tier small business subcontractors, section 868 amended section 8(d)(17) of the Small Business Act, 15 U.S.C. 637(d)(17), which previously discussed a pilot program to provide past performance ratings for other small business subcontractors. Under the section 868 program, small business concerns may obtain past performance ratings for performance as a first-tier subcontractor on a prime contract that included a subcontracting plan. The proposed rule would require the prime contractor on the prime contract to provide a rating of the small business's past performance with respect to that prime contract to the small business within 15 days of the request. If the small business elects to use the past performance rating, the contracting officer shall consider the past performance rating when evaluating the small business's offer on a prime contract.

Because section 868 replaced the prior pilot program in section 8(d)(17), SBA will no longer pursue the pilot program as described in 83 FR 17583. This proposed rule creates a separate mechanism for first-tier subcontractors to obtain past performance ratings. The Federal Acquisition Regulation (FAR) rule implementing this requirement will account for the information collection, and clearance for the information collection will be obtained by the FAR Council.

SBA requests comments on whether small business subcontractors have been negatively impacted in competing for prime contracts due to not having a past performance rating(s).

SBA also seeks comment on whether to prescribe a time frame within which the subcontractor must make a request to the prime contractor for a rating under this proposed rule. If the prime contractor is currently in the period of performance for its contract, the prime contractor would be bound by its subcontracting plan to respond to the subcontractor's request. After the period of performance, however, the prime contractor would not necessarily be required to respond, because the contract would have ended. SBA seeks comment on whether to recommend that a subcontractor submit its request for a rating within the period of performance of the prime contractor's contract. If there might be a reasonable period of time after the physical completion of the prime contractor's contract in which the subcontractor should or must submit its request, SBA seeks comment on how to implement that time period into the prime contractor's Federal contract and what the time period might be. SBA also seeks comment on if the prime contractor and subcontractor might negotiate time periods and procedures by which the subcontractor can request a rating, and, if so, how to recognize that ability to negotiate in this regulatory prescription. In particular, should SBA recommend that the subcontractor negotiate the procedures for submitting a request and the time frames?

## II. Section-by-Section Analysis

*13 CFR 125.3*

This proposed rule would add a requirement to prime contractors' subcontracting plans. The subcontracting plan will require the prime contractor to provide a rating of a first-tier subcontractor's past performance within 15 days of the first-tier subcontractor's request. The requested rating would be prepared to include, at a minimum, the following evaluation factors in the requested rating: (a) Technical (quality of product or service); (b) Cost control (not applicable for firm-fixed-price or fixed-price with economic price adjustment arrangements); (c) Schedule/timeliness; (d) Management or business relations; and (e) Other (as applicable).

*13 CFR 125.11*

This proposed rule renumbers 13 CFR 125.11 and subsequent sections to create a new § 125.11. New § 125.11(a) provides general guidance to require agencies to consider the past performance of certain small business offerors that have been members of joint ventures or first-tier subcontractors. The remainder of this proposed rule addresses the two scenarios from NDAA 2021.

First, a small business concern may receive past performance consideration for the past performance of a joint venture of which the small business was a member. To receive past performance consideration, where the small business does not independently demonstrate past performance necessary for award, the small business may elect to use the joint venture's past performance and the contracting officer shall consider the joint venture past performance that the small business has elected to use. In its offer for a prime contract, the small business must identify: (i) The joint venture; (ii) the contract(s) of the joint venture that the small business elects to use; and (iii) describe to the agency what duties or responsibilities the small business carried out as a joint venture member. The small business cannot, however, claim past performance credit for work performed exclusively by other partners to the joint venture.

As required by NDAA 2021, the contracting officer shall consider the information that the small business provided about its duties and responsibilities carried out as part of the joint venture. Where the small business does not independently demonstrate past performance necessary for award,

agencies shall consider a small business' successful rating of past performance through a joint venture. For example, a solicitation might require three past performance examples. This proposed rule would authorize the small business offeror to submit two examples from performance in its own name and one example from performance of a joint venture of which it was a member if the small business cannot independently provide the third example of past performance on its own. This proposed rule provides that the joint venture's past performance may supplement the relevant past performance of the small business when the small business cannot independently demonstrate the past performance on its own.

Second, a small business concern may receive past performance consideration for performance as a first-tier subcontractor. NDAA FY21 directs that this mechanism is limited to small businesses that performed as first-tier subcontractors on contracts that include subcontracting plans. The small business may request a rating of its subcontractor past performance from the prime contractor. Under the proposed rule, the prime contractor must provide a rating to the requesting small business withinwith 15 days of the request.

Under this proposed rule, the requested rating would be prepared to include, at a minimum, the following evaluation factors in the requested rating: (a) Technical (quality of product or service); (b) Cost control (not applicable for firm-fixed-price or fixed-price with economic price adjustment arrangements); (c) Schedule/timeliness; (d) Management or business relations; and (e) Other (as applicable). The proposed rule clarifies that one scenario where this applies is where the small business lacks a rating in the Contractor Performance Assessment Reporting System (CPARS). In that case, the agency shall consider the small business's subcontractor past performance rating as being equivalent to a CPARS rating.

This proposed rule clarifies that a joint venture composed of small businesses may receive past performance consideration for work that the joint venture performed as a first-tier subcontractor. A small business member of the joint venture subcontractor may request a past performance rating from the prime contractor for a contract that included a subcontracting plan. The prime contractor must provide the requested rating to the joint venture member within 15 days of the request. The requested rating would be prepared to include, at a minimum, the following evaluation factors in the requested record: (a) Technical (quality of product or service); (b) Cost control (not applicable for firm-fixed-price or fixed-price with economic price adjustment arrangements); (c) Schedule/timeliness; (d) Management or business relations; (e) Other (as applicable). The small business could then use that rating to establish its past performance in accordance with the prior provision on submitting joint venture past performance.

*13 CFR 125.28*

SBA is proposing to change the reference from § 125.15(a) to § 125.18(a) everywhere it appears in this section due to renumbering of sections. Section 125.18(a) provides the requirements for representation of service-disabled veteran-owned (SDVO) small business status.

*13 CFR 125.29*

SBA is proposed to change the reference from § 125.8 to § 125.12 everywhere it appears in this section due to renumbering of sections. Section 125.12 provides the definitions that are important in the Service-Disabled Veteran-Owned (SDVO) Small Business Concern (SBC) program.

*13 CFR 125.30*

SBA is proposing to change the reference from § 125.8 to § 125.12 everywhere it appears in this section due to renumbering of sections. Section 125.12 provides the definitions that are important in the SDVO SBC program.

## III. Compliance With Executive Orders 12866, 12988, 13132, 13175, 13563, the Paperwork Reduction Act (44 U.S.C., Ch. 35), and the Regulatory Flexibility Act (5 U.S.C. 601–612)

*Executive Order 12866*

The Office of Management and Budget (OMB) has determined that this rule is a significant regulatory action for the purposes of Executive Order 12866. Accordingly, the next section contains SBA's Regulatory Impact Analysis.

1. Regulatory Impact Analysis: *Is there a need for the regulatory action?*

This rule is necessary to satisfy statutory requirements to implement section 868 of National Defense Authorization Act of Fiscal Year 2021 (NDAA FY21). Section 868 (e) requires the Administrator to issue rules to carry out the section.

Absence of past performance has been a limitation for small businesses when pursuing procurement opportunities that evaluate past performance. Small businesses often have past performance through work performed as a joint venture partner or as a subcontractor, but this experience and past performance is often not acknowledged or credited to the relevant small business in the evaluation process. This proposed rule is necessary to address that shortcoming in the evaluation of past performance and experience.

The FAR states that ''past performance, except as set forth in paragraph (c)(3)(iii) of this section, shall be evaluated in all source selections for negotiated competitive acquisitions expected to exceed the simplified acquisition threshold.'' See FAR 15.304(c)(3). Past performance is ''one indicator of an offeror's ability to perform the contract successfully.'' See FAR 15.305(a)(2). FAR 15.302(a)(2)(iv) provides that, in the case of an offeror without a record of relevant past performance or for whom information on past performance is not available, the offeror may not be evaluated favorably or unfavorably on past performance. Because past performance may be considered a responsibility factor or because past performance affects an offeror's evaluation as compared to other offerors, the ability of small businesses that have been first-tier subcontractors or participated in joint ventures to demonstrate past performance increases their competitiveness in Federal contracting.

2. *What is the baseline, and the incremental benefits and costs of this regulatory action?*

OMB directs agencies to establish an appropriate baseline to evaluate any benefits, costs, or transfer impacts of regulatory actions and alternative approaches considered. The baseline should represent the agency's best assessment of what the world would look like absent the regulatory action. For a regulatory action that modifies or replaces an existing regulation, a baseline assuming no change to the regulation generally provides an appropriate benchmark for evaluating benefits, costs, or transfer impacts of proposed regulatory changes and their alternatives. This proposed rule would implement the changes, by modifying and expanding, the rating procedures of the unimplemented pilot program in 8(d)(17) of the Small Business Act (15 U.S.C. 637(d)(17)), which was added by section 1822 of the National Defense Authorization Act of 2017.

NDAA FY21 amended Section 8(d)(17) of the Act to allow small businesses that performed as first tier subcontractors to request a past performance rating from the prime contractor. The prime contractor must provide a rating of the small business past performance with respect to that prime contract to the small business

within 15 days of the request. The requested rating would be prepared to include, at a minimum, the following evaluation factors in the requested rating: (a) Technical (quality of product or service); (b) Cost control (not applicable for firm-fixed price or fixed-price with economic price adjustment arrangements); (c) Schedule/timeliness; (d) Management or business relations; (e) Other (as applicable). This proposed rule would modify the pilot program, in which a small business that had not performed as a prime contractor could request a past performance rating in the Contractor Performance Assessment Reporting System (CPARS), if the small business is a first tier subcontractor under a covered Federal Government contract requiring a subcontracting plan. Section 868(a) amends Section 15(e) of the Small Business Act to direct the establishment of regulations that allow the use of past performance in joint ventures in Federal contracting offers. This amendment expands the opportunities for past performance consideration by including consideration of the past performance of a joint venture of which the small business was a member.

The baseline is that which exists without implementation of the pilot program in section 8(d)(17) of the Small Business Act. In this environment, when a Federal agency creates a procurement opportunity requiring an offeror to provide examples of past performance, a newer small business concern may forego the opportunity because it individually lacks the required number of examples and then opt to join an established prime contractor's team as a subcontractor.

The most significant benefit of this proposed rule to small businesses is that it would enhance of the small businesses' ability to compete in Federal contracting opportunities. The FAR states that ''past performance, except as set forth in paragraph (c)(3)(iii) of this section, shall be evaluated in all source selections for negotiated competitive acquisitions expected to exceed the simplified acquisition threshold.'' See FAR 15.304(c)(3)(i). FAR 15.302(a)(2)(iv) provides that, in the case of an offeror without a record of relevant past performance or for whom information on past performance is not available, the offeror may not be evaluated favorably or unfavorably on past performance. Nevertheless, small businesses without past experience as prime contractors may forego seeking some Federal contracting opportunities. This enhancement of Federal contracting opportunities is consistent with the amendment of the Small Business Act, which states that ''procurement strategies used by a Federal department or agency having contract authority shall facilitate the maximum participation of small business concerns as prime contractors, subcontractors, and suppliers.'' 15 U.S.C. 644(e)(1).

With more small businesses able to demonstrate past performance, agencies will have a larger pool of small businesses competing for contracting opportunities. This added competition may result in lower prices to the Government. SBA cannot quantify this impact before proposal of applicable FAR rules.

Costs of this proposed rule to the private sector include the prime contractor's provision, upon request to provide a past performance rating. The time burden of this requirement to the prime contractor is similar to that of the pilot program's past performance rating requirement. SBA estimates the fulfillment of a past performance request to require about 30 minutes of time. Assuming that a compilation of a rating of past performance involves 30 minutes of work by an employee of the prime contractor and valuing the time at $93.44 per hour,[1] SBA estimates that each rating request costs a prime contractor $46.72 in labor plus de minimis costs of transmission of the rating. There were approximately 34,000 individual subcontracting plans with 24,000 at the prime contract level in fiscal year 2015 (81 FR 94249), but it is not known how many small businesses were involved in these subcontracting plans or how many small businesses were involved in multiple subcontracting plans. SBA notes that 1,461 small businesses have active SBA-approved Mentor-Protégé agreements.[2] SBA also notes that in FY2019, the Electronic Subcontracting Reporting System (eSRS) listed 2,082 commercial plans with small businesses.

Assuming that half, or 731, of the small businesses with active agreements in the Mentor-Protégé program request a rating of past performance each year, the annual cost to the private sector of fulfilling these requests for past performance ratings would be $34,152 plus de minimis costs. Assuming that small businesses with 10 percent of 24,000 subcontracting plans at the prime contract level, in addition to those in the Mentor-Protégé program, request a rating of past performance each year, the annual cost to the private sector of fulfilling these requests is $112,128. Assuming each of the 2,082 commercial plans has two to four subcontracts, and half of the total subcontracts represents small business that would request a past performance rating each year, then the annual cost to the private sector of fulfilling these requests would be $145,907 plus de minimis costs. With these assumptions, total annual costs to the private sector of fulfilling requests is $292,187 plus de minimis costs.

The requirement of small business offerors that have been members of joint ventures to identify the joint venture, identify the contract(s) of the joint venture, and describe duties or responsibilities as a joint venture member in order to receive consideration of past performance involves a resource cost to the small business offerors that compile the specified information. SBA notes that this cost would be voluntarily incurred by small businesses that assess the enhancement of Federal contracting opportunities from consideration of past performance to be of greater value than the incremental costs incurred.

If more small businesses meet past performance standards and then submit proposals to contracting agencies, administrative costs to the Government may increase when a contracting agency reviews an increased number of proposals and past performance ratings. SBA cannot quantify these costs and notes that increased competition may offset these costs to the Government.

The ability of more small businesses to demonstrate past performance may redistribute some Federal contracts from businesses that can demonstrate past performance in the baseline scenario that exists with no implementation of the pilot program. This redistribution would not affect overall economic activity. This proposed rule and its effects do not change the amount of dollars in all available Federal contracts. SBA cannot quantify the actual outcome of the gains and losses from the redistribution of contracts among different groups of small businesses that would result from an increased number of small businesses with the ability to demonstrate their experience and past performance, but it expects that competition from small businesses with newly established past performance

[1] The median hourly wage for construction managers is $46.72, according to 2020 Bureau of Labor Statistics (BLS) data, and the hourly rate of $93.44 includes 100 percent more for benefits and overhead. Source for hourly rate: *https://www.bls.gov/ooh/management/construction-managers.htm.* Retrieved June 8, 2021.

[2] One of the goals of the SBA's Mentor-Protégé program is to promote the ability of small protégé businesses to successfully compete for government contracting opportunities. Protégé small businesses often form joint ventures with their mentors to pursue specific procurement requirements in order to gain experience and be able independently perform similar requirements in the future.

ratings may displace some small businesses that had established ratings in Federal contracting opportunities. A partial offset of this transfer impact among small businesses may occur with increased numbers of contracts set aside for small businesses through the Rule of Two, which states there is a reasonable expectation that the contracting officer will obtain offers from at least two small businesses and award will be made at fair market price.

3. *What are the alternatives to this rule?*

This proposed rule would implement specific statutory provisions in Section 868 of the NDAA FY21. There are no alternatives that would meet the statutory requirements.

*Executive Order 12988*

This proposed rule 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*

This proposed rule does not have federalism implications as defined in Executive Order 13132. It will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in the Executive order. As such it does not warrant the preparation of a Federalism Assessment.

*Executive Order 13175*

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.

*Executive Order 13563*

This Executive order directs agencies to, among other things: (a) Afford the public a meaningful opportunity to comment through the internet on proposed regulations, with a comment period that should generally consist of not less than 60 days; (b) provide for an ''open exchange'' of information among government officials, experts, stakeholders, and the public; and (c) seek the views of those who are likely to be affected by the rulemaking, even before issuing a notice of proposed rulemaking. As far as practicable or relevant, SBA considers these requirements in developing this rule, as discussed below.

1. Did the agency use the best available techniques to quantify anticipated present and future costs when responding to E.O. 12866 (*e.g.,* identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes)?

To the extent possible the agency utilized the most recent data available in the Federal Procurement Data System-Next Generation, System for Award Management, and Electronic Subcontracting Reporting System.

2. Public participation: Did the agency: (a) Afford the public a meaningful opportunity to comment through the internet on any proposed regulation, with a comment period that should generally consist of not less than 60 days; (b) provide for an ''open exchange'' of information among Government officials, experts, stakeholders, and the public; (c) provide timely online access to the rulemaking docket on *Regulations.gov*; and (d) seek the views of those who are likely to be affected by rulemaking, even before issuing a notice of proposed rulemaking?

The proposed rule will have a 60-day comment period and will be posted on *www.regulations.gov* to allow the public to comment meaningfully on its provisions.

3. Flexibility: Did the agency identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public?

Yes, the proposed rule implements statutory provisions that provide new methods for small business government contractors to obtain past performance ratings to be used with offers on prime contracts with the Federal Government. The proposed rule would update the requirements for small business subcontracting plans to add a requirement for prime contractors to report past performance to a small business, first-tier subcontractor when requested by the small business first-tier subcontractor. The proposed rule will enhance the small business' ability to compete for Federal Government prime contracting opportunities.

*Paperwork Reduction Act*

This rule, if adopted in final form, would update the requirements for small business subcontracting plans to add a requirement for prime contractors to report past performance to a small business, first-tier subcontractor when requested by the small business first-tier subcontractor. The FAR rule implementing this requirement will account for this information collection, and clearance for the information collection will be obtained by the FAR Council.

In this proposed rule, SBA also proposes that a small business concern may receive past performance consideration for the past performance of a joint venture of which the small business was a member. This does not require a new information collection because the Government contracting officer rates the joint venture entity.

*Regulatory Flexibility Act*

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. The RFA defines ''small entity'' to include ''small businesses,'' ''small organization,'' and ''small governmental jurisdictions.''

This proposed rule provides new methods for small business contractors to obtain past performance ratings to be used with offers on prime contracts, as such the rule relates to small business concerns but would not affect ''small organizations'' or ''small governmental jurisdictions'' because those programs generally apply only to ''business concerns'' as defined by SBA regulations, in other words, to small businesses organized for profit. ''Small organizations'' or ''small governmental jurisdictions'' are non-profits or governmental entities and do not generally qualify as ''business concerns'' within the meaning of SBA's regulations.

There are approximately 1,431 active SBA-approved Mentor-Protégé agreements and SBA estimates that half, or 731, small businesses with active agreements would request a past performance rating from its prime contractor in a year. Of the 24,000 subcontracting plans at the prime contract level in fiscal year 2015, SBA assumes for this analysis that up to 2,400 that are not in the Mentor-Protégé program may request a past performance rating each year. Additionally, in FY2019 there were 2,082 commercial

plans with small businesses. Assuming two to four subcontracts for each commercial plan, and half of them request a past performance rating, SBA estimates that up to 3,123 small businesses involved in commercial plans may request a past performance rating each year. The proposed changes allow small business contractors to request a past performance rating from a prime contractor for whom they performed work as a first-tier subcontractor or as a member of a joint venture. In addition, the proposed rule updates the requirements for small business subcontracting plans to add a responsibility for prime contractors to report past performance of the first-tier when requested by that first-tier subcontractor.

As a result, SBA does not believe the proposed rule would have a disparate impact on small businesses or would impose any additional significant costs. For the reasons discussed, SBA certifies that this proposed rule would not have a significant economic impact on a substantial number of small business concerns.

**List of Subjects in 13 CFR Part 125**

Government contracts, Government procurement, Reporting and recordkeeping requirements, Small businesses, Small business subcontracting.

For the reasons stated in the preamble, SBA proposes to amend 13 CFR part 125 as follows:

## PART 125—GOVERNMENT CONTRACTING PROGRAMS

■ 1. The authority citation for part 125 continues to read as follows:

**Authority:** 15 U.S.C. 632(p), (q), 634(b)(6), 637, 644, 657f, 657q, 657r, and 657s; 38 U.S.C. 501 and 8127.

■ 2. Amend § 125.3 by:
■ a. Removing the word ''and'' at the ends of pargarphs (c)(1)(ix) and (x);
■ b. Removing the period at the end of paragraph (c)(1)(xi) and adding ''; and'' in its place; and
■ c. Adding paragraph (c)(1)(xii).

The addition reads as follows:

### § 125.3 What types of subcontracting assistance are available to small businesses?

* * * * *

(c) * * *

(1) * * *

(xii)(A) The prime contractor, upon request from a first-tier small business subcontractor, shall provide the subcontractor with a rating of the subcontractor's past performance. The prime contractor must provide the small business subcontractor the requested rating within 15 days of the request. If the subcontractor will use the rating for an offer on a prime contract it must include, at a minimum, the following evaluation factors in the requested rating:

(*1*) Technical (quality of product or service);

(*2*) Cost control (not applicable for firm-fixed-price or fixed-price with economic price adjustment arrangements);

(*3*) Schedule/timeliness;

(*4*) Management or business relations; and

(*5*) Other (as applicable).

(B) The requirement in paragraph (c)(1)(xii)(A) of this section is not subject to the flowdown in paragraph (c)(1)(x) of this section.

* * * * *

### § § 125.11 through 125.14 [Redesignated as §§ 125.12 through 125.15]

■ 3. Redesignate §§ 125.11 through 125.14 as §§ 125.12 through 125.15.4. Add new § 125.11 before subpart A to read as follows:

### § 125.11 Past performance ratings for certain small business concerns.

(a) *General.* In accordance with sections 15(e)(5) and 8(d)(17) of the Small Business Act, agencies are required to consider the past performance of certain small business offerors that have been members of joint ventures or have been first-tier subcontractors. The agencies shall consider the small business' past performance for the completion of the performance of the evaluated contract or order.

(b) *Small business concerns that have been members of joint ventures*—(1) *Joint venture past performance.* (i) When submitting an offer for a prime contract, a small business concern that has been a member of a joint venture may elect to use the experience and past performance of the joint venture (whether or not the other joint venture partners were small business concerns) where the small business does not independently demonstrate past performance necessary for award. The small business concern, when making such an election, shall:

(A) Identify to the contracting officer the joint venture of which the small business concern is or was a member;

(B) Identify the contract or contracts of the joint venture that the small business elects to use for its experience and past performance for the prime contract offer; and,

(C) Inform the contracting officer what duties and responsibilities the concern carried out or is carrying out as part of the joint venture.

(ii) A small business cannot identify and use as its own experience and past performance work that was performed exclusively by other partners to the joint venture.

(2) *Evaluation.* When evaluating the past performance of a small business concern that has submitted an offer on a prime contract, the contracting officer shall consider the joint venture past performance that the concern elected to use under paragraph (b)(1) of this section, giving due consideration to the information provided under paragraph (b)(1)(i)(C) of this section for the performance of the evaluated contract or order. This includes where the small business concern lacks a past performance rating as a prime contractor in the Contractor Performance Assessment Reporting System, or successor system used by the Federal Government to monitor or rate contractor past performance.

(c) *Small business concerns that have performed as first-tier subcontractors*—(1) *Responsibility of prime contractors.* A small business concern may request a rating of its subcontractor past performance from the prime contractor for a contract on which the concern was a first-tier subcontractor and which included a subcontracting plan. The prime contractor shall provide the rating to the small business concern within 15 days of the request. The prime contractor must include, at a minimum, the following evaluation factors in the requested rating:

(i) Technical (quality of product or service);

(ii) Cost control (not applicable for firm-fixed-price or fixed-price with economic price adjustment arrangements);

(iii) Schedule/timeliness;

(iv) Management or business relations; and

(v) Other (as applicable).

(2) *Joint ventures that performed as first-tier subcontractors.* A small business member of a joint venture may request a past performance rating under pararaph (c)(1) of this section, where a joint venture performed as a first-tier subcontractor. The joint venture member may then submit the subcontractor past performance rating to a procuring agency in accordance with paragraph (b) of this section.

(3) *Evaluation.* When evaluating the past performance of a small business concern that elected to use a rating for its offer on a prime contract, a contracting officer shall consider the concern's experience and rating of past performance as a first-tier subcontractor

and that is within three years (six for construction and architect-engineering) of the completion of performance of the evaluated contract or order. This includes where the small business concern lacks a past performance rating as a prime contractor in the Contractor Performance Assessment Reporting System, or successor system used by the Federal Government to monitor or rate contractor past performance.

**§ 125.28 [Amended]**

■ 5. Amend § 125.28(a) by removing ''§ 125.15(a)'' and adding ''§ 125.18(a)'' in its place.

**§§ 125.29 and 125.30 [Amended]**

■ 6. In addition to the amendments set forth above, in 13 CFR part 125, remove ''§ 125.8'' and add ''§ 125.12'' in its place in the following places:

■ a. § 125.29(a); and

■ b. § 125.30(g)(4).

**Isabella Casillas Guzman,**

*Administrator.*

[FR Doc. 2021–25002 Filed 11–17–21; 8:45 am]

**BILLING CODE 8026–03–P**

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 39

**[Docket No. FAA–2021–1006; Project Identifier MCAI–2021–00700–T]**

**RIN 2120–AA64**

## Airworthiness Directives; Airbus SAS Airplanes

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** The FAA proposes to supersede Airworthiness Directive (AD) 2019–26–01, which applies to certain Airbus SAS Model A350–941 and –1041 airplanes. AD 2019–26–01 requires repetitive detailed inspections, and applicable corrective actions, and provides an optional modification that would terminate the inspections. Since the FAA issued AD 2019–26–01, a determination was made that a related production modification was not properly installed on certain airplanes. This proposed AD would retain the requirements of AD 2019–26–01, and, for certain airplanes, would add a one-time detailed inspection of the modification for proper installation, and applicable corrective actions if necessary, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference. The FAA is proposing this AD to address the unsafe condition on these products.

**DATES:** The FAA must receive comments on this proposed AD by January 3, 2022.

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

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

For the material that will be incorporated by reference (IBR) in this AD, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu*; internet *www.easa.europa.eu.* You may view this IBR material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1006.

### Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1006; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above.

**FOR FURTHER INFORMATION CONTACT:** Dan Rodina, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3225; email *dan.rodina@faa.gov.*

**SUPPLEMENTARY INFORMATION:**

### Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2021–1006; Project Identifier MCAI–2021–00700–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

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

### Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Dan Rodina, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3225; email *dan.rodina@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

### Background

The FAA issued AD 2019–26–01, Amendment 39–21023 (85 FR 4199, January 24, 2020) (AD 2019–26–01), which applies to certain Airbus SAS Model A350–941 and –1041 airplanes. AD 2019–26–01 requires repetitive detailed inspections, and applicable corrective actions, and provides an optional modification that would terminate the inspections. The FAA issued AD 2019–26–01 to address possible water ingress due to sealant bead damage, which could result in

corrosion damage in the aluminum corner fitting. This condition, if not addressed, could lead to detachment and loss of the trimmable horizontal stabilizer (THS), possibly resulting in loss of control of the airplane and injury to persons on the ground.

**Actions Since AD 2019–26–01 Was Issued**

Since the FAA issued AD 2019–26–01, it has been determined that Airbus production modification 113102 was not properly installed on certain Airbus SAS Model A350–941 and –1041 airplanes.

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2021–0141, dated June 15, 2021 (EASA AD 2021–0141) (also referred to as the Mandatory Continuing Airworthiness Information, or the MCAI), to correct an unsafe condition for certain Airbus SAS Model A350–941 and –1041 airplanes. EASA AD 2021–0141 supersedes EASA AD 2019–0206 (which corresponds to FAA AD 2019–26–01).

This proposed AD was prompted by a determination that a related production modification was not properly installed on certain airplanes. The FAA is proposing this AD to address possible water ingress due to sealant bead damage, which could result in corrosion damage in the aluminum corner fitting. This condition, if not addressed, could lead to detachment and loss of the THS, possibly resulting in loss of control of the airplane and injury to persons on the ground. See the MCAI for additional background information.

**Explanation of Retained Requirements**

Although this proposed AD does not explicitly restate the requirements of AD 2019–26–01, this proposed AD would retain all of the requirements of AD 2019–26–01. Those requirements are referenced in EASA AD 2021–0141, which, in turn, is referenced in paragraph (g) of this proposed AD.

**Related Service Information Under 1 CFR Part 51**

EASA AD 2021–0141 describes procedures for repetitive detailed inspections for damage of the fillet sealant and corrosion on aluminum in the lower and upper corner fittings and bearing assembly attachment interface at frame (FR) 102, left-hand and right-hand sides, and an optional modification (application of new corrosion protection in the THS upper and lower attachment fitting bearing assembly) that would eliminate the need for the repetitive inspections. EASA AD 2021–0141 also describes procedures for a one-time detailed inspection of the modification of the lower and upper corner fittings and bearing assembly attachment interface at FR 102, left-hand and right-hand sides (Airbus production modification 113102) for discrepancies (including missing sealant bead, cracks in the sealant bead, and corrosion on the affected bearing zone) and corrective actions (including, but not limited to, a check for grease, a check for cracks in the sealant bead, applying sealant, torqueing the bearing nut, inspecting for corrosion on the affected bearing zone, applying corrosion preventative compound and actions to address missing grease and corrosion). This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

**FAA's Determination and Requirements of This Proposed AD**

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the State of Design Authority, the FAA has been notified of the unsafe condition described in the MCAI referenced above. The FAA is proposing this AD because the FAA evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

**Proposed AD Requirements**

This proposed AD would require accomplishing the actions specified in EASA AD 2021–0141 described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this AD.

**Explanation of Required Compliance Information**

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate EASA AD 2021–0141 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2021–0141 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2021–0141 does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2021–0141. Service information required by EASA AD 2021–0141 for compliance will be available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1006 after the FAA final rule is published.

**Costs of Compliance**

The FAA estimates that this proposed AD affects 15 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

| Action | Labor cost | Parts cost | Cost per product | Cost on U.S. operators |
|---|---|---|---|---|
| Retained actions from AD 2019–26-01 | 30 work-hours × $85 per hour = $2,550 | $0 | $2,550 | $38,250 |
| New proposed actions | 32 work-hours × $85 per hour = $2,720 | 0 | 2,720 | 40,800 |

The FAA has received no definitive data that would enable the agency to provide cost estimates for the corrective actions (including repair) specified in this proposed AD.

ESTIMATED COSTS OF OPTIONAL ACTIONS

| Labor cost | Parts cost | Cost per product |
|---|---|---|
| 34 work-hours × $85 per hour = $2,890 | $0 | $2,890 |

## Authority for This Rulemaking

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

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

## Regulatory Findings

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

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

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

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

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

## List of Subjects in 14 CFR Part 39

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

## The Proposed Amendment

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

## PART 39—AIRWORTHINESS DIRECTIVES

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

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

### § 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2019–26–01, Amendment 39–21023 (85 FR 4199, January 24, 2020); and

■ b. Adding the following new AD:

**Airbus SAS:** Docket No. FAA–2021–1006; Project Identifier MCAI–2021–00700–T.

**(a) Comments Due Date**

The FAA must receive comments on this airworthiness directive (AD) by January 3, 2022.

**(b) Affected ADs**

This AD replaces AD 2019–26–01, Amendment 39–21023 (85 FR 4199, January 24, 2020) (AD 2019–26–01).

**(c) Applicability**

This AD applies to Airbus SAS Model A350–941 and –1041 airplanes, certificated in any category, as identified in European Union Aviation Safety Agency (EASA) AD 2021–0141, dated June 15, 2021 (EASA AD 2021–0141).

**(d) Subject**

Air Transport Association (ATA) of America Code 53, Fuselage.

**(e) Reason**

This AD was prompted by reports of sealant bead damage caused by rotation of the attachment fitting bearing assembly of a trimmable horizontal stabilizer (THS) and a determination that a related production modification was not properly installed on certain airplanes. The FAA is issuing this AD to address possible water ingress due to sealant bead damage, which could result in corrosion damage in the aluminum corner fitting. This condition, if not addressed, could lead to detachment and loss of the THS, possibly resulting in loss of control of the airplane and injury to persons on the ground.

**(f) Compliance**

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

**(g) Requirements**

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2021–0141.

**(h) Exceptions to EASA AD 2021–0141**

(1) Where EASA AD 2021–0141 refers to February 21, 2018 (the effective date of EASA AD 2018–0037), this AD requires using February 28, 2020 (the effective date of FAA AD 2019–26–01).

(2) Where EASA AD 2021–0141 refers to its effective date, this AD requires using the effective date of this AD.

(3) The ''Remarks'' section of EASA AD 2021–0141 does not apply to this AD.

**(i) Other FAA AD Provisions**

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Large Aircraft Section, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (j)(2) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.*

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

(ii) AMOCs approved previously for AD 2019–26–01 are approved as AMOCs for the corresponding provisions of EASA AD 2021–0141 that are required by paragraph (g) of this AD.

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

(3) *Required for Compliance (RC):* For any service information referenced in EASA AD 2021–0141 that contains RC procedures and tests: Except as required by paragraph (i)(2) of this AD, RC procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

**(j) Related Information**

(1) For information about EASA AD 2021–0141, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu*; internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.* You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. This material may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1006.

(2) For more information about this AD, contact Dan Rodina, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3225; email *dan.rodina@faa.gov.*

Issued on November 12, 2021.

**Lance T. Gant,**

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

[FR Doc. 2021–25072 Filed 11–17–21; 8:45 am]

BILLING CODE 4910–13–P

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Parts 61 and 68

**[Docket No. FAA–2021–1040; Notice No. 22–02]**

**RIN 2120–AL51**

## Medical Certification Standards for Commercial Balloon Operations

**AGENCY:** Federal Aviation Administration (FAA), Department of Transportation (DOT).

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** The FAA proposes that airmen hold a valid second-class medical certificate when exercising the privileges of a commercial pilot certificate in a balloon for compensation or hire except when conducting flight training in a balloon. In addition, the FAA proposes miscellaneous amendments related to medical certification requirements for medical flight tests and a minor change to the BasicMed regulations.

**DATES:** Send comments on or before January 18, 2022.

**ADDRESSES:** Send comments identified by docket number FAA–2021–1040 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at (202) 493–2251.

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

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

**FOR FURTHER INFORMATION CONTACT:** Bradley Zeigler, Airman Training and Certification Branch, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; (202) 267–9601; email *Bradley.C.Zeigler@faa.gov.*

**SUPPLEMENTARY INFORMATION:**

### List of Abbreviations and Acronyms Frequently Used in This Document

AMCD Aerospace Medical Certification Division
ADHD Attention Deficit Hyperactivity Disorder
AME Aviation Medical Examiner
ASI Aviation Safety Inspector
ATP Airline Transport Pilot
BFA Balloon Federation of America
IRFA Initial Regulatory Flexibility Analysis
LOA Letter of Authorization
NDR National Driver Register
NPRM Notice of proposed rulemaking
NTSB National Transportation Safety Board
PDPS Problem Driver Pointer System
PIC Pilot in Command
SIC Second in Command
SODA Statement of Demonstrated Ability

### I. Executive Summary

This rulemaking proposes amendments in §§ 61.3 and 61.23 of title 14 of the Code of Federal Regulations (14 CFR) to require commercial balloon pilots [1] conducting operations for compensation or hire to hold a valid second-class medical certificate. Additionally, this proposed rule would continue to allow pilots to provide flight training in balloons without requiring a medical certificate. The proposed rule includes related amendments to the table of medical certificate duration in § 61.23(d) for consistency with the proposed amendments to §§ 61.3 and 61.23(a) and (b). The FAA is also proposing miscellaneous amendments related to medical certification for medical flight tests and a minor change to the Alternative Pilot Physical Examination and Education Requirements final rule, which amended sections of part 61 and established part 68. In this preamble, these regulations will be referred to as BasicMed.

This rulemaking would implement section 318 (''Commercial Balloon Pilot Safety Act of 2018'') of Public Law 115–254, the FAA Reauthorization Act of 2018. In addition, this rulemaking responds to National Transportation Safety Board (NTSB) Safety Recommendation A–17–034, which recommends that the FAA remove the medical certification exemption in part 61 for commercial balloon pilots receiving compensation for transporting passengers.

The proposed rule would generate costs for balloon pilots to obtain a second-class medical certificate and for some pilots to seek authorization through special issuance. There would also be costs to the FAA to implement this requirement in terms of reviewing and processing submissions related to certification. The FAA estimates the present value of total costs over ten years is $2.6 million to $17.8 million with a mid-estimate of $7.5 million at a 7 percent discount rate and $3.1 million to $21.7 million with a mid-estimate of $9.1 million at a 3 percent discount rate. The annualized costs over ten years is $0.4 million to $2.5 million with a mid-estimate of $1.1 million at a 7 percent discount rate and $0.4 million to $2.5 million with a mid-estimate of $1.1 million at a 3 percent discount rate. The wide range in the cost estimates primarily reflect the uncertainty on the number of commercial balloon pilots.[2]

The benefits of the proposed rule include enhanced safety of commercial

[1] The FAA uses the term ''commercial balloon pilots'' in this NPRM to refer to airmen conducting operations in a balloon for compensation or hire, including operations involving the carriage of persons or property.

[2] For more detail on the model used to predict the range, please refer to the ''Affected Entities'' under section V.A. of this preamble.

balloon operations through reduced risks of accidents, fatalities, and injuries caused by medical impairment of balloon pilots.

## II. Authority for the Rulemaking

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

The FAA is issuing this proposal under the authority described in Subtitle VII, Part A, Subpart iii, Section 44701, General Requirements; Section 44702, Issuance of Certificates; and Section 44703, Airman Certificates. Under these sections, the FAA prescribes regulations and minimum standards for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. The FAA is also authorized to issue certificates, including airman certificates and medical certificates, to qualified individuals. This rulemaking proposal is within the scope of that authority.

Further, Section 318 of Public Law 115–254, directs the Administrator to revise 14 CFR 61.3(c) (relating to second-class medical certificates) to apply to an operator of an air balloon to the same extent such regulations apply to a pilot flightcrew member of other aircraft.

## III. Background

### *A. Current Regulatory Framework*

Under current regulations, a person may serve as a required pilot flightcrew member of an aircraft only if that person holds the appropriate medical certificate.[3] There are certain exceptions to this requirement, including pilots operating under the provisions of BasicMed,[4] or those flying balloons, gliders, or light sport aircraft.[5] Additionally, part 61 sets forth which operations require a medical certificate.[6]

A medical certificate provides validation that a person meets FAA medical certification requirements. Airmen must meet the applicable medical standards of part 67 to receive an unrestricted medical certificate. An aviation medical examiner (AME) makes this determination by conducting a physical examination and medical history review. In cases where the airman's medical condition does not meet the part 67 standard, the airman may be issued a medical certificate by authorization for special issuance or statement of demonstrated ability (SODA) when the Federal Air Surgeon has determined that the risk associated with the medical condition(s) is sufficiently mitigated.[7]

Part 67 provides for the issuance of three classes of medical certificates—first-, second-, and third-class medical certificates. In most cases, a first-class medical certificate is required for operations requiring an airline transport pilot (ATP) certificate. At minimum, a second-class medical certificate is required for operations requiring a commercial pilot certificate. Unless an airman chooses to operate under the conditions and limitations of BasicMed, a third-class medical certificate is required for operations requiring a private pilot certificate, a recreational pilot certificate, a flight instructor certificate (when acting as pilot-in-command (PIC) or serving as a required flightcrew member in operations other than a light sport aircraft, glider, or balloon), or a student pilot certificate (other than a light sport aircraft, glider or balloon).[8]

A person obtains a medical certificate by completing an online application (FAA form 8500–8, Application for Medical Certificate) using the FAA's medical certificate application tool, MedXPress[9] and undergoing a physical examination with an FAA-designated AME. An AME may defer an applicant to the FAA for further review when there is information indicating the existence or potential of an adverse medical finding that may warrant further FAA medical evaluation or oversight.

Under § 61.53, all airmen—regardless of whether they are required to hold a medical certificate—are prohibited from operating an aircraft during a medical deficiency. Specifically, § 61.53(b) prohibits a person who is not required to hold a medical certificate from conducting operations while that person knows or has reason to know of any medical condition that would make him or her unable to operate the aircraft in a safe manner. Accordingly, even in the absence of an existing requirement for balloon pilots to hold a medical certificate, all balloon pilots are currently subject to the requirements of § 61.53(b).

As discussed earlier, pilots conducting operations in a balloon are not required to hold a medical certificate. Specifically, under § 61.3(c)(2)(vi), a person holding a pilot certificate with a balloon class rating who is piloting or providing training in a balloon is excepted from the requirement to hold a medical certificate.

A person holding a commercial pilot certificate with a balloon class rating is granted privileges to conduct flights for compensation or hire and to provide flight training. As described in § 61.133(a), an airman who holds a commercial pilot certificate may act as PIC of an aircraft for compensation or hire, including operations involving the carriage of persons or property, provided the person is qualified in accordance with part 61 and other parts (such as part 91, 121 or 135) that apply to the operation. Further, the FAA does not issue flight instructor certificates with lighter-than-air category ratings.[10] Flight training privileges in a balloon are included in the privileges conveyed to the holder of a commercial pilot certificate with a balloon class rating. This approach is unlike other aircraft categories such as airplanes, gliders, and rotorcraft, which require a person to hold a flight instructor certificate in order to exercise such privileges.[11]

### *B. Medical Certificate Requirements for Commercial Flight Operations*

While unpowered[12] commercial operations in balloons and gliders currently have no associated medical

[3] 14 CFR 61.3(c)(1). When referring to a ''medical certificate'' in this NPRM, the FAA is referring only to a current and valid first-, second-, or third-class FAA airman medical certificate issued under 14 CFR part 67, which may have been issued under an authorization for special issuance. Under certain circumstances, this may include other documentation acceptable to the FAA, such as temporary documentation provided to the airman by the FAA when that person is awaiting the replacement of a lost or destroyed certificate. 62 FR 16220, page 16237 (Apr. 4, 1997).

[4] In order to establish medical eligibility to conduct operations under BasicMed, a person must meet the requirements of § 61.23(c)(3).

[5] 14 CFR 61.3(c)(2).

[6] 14 CFR 61.23(a).

[7] 14 CFR 67.401.

[8] Airmen exercising sport pilot privileges in a light sport aircraft without a medical certificate must meet the requirements of § 61.23(c)(2).

[9] *https://medxpress.faa.gov/.*

[10] There are two classes within the lighter-than-air aircraft category: Airship and balloon.

[11] Section 61.133(a)(2) sets forth certain additional privileges granted to airmen holding commercial pilot certificates with a lighter-than-air category rating. Airmen who hold a lighter-than-air category with balloon class rating on their commercial pilot certificate have the following privileges:

1. Give flight and ground training in a balloon for the issuance of a certificate or rating;
2. Give an endorsement for a pilot certificate with a balloon rating;
3. Endorse a pilot's logbook for solo operating privileges in a balloon; and
4. Give ground and flight training and endorsements that are required for a flight review, an operating privilege, or recency-of-experience requirements of part 61.

[12] For the purposes of this rulemaking proposal, the phrase ''unpowered aircraft'' includes self-launch gliders, which are considered by type certificate to be gliders.

certificate requirement, similar commercial operations in powered aircraft require either a first- or second-class medical certificate. Powered aircraft operations that require a commercial pilot certificate require the airman to hold at least a second-class medical certificate. *See* 14 CFR 61.23(a)(2). Generally, these operations include any operation for compensation or hire that does not require an ATP certificate (which requires a first-class medical certificate) and does not qualify under the compensation or hire exceptions in § 61.113(b) through (h) for persons holding a private pilot certificate. Examples of powered aircraft operations that require a commercial pilot certificate with at least a second-class medical certificate include sightseeing flights conducted under § 91.147; [13] commercial transportation of skydivers, banner towing, or aerial photography; and part 135 non-turbine operations of nine passengers or less.

Currently, operations in balloons for compensation or hire that may be conducted without a medical certificate include, but are not limited to, operations for purposes of passenger sightseeing, aerial advertising, maintenance test flights, and research and development flights. There are no operating rules under part 91 that limit the number of passengers an operator may carry. While an operator of a sightseeing flight in a powered aircraft conducted under § 91.147 is required to hold a second-class medical certificate when transporting a single passenger, an operator of a balloon carrying any number of passengers has no requirement to hold a medical certificate. This NPRM includes a proposal to address this disparity.

### *C. Commercial Balloon Operations* [14] *in the U.S.*

Approximately 4,870 commercial pilots hold balloon ratings,[15] and approximately 4,940 balloons are registered with the FAA.[16] The FAA does not have a database of commercial balloon operators actively operating in the United States. Using commercial sources, the FAA estimates there are about 356 individual operators.[17] The commercial balloon industry estimates it conducts 100,000 to 250,000 passenger rides annually, as well as aerial advertising and other commercial activities.[18]

When ballooning was first regulated as an aeronautical activity in the 1940s by the predecessor of the FAA, the Civil Aeronautics Administration, pilots were required to complete a medical examination (CAR part 22).[19] This requirement continued through the establishment of part 61 in 1962.[20]

By the late 1960s, sport ballooning had grown significantly.[21] In 1973, part 61 was revised substantially. Under the revision, a part 67 medical certificate was no longer required for either private or commercial free balloon [22] operations.[23] The medical certificate requirements for balloon operations have remained substantively unchanged since the 1973 revision.

### *D. FAA Oversight*

In the decades following the 1973 revisions, the FAA generally considered commercial balloon operations to be a low-risk and extremely small segment of aviation in the United States. Research conducted by the Agency revealed 54 commercial hot air balloon accidents between 2003 and 2013, including four fatal accidents. In 2015, commercial sightseeing balloon operations represented .057% of the flight hours of total civil aircraft operations.[24]

### *E. 2016 Heart of Texas Hot Air Balloon Accident* [25]

On the morning of July 30, 2016, a hot air balloon, N2469L, operated by Heart of Texas Hot Air Balloon Rides, impacted power lines and burst into flames over a pasture near Lockhart, Texas. The pilot and all 15 passengers were killed. The balloon was destroyed by impact forces and post-crash fire. The flight was conducted under part 91 as a sightseeing passenger flight, and the pilot was exercising the privileges of a commercial pilot certificate.

The NTSB determined that forecast information before launch showed that weather conditions were marginal and deteriorating. While the pilot could have decided to cancel the flight, he opted to launch the hot air balloon and continue the flight into worsening weather conditions. The NTSB also determined that the pilot had been diagnosed with depression and attention deficit hyperactivity disorder (ADHD). These medical conditions are known to cause cognitive deficits that may affect decision-making and, ultimately, safety of flight. The NTSB stated that the medical conditions ''would likely have led an aviation medical examiner (AME) to either defer or deny a medical certificate.'' In addition, the NTSB reported that medications were found in the pilot's system that are known to cause impairment.[26] The NTSB stated, ''[a]n AME would likely have deferred or denied a medical certificate to a pilot reporting use of these medications.'' [27]

The NTSB determined that the probable cause of this accident was the pilot's pattern of poor decision-making that led to the initial launch, continued flight in fog and above clouds, and descent near or through clouds that decreased the pilot's ability to see and avoid obstacles. The NTSB further determined that (1) the pilot's impairing medical conditions and medications, and (2) the FAA's policy to not require a medical certificate for commercial

[13] Section 91.147 is a provision for airplane and helicopter operations conducting passenger-carrying flights for compensation or hire. This provision requires the operators to obtain a Letter of Authorization (LOA) from the FAA, to comply with the various safety provisions of part 136, subpart A, and to implement a drug and alcohol testing program.

[14] The FAA uses the term ''Commercial Balloon Operations'' in this NPRM to refer to the operation of a balloon for compensation or hire, including operations involving the carriage of persons or property.

[15] FAA Airman Registry, as of July 2021. *https://www.faa.gov/licenses_certificates/airmen_certification/releasable_airmen_download/.*

[16] FAA Aircraft Registry, as of October 2019 *https://registry.faa.gov/currentreg/.*

[17] Estimate based on number of commercial operators advertising on *www.blastvalve.com.* Accessed on April 27, 2021.

[18] Testimony of Scott Appelman, Representing the Professional Ride Operators Division of the Balloon Federation of America to NTSB Investigative Hearing, December 9, 2016. Transcript Page 53–54, a copy of which has been placed in the docket for this rulemaking.

[19] Amendment 127 to Civil Air Regulations, Part 22 *Lighter-Than-Air Pilot Certificates.* Effective September 15, 1941. Section 22.13 required the holder to complete ''a physical examination conducted by an authorized medical examiner of the Administrator.'' This requirement was further refined in an October 15, 1942, amendment, requiring a free balloon pilot certificate holder to meet the third-class physical standards prescribed in CAR part 29.

[20] 27 FR 7954 (Aug. 10, 1962), *Subchapter D Airmen [New] Addition of Subchapter.* Effective November 1, 1962, CAR part 22 was recodified as 14 CFR part 61. Free balloon pilot certificates were prescribed in § 61.181 with a requirement for those certificate holders to hold at least a third-class medical certificate issued under the newly created part 67.

[21] National Balloon Museum: *History of Ballooning https://www.nationalballoonmuseum.com/about/history-of-ballooning/.*

[22] The term ''free balloon'' was later replaced with ''balloon'' in April 4, 1997 revision of Part 61. 62 FR 16220.

[23] 37 FR 6012, 6018 (Mar. 23, 1972).

[24] FAA Docket Submission to the National Transportation Safety Board for the investigation of the Heart of Texas Hot Air Balloon Accident Balony Kubicek BB85Z balloon, N2469L, Lockhart, Texas; July 30, 2016, Dated April 19, 2017. Page 6.

[25] NTSB accident No. DCA16MA204, Lockhart, TX, July 30, 2016 Accident Report NTSB/AAR–17/03 PB2018–100161.

[26] The medications identified by the NTSB are listed on the FAA's ''Do Not Issue'' and ''Do Not Fly'' lists found in the AME Guide.

[27] NTSB accident No. DCA16MA204, Lockhart, TX, July 30, 2016 Accident Report NTSB/AAR–17/03 PB2018–100161 Executive Summary Page vii.

balloon pilots, were contributing factors in the accident.[28]

*F. NTSB Recommendations Following the 2016 Heart of Texas Balloon Accident*

On October 31, 2017, the NTSB made two Safety Recommendations in response to the 2016 Heart of Texas balloon accident. Safety Recommendation A–17–034 [29] urged the FAA to ''remove the medical certificate exemption in 14 [CFR] 61.23(b) for pilots who are exercising their privileges as commercial balloon pilots and are receiving compensation for transporting passengers.'' Safety Recommendation A–17–045 [30] urged the FAA to ''analyze your current policies, procedures, and tools for conducting oversight of commercial balloon operations in accordance with your Integrated Oversight Philosophy, taking into account the findings of this accident; [and] based on this analysis, develop and implement more effective ways to target oversight of the operators and operations that pose the most significant safety risks.''

The FAA agreed with the safety benefits of recommendation A–17–034 and stated its intention to add the proposed change to its rulemaking agenda. The FAA responded to Safety Recommendation A–17–045 by initiating a plan to develop and implement more effective ways to target oversight of operators posing the most significant safety risk to the public. The FAA identified and increased surveillance on the operators of the largest classes of balloons using information obtained from the Civil Aviation Registry, repair stations, and industry.

*G. Industry Efforts and Voluntary Compliance*

Immediately following the 2016 Heart of Texas accident, the FAA worked with an industry group, Balloon Federation of America (BFA), to support its 2017 Envelope of Safety Program. The program promotes safety within the commercial balloon industry by educating consumers with information when making balloon ride purchase decisions. The program includes voluntary standards for both pilots and operators and offers multiple tiers of safety accreditation by the BFA.[31]

The FAA supports the efforts of the BFA to enhance safety and professionalism of the industry while providing consumers with more information when choosing a commercial balloon ride operator. The agency notes, however, that not all balloon operators are members of BFA. Moreover, members are not required to adhere to any specific standards in order to maintain professional membership. Consequently, the FAA considers BFA's efforts to achieve voluntary compliance with industry standards to be insufficient alone to address the need for additional oversight of airmen conducting balloon operations for compensation or hire.

## IV. Discussion of the Proposed Rule

This proposed rule would amend part 61 to require a person who holds a commercial pilot certificate with a lighter-than-air category balloon class rating to hold a valid second-class medical certificate when exercising the privileges of that certificate in a balloon for compensation or hire, unless that person is conducting flight training in accordance with § 61.133(a)(2)(ii).

*A. Proposed Rule Amendments*

As previously discussed, balloon pilots currently are not required to hold a medical certificate when exercising the privileges of a commercial pilot certificate. Section 318 (''Commercial Balloon Pilot Safety Act of 2018'') of Public Law 115–254, The FAA Reauthorization Act of 2018, directed the FAA to ''revise section 61.3(c) of title 14, Code of Federal Regulations (relating to second-class medical certificates), to apply to an operator of an air balloon to the same extent such regulations apply to a pilot flightcrew member of other aircraft.'' While the statute specifically directs the FAA to revise § 61.3(c), the FAA notes that § 61.23, *Medical certificates: Requirement and duration,* establishes the requirements and exceptions for medical certificates based on certain types of operations. The FAA proposes to amend § 61.23 in addition to § 61.3(c) for purposes of implementing the statutory requirement.

Section 61.3(c)(1) sets forth the requirement for any person serving as a required pilot flightcrew member of an aircraft to hold the appropriate medical certificate issued under part 67 and to keep evidence of such certificate in the person's physical possession or readily accessible in the aircraft. Exceptions to the medical certificate requirement are set forth in § 61.3(c)(2). Currently, under § 61.3(c)(2)(vi), a person holding a pilot certificate with a balloon class rating who is piloting or providing training in a balloon is not required to hold a medical certificate.

Consistent with the legislative directive, the FAA proposes to amend the medical certificate requirement exception in § 61.3(c)(2)(vi) by limiting it to certain balloon operations. Specifically, the exception would be amended to reflect that any person holding a pilot certificate with a balloon class rating who is (A) exercising the privileges of a private pilot certificate in a balloon; or (B) providing flight training in a balloon in accordance with § 61.133(a)(2)(ii) is not required to hold a medical certificate. By revising the exception in § 61.3(c)(2)(vi), balloon pilots conducting operations for compensation or hire in a balloon (other than flight training), such as carrying passengers or property and advertising operations, would be required under § 61.3(c)(1) to hold a medical certificate issued under part 67.

Section 61.23 sets forth the specific requirements for when a particular class of medical certificate is required. Under § 61.23(a)(2)(ii), a second-class medical certificate generally is required when exercising the privileges of a commercial pilot certificate. However, under § 61.23(b)(3), a second-class medical certificate is not required when exercising the privileges of a pilot certificate with a glider category rating or balloon class rating in a glider or balloon, as appropriate.

The FAA proposes amending § 61.23 to require any person exercising the privileges of a commercial pilot certificate for compensation or hire in a balloon, except when conducting flight training, to hold a second-class medical certificate. First, the FAA proposes to amend § 61.23(a)(2) to add a requirement for any person exercising the privileges of a commercial pilot certificate for compensation or hire in a balloon to hold a second-class medical certificate. Second, the FAA proposes to amend § 61.23(b) to remove the allowance to exercise the privileges of a balloon pilot certificate without a medical certificate. Third and finally, the FAA proposes to add an exception at § 61.23(b)(4)–(5) to explain under what circumstances balloon operations are excepted from the proposed requirement to hold a second-class medical certificate. This exception would specify that a medical certificate is not required when exercising the privileges of a private pilot certificate

[28] NTSB accident No. DCA16MA204, Lockhart TX, July 30, 2016 Accident Report NTSB/AAR–17/03 PB2018–100161 Page 49.

[29] NTSB Safety Recommendation A–17–034 *https://www.ntsb.gov/_layouts/ntsb.recsearch/Recommendation.aspx?Rec=A-17-034.*

[30] NTSB Safety Recommendation A–17–045 *https://www.ntsb.gov/_layouts/ntsb.recsearch/Recommendation.aspx?Rec=A-17-045.*

[31] BFA Envelope of Safety Program *https://www.bfa.net/envelope-of-safety-program.*

with a balloon class rating in a balloon or when exercising the privileges of a commercial pilot certificate with a balloon class rating in a balloon if the PIC is providing flight training in accordance with § 61.133(a)(2)(ii).

Further, § 61.23(d) includes a table providing the duration for each class of medical certificate depending on the several factors including the certificate privilege that is being exercised. The FAA proposes to make related amendments to the table of medical certificate durations at § 61.23(d)(1)(iii) and (d)(2)(i). Specifically, the FAA proposes to add persons who are exercising the privileges of a commercial pilot certificate (other than for flight training) in a balloon to the established medical certificate durations in § 61.23(d).[32] These proposed amendments are for clarification and consistency with the other proposed amendments to §§ 61.3 and 61.23. The FAA does not propose to amend any existing substantive requirement to change the duration of a medical certificate.

All certificated airmen are prohibited from operating an aircraft in the national airspace system during a medical deficiency, regardless of whether they hold a medical certificate or not. This requirement in § 61.53 for medical self-evaluation applies to every flight a person conducts as a required flightcrew member. Airmen conducting commercial balloon operations are currently subject to the requirements of § 61.53(b). Under the proposal, these airmen would be subject to § 61.53(a) by virtue of exercising the privileges of a commercial pilot certificate in a balloon for compensation or hire.

*B. Rationale for Medical Requirement for Commercial Balloons*

Some medical conditions, such as mental health conditions, inherently impair the judgement of the person to properly self-evaluate their medical condition. A lack of medical knowledge about one's own condition may also preclude an airman from effectively determining his or her ability to safely operate the aircraft. Lastly, external factors, such as economic factors or concerns about customer dissatisfaction, may affect the ability of a commercial balloon pilot to make an impartial assessment of his or her health.

Operators conducting flights for compensation or hire are held to a higher safety standard with increased oversight. The commercial balloon industry has evolved and commercial operators today fly much larger balloons carrying many more passengers than in the past. As a result, the risk associated with commercial balloon operations has increased. This increased risk justifies a level of medical oversight equivalent to that of pilots of powered aircraft for certain operations such as commercial sightseeing operations.

The purpose of the FAA medical certification program is to ensure that only pilots, who are physically and mentally fit, will be authorized to operate aircraft, thereby enhancing aviation safety by mitigating the risk of medical factors as a cause of aircraft accidents.

Prior to the Heart of Texas accident, pilots conducted commercial balloon operations in the U.S. for decades without any accidents attributed to medical deficiencies. However, the FAA agrees with the NTSB and Congress that a second-class medical certificate is necessary to increase balloon passenger safety and other balloon operations conducted for compensation or hire. The Heart of Texas accident highlights how the medical certification process could reduce the risk of a similar accident in the future by increasing the level of FAA oversight of commercial balloon operations.

For instance, the pilot in the Heart of Texas accident had a 20-year history of drug and alcohol convictions, which he failed to report to the FAA in accordance with § 61.15(e). If the airman had been required to hold a medical certificate, he would have been required to disclose any history of those arrests and convictions on his medical application form, completed through MedXPress. By signing and submitting the medical application, the airman authorizes the FAA to receive National Driver Register (NDR) pointer data as well as any individual state records, as applicable, as part of the medical certificate application.[33]

The NDR Problem Driver Pointer System (PDPS) identifies records on individuals whose privilege to operate a motor vehicle has been revoked, suspended, canceled or denied, or who have been convicted of serious traffic-related offenses. Even if an airman fails to disclose these convictions on the application, the FAA receives a report from the NDR, providing an additional safeguard and mechanism for verifying the accuracy of the information provided by the airman.

In addition, this pilot had multiple known medical conditions—notably depression and ADHD—which generally could be disqualifying for any class of medical certification under §§ 67.107(c), 67.207(c), and 67.307(c), respectively. Unless the airman was able to demonstrate, to the satisfaction of the Federal Air Surgeon, that the risk associated with each condition and associated treatment warranted an authorization for special issuance, an application for a medical certificate with this medical history disclosed would likely have been denied, if a medical certificate had been required as provided for in this proposal.[34]

Finally, the accident pilot was also using medications that typically are disqualifying[35] for use due to sedation and cognitive impairment. Had he reported their usage to an AME during a medical review, the AME would have discussed this matter with the airman and addressed appropriate usage.

Performance demands of a commercial balloon pilot are very similar to the performance demands of a pilot operating a powered aircraft. In both contexts, commercial pilots should be required to be both physically and mentally fit to operate their respective aircraft. The Heart of Texas accident serves as an example of how a lack of medical oversight allowed the pilot to continue to operate a balloon for compensation or hire in spite of a questionable medical history. The FAA therefore concludes the unpowered nature of commercial balloon operations no longer justifies excepting operators from holding a second-class medical certificate in order to act as PIC.

Flight Training

Unlike other categories of aircraft, the FAA does not issue a flight instructor certificate with a lighter-than-air category rating for part 61 subpart H flight instructors. Flight training privileges in a balloon are conferred to commercial pilots via a balloon rating

[32] As a miscellaneous amendment, the FAA has added flight engineers to § 61.23(d). Section 65.3(b) requires a person serving as a flight engineer of an aircraft to hold a current second-class (or higher) medical certificate issued to that person under part 67, or other documentation acceptable to the FAA, that is in that person's physical possession or readily accessible in the aircraft. In developing this rule, the FAA identified that flight engineers had been inadvertently omitted from the medical certificate duration in § 61.23(d). The FAA proposes to correct that error in this rulemaking.

[33] When applying for a medical certificate in MedXPress, an applicant authorizes the National Driver Register (NDR), through a designated State Department of Motor Vehicles, to furnish to the FAA information pertaining to his or her driving record consistent with 49 U.S.C. 30305(b)(3).

[34] FAA AME Guide: *Pharmaceuticals https://faa.gov/go/ameguide.*

[35] Such medications are typically prohibited for a period of five half-lives. A half-life is a pharmacologic term for the period of time, based on average human physiology, that 50% of the drug can be expected to remain in the body following consumption.

on the individual's commercial pilot certificate.

While the FAA considers flight training to be a commercial operation, it has—for purposes of medical certification—distinguished instructors providing flight training from pilots engaged in other commercial operations involving the carriage of passengers or property for compensation or hire. For example, under current regulations, conducting flight training while serving as PIC in either a glider or balloon does not require any medical certification. *See* §§ 61.3(c)(2) and 61.23(b).

The FAA acknowledges that a flight instructor serving as PIC in an operation other than a glider or lighter-than-air aircraft during which private pilot privileges are being exercised must hold a third-class medical certificate or opt into the requirements of BasicMed in accordance with § 61.23(a)(3) or § 61.23(c). However, section 318 of Public Law 115–254 specifically directs the FAA to ''revise section 61.3(c) of title 14, Code of Federal Regulations (*relating to second-class medical certificates*), to apply to an operator of an air balloon to the same extent such regulations apply to a pilot flightcrew member of other aircraft'' (emphasis added). Therefore, the FAA has determined that Congress did not intend amendments to be made to other classes of medical certification. As such, the FAA is not proposing in this NPRM to extend third-class medical certification requirements to balloon operations during which flight instruction is conducted by an airman serving as PIC. However, the FAA invites comment on this issue.

As previously explained, § 61.23(b)(4) and (5) would specify that a medical certificate is not required when exercising the privileges of a private pilot certificate with a balloon class rating in a balloon or when exercising the privileges of a commercial pilot certificate with a balloon class rating in a balloon if the PIC is providing flight training in accordance with § 61.133(a)(2)(ii). The FAA notes that, in some cases, flight training may be conducted concurrently with an operation conducted for compensation or hire.[36] In circumstances such as this, the PIC would be required to hold either a first- or second-class medical certificate, as appropriate, for the commercial operation being conducted in conjunction with the flight instruction.

While the medical certificate requirements in §§ 61.3(c)(2) and 61.23(b) do not apply to both balloons and gliders, the FAA is not proposing to extend the second-class medical certification requirement described in this NPRM to commercial glider operations at this time. Due to the limited passenger carrying capacity of gliders,[37] the FAA has not identified a safety risk basis for imposing similar medical certification requirements on glider operations. However, the FAA invites comment on this issue.

*C. Invitation for Comment Regarding Options for Enhanced Safety Oversight of Commercial Balloon Operations*

As previously discussed, balloon operations conducted for compensation or hire–many of which involve passenger-carrying operations conducted for purposes of sightseeing–are not required under § 91.147 to obtain a Letter of Authorization (LOA) from the FAA. Under § 91.147, to obtain an LOA, a sightseeing operator must: (1) Identify the business, where it is located, where it principally operates from, and who is responsible for management and maintenance; (2) identify the type of aircraft used; and (3) implement an Antidrug and Alcohol Misuse Prevention Program in accordance with 14 CFR part 120.

Following a 2013 non-fatal accident of a commercially operated balloon carrying 10 passengers, the NTSB issued Safety Recommendations A–14–011 [38] and A–14–012.[39] The recommendations urged the FAA to require commercial balloon operators to obtain and maintain an LOA under § 91.147 to conduct air tour flights and to enhance oversight by including commercial balloon operators in general surveillance activities. Recommendations A–14–011 and A–14–012 were ultimately superseded by Safety Recommendation A–17–045, described previously.

The FAA is not proposing to apply similar requirements to balloon operations conducted for compensation or hire in this rulemaking. The FAA, however, invites comment on whether the FAA should consider rulemaking in the future to expand the definition of an operator under § 91.147 to include nonstop passenger-carrying flights in a balloon, which would require an LOA and drug and alcohol testing requirements for balloon operations conducted for compensation or hire.[40] Specifically, the FAA requests information and data regarding the following:

(1) Should the applicability of § 91.147 LOA and drug and alcohol testing requirements be limited to certain thresholds of balloon operations? If so, what thresholds, such as passenger capacity, number of annual operations, or size of aircraft should be used?

(2) Currently, operators who are required to comply with drug and alcohol testing under part 120 must establish a program that covers all individuals performing safety-sensitive functions directly or by contract. In the context of balloon operations, this testing would include non-pilots, such as persons conducting maintenance of the balloon. If the applicability of such testing was extended to operators conducting passenger carrying operations in a balloon for compensation or hire, what factors might affect the ability of the balloon operator to comply with a requirement to test all individuals performing safety-sensitive functions? How many personnel conducting safety-sensitive functions does each operator have and what are their functions?

(3) What current voluntary drug and alcohol testing is being conducted among commercial balloon operators? Do these testing programs apply only to persons serving as PIC or to all individuals performing safety-sensitive functions?

(4) What are the incremental initial and recurring costs and benefits of implementing and executing drug and alcohol testing and complying with LOA requirements?

*D. Miscellaneous Amendments*

The FAA is also proposing miscellaneous amendments to alleviate confusion and eliminate burdens for persons obtaining medical flight tests and for persons operating under BasicMed.

First, the FAA proposes an amendment to §§ 61.3(c)(2) and 61.23(b) to allow persons to receive medical flight tests authorized under part 67 without holding a medical certificate. Some medical certificate applicants are

[36] An example of this may be an operator who is providing flight instruction, but is conducting the instruction in a balloon that displays aerial advertising and the operator has received compensation to display the advertising.

[37] Gliders are typically limited to a capacity of 1–2 passengers in addition to the pilot in command.

[38] NTSB Safety Recommendation A–14–011 *https://www.ntsb.gov/_layouts/ntsb.recsearch/Recommendation.aspx?Rec=A-14-011.*

[39] NTSB Safety Recommendation A–14–012 *https://www.ntsb.gov/_layouts/ntsb.recsearch/Recommendation.aspx?Rec=A-14-012.*

[40] More information about initiating a Drug and Alcohol Testing Program can be found at: *http://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/drug_alcohol/starting/media/Air_Tour_Operators_Defined_in_Section_91_147_Implementation.pdf.*

not qualified for an unrestricted medical certificate due to disqualifying medical conditions and therefore require the issuance by authorization for a special issuance or SODA as discussed above. In most cases, the FAA can determine if an individual is eligible for a special issuance or SODA by means of additional medical evaluations. However, for some conditions, a medical flight test is necessary to determine whether the individual is qualified to hold a medical certificate.

In the past, the FAA issued a medical certificate to applicants for the sole purpose of conducting a medical flight test to determine whether a special issuance was appropriate. The FAA has determined that temporary issuance of medical certificates for this purpose is inconsistent with the requirements in part 67. Accordingly, the FAA has ceased issuing them. As a result, a person authorized to take a medical flight test may not currently act as PIC during the test because he or she does not hold a medical certificate (for those aircraft for which a medical certificate is required).[41] This places an unintentional burden on the FAA aviation safety inspector (ASI) who conducts the medical flight test because to complete the medical flight test, the ASI would need to assume the duties of PIC.[42] To allow persons to continue to act as PIC during these medical flight tests, the FAA is proposing to amend § 61.3(c)(2) by adding new paragraph (xv), which would allow persons to act as PIC during authorized medical flight tests without holding a medical certificate.[43] The FAA has also proposed to add a parallel provision in § 61.23(b)(12). This proposed change would not apply to any other flight activity for which a medical certificate is required. The FAA has determined that this action would not compromise safety. First, by policy, the ASI must hold a valid medical certificate in order to conduct medical flight tests regardless of whether the ASI acts as PIC.[44] Second, in order for the FAA to initiate an LOA for a medical flight test, the applicant must have a medical evaluation that determines that the applicant is otherwise medically qualified.[45]

Additionally, the FAA is proposing to amend §§ 61.3(c)(2), 61.23(c)(3), 61.113(i), 68.3, and 68.9 to alleviate certain burdens that resulted from the BasicMed final rule.[46] This rule codified section 2307 of the FAA Extension, Safety, and Security Act of 2016, (Pub. L. 114–190) (FESSA). Section 2307 directed the FAA to ''issue or revise regulations to ensure that an individual may operate as pilot in command of a covered aircraft'' without having to undergo the medical certification process under part 67. In that final rule, the FAA adopted the statutory language set forth in section 2307, without interpretation.

To accommodate safety pilots[47] who wish to operate under BasicMed, but who are not acting as PIC, the FAA is proposing to expand the BasicMed requirements to include persons serving as required pilot flightcrew members who are not acting as PIC. Currently, BasicMed applies only to PICs, because section 2307 of FESSA applies only to PICs.[48] As a result, BasicMed does not provide relief from the requirement to hold a medical certificate under § 61.3(c) to a person who is not acting as PIC. Specifically, pilots who are acting as safety pilots in accordance with § 91.109(c), but who are not acting as PIC, must hold a medical certificate because they are required flightcrew members. Instead, a safety pilot who intends to operate under BasicMed must agree to act as PIC for the portion of the flight in which they will serve as safety pilot.[49]

The FAA encourages pilots to seek opportunities to increase proficiency through operations, such as simulated instrument flying. As such, the FAA proposes to alleviate the current burden on safety pilots by allowing persons to operate under BasicMed while serving as required pilot flightcrew members.

Specifically, the FAA is proposing to amend §§ 61.3(c)(2)(xiv), 61.23(c)(3)(i)(C) through (E), 61.113(i), 68.3(a) and (b), and 68.9(a) by expanding the requirements to include required pilot flightcrew members. The FAA notes that, in very limited circumstances, this amendment would also allow a private pilot to act as second-in-command (SIC) of an aircraft type certificated for more than one required pilot flightcrew member or in operations requiring a SIC flightcrew member while operating under BasicMed, provided the aircraft meets the covered aircraft requirements of § 61.113(i)(1).

*E. Effective Date*

The FAA proposes that the medical certificate requirement of this proposed rule become effective no less than 180 days from publication of the final rule. This time span would provide sufficient time for affected persons to comply with this rule by obtaining a medical certificate in a timely manner. The FAA notes that airman with certain medical conditions may be required to obtain an authorization for special issuance. The process for obtaining a special issuance may require additional time for the FAA to review additional medical information provided by the airman. As such, persons who are required by this rule provision to obtain a medical certificate should seek to obtain a medical certificate in a timely manner in order to avoid a loss of operating privileges due to the inability to comply with the requirement.

The FAA proposes that the two miscellaneous amendments of this proposed rule related to BasicMed become effective 30 days from publication of the final rule.

## V. Regulatory Notices and Analyses

Federal agencies consider impacts of regulatory actions under a variety of executive orders and other requirements. First, Executive Order 12866 and Executive Order 13563 direct that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify the costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96–354) requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (Pub. L. 96–39) prohibits agencies

[41] Under the current regulations, a person may act as PIC during a medical flight test only if that person holds a medical certificate issued under part 67. 14 CFR 61.3(c)(1).

[42] A PIC is the person who has final authority and responsibility for the operation and safety of the flight. 14 CFR 1.1. By FAA policy, Aviation Safety Inspectors (ASI) do not routinely act as PIC during airman evaluation flights (*e.g.,* practical tests, medical flight tests, etc.).

[43] The FAA notes that it proposes to remove the ''or'' from paragraph (c)(2)(xiii) and relocate it to paragraph (c)(2)(xiv) to coincide with the additional paragraph FAA proposes to add to the list of exceptions in § 61.3(c)(2).

[44] FAA order 8900.1 Volume 5, Chapter 8, Section 1, paragraph 5–1523(D)(3) and Volume 1, Chapter 3, Section 6.

[45] FAA order 8900.1 Volume 5, Chapter 8, Section 1, paragraph 5–1523(B).

[46] 82 FR 3149 (Jan. 11, 2017).

[47] A safety pilot is a person who occupies a control seat in an aircraft and maintains a visual watch when the pilot manipulating the flight controls of the aircraft is using a view-limiting device to simulate flight by reference to instruments. *See* 14 CFR 91.109.

[48] There is statutory evidence that the provision creating BasicMed was not intended to be limited to only persons acting as PIC. One of the attestations that a person intending to operate under BasicMed must agree to states ''I understand that I cannot act as pilot in command, *or any other capacity as a required flight crew member* [emphasis added], if I know or have reason to know of any medical condition that would make me unable to operate the aircraft in a safe manner.''

[49] In certain circumstances, a person who is qualified to act as a safety pilot may not meet the regulatory requirements to act as PIC for the flight. Further, a person may not agree to act as PIC while acting as safety pilot for several non-regulatory reasons, personal limits, operating experience, aircraft rental requirements, or insurance coverage.

from setting standards that create unnecessary obstacles to the foreign commerce of the United States. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year. The current threshold after adjustment for inflation is $158,000,000, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product.

In conducting these analyses, the FAA has determined that this rule: Is not a ''significant regulatory action'' as defined in section 3(f) of Executive Order 12866; may have a significant economic impact on a substantial number of small entities; will not create unnecessary obstacles to the foreign commerce of the United States; and will not impose an unfunded mandate on State, local, or tribal governments, or on the private sector.

*A. Regulatory Impact Analysis*

Summary of Benefits and Costs of This Rule

The proposed rule would generate costs for balloon pilots to obtain a second-class medical certification and for some pilots to seek authorization through special issuance. There would also be costs to the FAA to implement this requirement in terms of reviewing and processing submissions related to certification. The FAA estimates the present value of total costs over ten years is $2.6 million to $17.8 million with a mid-estimate of $7.5 million at a 7 percent discount rate and $3.1 million to $21.7 million with a mid-estimate of $9.1 million at a 3 percent discount rate. The FAA estimates the annualized costs over ten years is $0.4 million to $2.5 million with a mid-estimate of $1.1 million at a 7 percent discount rate and $0.4 million to $2.5 million with a mid-estimate of $1.1 million at a 3 percent discount rate. While lack of data on the effectiveness of the rulemaking prevents quantification of benefits, the FAA anticipates the rulemaking will enhance safety of commercial balloon operations, including reduced risks of accidents, fatalities, and injuries caused by medical impairment of balloon pilots. The FAA estimates that it would take between 0.4 to 3.0 averted fatalities in the next ten years for the benefits to breakeven with the costs of this rulemaking.

In addition to the requirement for commercial balloon pilots to hold a second-class medical certificate, the rule proposes two miscellaneous amendments. The first amendment addresses certain inconsistencies in current regulations for conducting medical flight tests and the second amendment addresses inconsistencies regarding who may operate under BasicMed. The FAA does not quantify the effects of the two miscellaneous amendments but anticipates there would be minor cost savings. By allowing persons to receive medical flight tests under part 67 without holding a medical certificate, the FAA ASI will no longer have the burden of assuming the responsibility as PIC. This would also eliminate the inconsistency of both having to hold a medical certificate for the purposes of receiving a medical flight test and needing the medical flight test to obtain medical certification. The amendment to extend BasicMed eligibility to other pilot flightcrew members would reduce the burden for those pilots not acting as PIC of having to hold a medical certificate under current regulations and would hold them to the same standard as those acting as PIC. This may also result in more pilots seeking opportunities to serve as safety pilot by lowering the medical certificate barrier without compromising safety. It would also increase the number of pilots eligible to serve as safety pilot, easing the burden of pilots with instrument privileges conducting flights to meet recent flight experience requirements and consequently increasing overall safety in the national airspace system.

Statement of Need

This rulemaking addresses the need for additional oversight of airmen conducting balloon operations for compensation or hire by implementing the statutory mandate under the Commercial Balloon Pilot Safety Act of 2018 and NTSB Safety Recommendation A–17–034 to extend second-class medical certification requirements to operators of air balloons. As discussed elsewhere in the preamble, the 2016 Heart of Texas balloon accident highlights the potential for a pilot's medical condition to pose safety risks, which are not necessarily less than that of powered aircraft sightseeing operations that require at least a second-class medical certificate (*e.g.,* commercial transportation of skydivers, banner towing, or aerial photography). Following the 2016 Heart of Texas accident, there have been voluntary efforts by the industry to raise the standard for balloon pilots notably through the Envelope of Safety Program. While incentives to ensure a certain level of safety exist in the private market for commercial balloon operations, it is unlikely in the absence of federal regulation that all balloon pilots would choose to comply with the requirements of a second-class medical certification. At the same time, consumers may be insufficiently aware of the risks associated with balloon pilots operating under a lower standard to demand full compliance. Therefore, this rulemaking is necessary to achieve a higher level of safety for commercial balloon operations.

Data and Assumptions

This section summarizes key data sources and assumptions used throughout the analysis:

- Costs and benefits are estimated over 10 years.
- Costs and benefits are presented in 2020 dollars.
- The present value discount rate of seven and three percent is used as required by the Office of Management and Budget.
- The cost for a medical examination fee with an AME is in the following range: Low = $100, Mid = $150 or High = $200.[50]
- The hourly rate of a pilot (VPT) exercising their commercial balloon rating varies greatly. Therefore, the FAA used the following hourly wages: Low= $15, Mid= $31.50 or High= $48.[51]
- Vehicle operating cost per mile (VOC) as determined by the Internal Revenue Service (IRS) is $0.16.[52]
- The FAA assumes 1.5 hour to complete the MedXPress form.[53]
- The FAA assumes 1 hour to complete a medical examination.

Affected Entities

At the time of writing, the FAA used 2021 data from the Airmen Certification database to identify pilots certified as commercial balloon pilots. There are currently 4,869 commercial pilots with balloon class ratings. This balloon class

[50] According to FAA subject matter experts and Phoenix East Aviation, *https://www.pea.com/blog/posts/the-faa-medical-exam-common-questions/,* the cost per medical exam ranges from $100 to $200.

[51] According to the FAA subject matter experts, responses from the Balloon Federation of America and online sources, the FAA estimates a commercial balloon pilot earns from $15 to $48 an hour. Online source: *https://www.jobmonkey.com/uniquejobs3/hot-air-balloon-pilot-jobs/.*

[52] *https://www.irs.gov/newsroom/irs-issues-standard-mileage-rates-for-2021* Accessed on April 21, 2021.

[53] This estimate is consistent with FAA's estimated burden hours associated with the MedXPress form 8500–8 approved under OMB No. 2120–0034.

rating does not have an expiration. Unlike other pilot ratings, a person exercising the privileges of a balloon class rating does not require an active first-, second-, or third-class medical certificate. Because of this, there is uncertainty in the number of active commercial balloon pilots actively exercising commercial pilot privileges. For this reason, the FAA produced a low, mid, and high range estimate of how many pilots would possibly be affected by this proposed rule.

In addition to the current number of certificated pilots with a commercial balloon rating, the FAA gathered data from the last 14 years to estimate an average growth of newly certificated commercial balloon pilots per year. Over the course of the last 14 years from 2007 through 2020, there was on average 56 newly certificated commercial balloon pilots per year.

As mentioned earlier, there is uncertainty with the number of active pilots exercising their commercial balloon privileges. The FAA assumes a low estimate of 20%, a mid-estimate of 50% and a high estimate of 100% of the 4,869 commercial pilots with a balloon class rating would be active. Table 1 displays the potential number of airmen that would be affected by the proposed rule over the course of ten years. Corresponding to the number of active balloon pilots is the number of expected submissions for second-class medical certifications each year.

TABLE 1—LOW, MIDDLE AND HIGH ESTIMATES OF ACTIVE BALLOON PILOTS

| Year | Low | Middle | High |
|---|---|---|---|
| 1 | 1,030 | 2,491 | 4,925 |
| 2 | 1,086 | 2,547 | 4,981 |
| 3 | 1,142 | 2,603 | 5,037 |
| 4 | 1,198 | 2,659 | 5,093 |
| 5 | 1,254 | 2,715 | 5,149 |
| 6 | 1,310 | 2,771 | 5,205 |
| 7 | 1,366 | 2,827 | 5,261 |
| 8 | 1,422 | 2,883 | 5,317 |
| 9 | 1,478 | 2,939 | 5,373 |
| 10 | 1,534 | 2,995 | 5,429 |
| Total | 12,820 | 27,430 | 51,770 |

Benefits

The benefits of this rulemaking come from the value of averted accidents attributable to pilots operating commercial balloons with medical deficiencies. While under current regulations, balloon pilots must comply with § 61.53(b), which states that ''a person shall not act as pilot in command, or in any other capacity as a required pilot flight crewmember, while that person knows or has reason to know of any medical condition that would make the person unable to operate the aircraft in a safe manner,'' the second-class medical certification requirement would provide greater assurances of safety to balloon passengers and other balloon operations conducted for compensation or hire. By requiring balloon pilots to undergo a medical certification process, an AME should identify potentially impairing medical conditions and treatments thereof to ensure sufficient mitigation of any associated risks.

To quantify the benefits from this rule, it is necessary to: (1) Forecast a baseline level of accidents attributable to medically impaired balloon pilots in the absence of this rule and (2) estimate the extent to which the medical certification requirement effectively reduces the risk. As previously discussed, based on the FAA's analysis of the NTSB accident database during the ten-year period from 2010–2020, the FAA finds that there has been one accident, the Heart of Texas accident, where the medical condition of the pilot was a factor. The Heart of Texas accident resulted in 16 fatalities. The commercial pilot and all 15 passengers were killed, and the balloon was destroyed by impact forces and post-crash fire. For an accident of this magnitude, the FAA estimates that the social cost associated with the loss of life alone is $185.6 million using a value of statistical life of $11.6 million.[54] Additional costs of a similar accident would include non-fatal injuries, the value of property loss and damage as well as the cost of the accident investigation and clean-up efforts. However, the FAA currently does not have enough information to monetize those additional costs.

The FAA finds that the requirement for a second-class medical certification could have prevented the Heart of Texas accident if: (1) Information made available through the NDR database as part of the medical review process revealed the pilot's history of drug- and alcohol-related traffic offenses and resulted in a disqualification, (2) a medical review either prompted effective treatment of or disqualification for the pilot's medical conditions (depression and ADHD), or (3) use of certain medications were discussed with an AME would have resulted in the pilot adjusting his behavior to avoid usage as a PIC during a balloon operation.

Due to the infrequency of such events and limitations in the available data, it is difficult to quantify and monetize the benefits of the rulemaking. The FAA intends to update its estimates of quantified benefits for the final rule based on additional information and data identified during the comment period. Specifically, the FAA requests information and data, including references and sources, that can be used to predict the number of similar accidents that may occur in the future and the number of accidents that could be averted by this rulemaking.

While the FAA describes the benefits of the rulemaking qualitatively, the FAA expects that second-class medical certification provides additional screening to reduce the risk of commercial balloon pilots operating while medically impaired. In the section below, the FAA conducted a breakeven analysis to show that the monetized benefits of the rulemaking equates costs if it averts 0.4 to 3.0 fatalities in the next ten years.

Costs

This rulemaking would result in private sector costs to balloon pilots for obtaining a second-class medical certificate, including the opportunity

[54] Value of a statistical life in 2020 is $11.6 million. Letter from Acting Assistant Secretary for Transportation Policy April 1, 2021.

cost of time and fee for the medical exam with an AME. Some balloon pilots with certain health conditions that are otherwise disqualifying may also incur the cost of obtaining a LOA by special issuance. The FAA would incur costs for reviewing and processing the applications (*i.e.,* MedXPress forms) and reviewing NDR information for a subset of submissions.

Cost to Industry

(1) Costs of Obtaining Second-Class Medical Certification

To obtain a second-class medical certificate, an applicant would need to complete the MedXPress form and a medical exam with an AME. Because the second-class medical certificate expires 12 months after the date of the medical exam, the FAA assumes that pilots would incur these costs on an annual basis. The FAA estimates the opportunity cost of time for each applicant would include 1.5 hour to complete the MedXPress form, 1 hour for the medical examination, and 1 hour of travel time to and from the exam for a total of 3.5 hours.[55] The FAA assumes an hourly wage for a balloon pilot ranges from $15 per hour to $48 per hour, with a mid-estimate of $31.50 per hour, to value time for the medical exam and completing the MedXPress form. For valuing travel time, the FAA uses an estimate of $13.60 per hour consistent with 2016 DOT guidance (in this analysis, $14.30 was used for year 2020).[56] Multiplying the value of time by the amount of time spent yields an estimate of $51.80 to $134.30, with a mid-estimate of $93.05 per applicant in opportunity cost of time. FAA subject matter experts estimate the cost per medical exam with an AME ranges from $100 to $200, with an average of $150. Additional costs arise from vehicle operating costs (VOC) of 16 cents per mile for an average of 50 miles traveled by vehicle to and from a medical exam, which yields $8 for each exam. Taking the sum of the value of time spent, medical exam fee, and VOC, the FAA estimates that each applicant would incur costs of approximately $160 to $342, with a mid-estimate of $251 to obtain a second-class medical certificate each year.

Table 2 below shows the range of total costs to industry for obtaining a second-class medical certificate. The FAA derives the aggregated low, middle, and high costs by multiplying the estimated number of active pilots (low, middle, high) as shown in Table 1 by the corresponding low, middle, and high costs per applicant by cost category.

TABLE 2—COSTS TO INDUSTRY BY CATEGORY TO OBTAIN SECOND-CLASS MEDICAL CERTIFICATION

| Year | Opportunity cost of time for exam, MedXPress form, and travel | | | Fee for medical exam with AME | | | Vehicle operating costs | | |
|---|---|---|---|---|---|---|---|---|---|
| | Low | Middle | High | Low | Middle | High | Low | Middle | High |
| 1 | $53,354 | $231,788 | $661,428 | $103,000 | $373,650 | $985,000 | $8,240 | $19,928 | $39,400 |
| 2 | 56,407 | 237,355 | 669,646 | 108,600 | 382,050 | 996,200 | 8,688 | 20,376 | 39,848 |
| 3 | 59,475 | 242,938 | 677,879 | 114,200 | 390,450 | 1,007,400 | 9,136 | 20,824 | 40,296 |
| 4 | 62,572 | 248,563 | 686,180 | 119,800 | 398,850 | 1,018,600 | 9,584 | 21,272 | 40,744 |
| 5 | 65,685 | 254,205 | 694,497 | 125,400 | 407,250 | 1,029,800 | 10,032 | 21,720 | 41,192 |
| 6 | 68,814 | 259,864 | 702,831 | 131,000 | 415,650 | 1,041,000 | 10,480 | 22,168 | 41,640 |
| 7 | 71,961 | 265,540 | 711,182 | 136,600 | 424,050 | 1,052,200 | 10,928 | 22,616 | 42,088 |
| 8 | 75,124 | 271,233 | 719,550 | 142,200 | 432,450 | 1,063,400 | 11,376 | 23,064 | 42,536 |
| 9 | 78,304 | 276,942 | 727,934 | 147,800 | 440,850 | 1,074,600 | 11,824 | 23,512 | 42,984 |
| 10 | 81,501 | 282,668 | 736,335 | 153,400 | 449,250 | 1,085,800 | 12,272 | 23,960 | 43,432 |

**Note:** The low, middle, and high estimates correspond to the low, middle, and high estimates of the number of active pilots and the range of costs per applicant in each category of costs.

(2) Cost of Obtaining a Special Issuance

For applicants that do not initially meet the requirements of a second-class medical certification, there may be an additional cost to seek a LOA by special issuance. The FAA assumes that an applicant seeking special issuance would incur the same costs and time of a second-class medical certification as estimated per applicant above. Based on the historical rate of special issuances, the FAA assumes that approximately 10 percent of affected balloon pilots would seek special issuance. Therefore, the FAA takes the sum of costs in each cost category for obtaining a second-class medical certification and multiplies by 0.1 to obtain the total industry cost for obtaining special issuances. Table 3 below shows the range of special issuance costs in each year.

TABLE 3—TOTAL INDUSTRY COST FOR SPECIAL ISSUANCES

| Year | Total private sector costs for special issuance | | |
|---|---|---|---|
| | Low | Middle | High |
| 1 | $16,459 | $62,537 | $168,583 |
| 2 | 17,369 | 63,978 | 170,569 |
| 3 | 18,281 | 65,421 | 172,558 |
| 4 | 19,196 | 66,869 | 174,552 |
| 5 | 20,112 | 68,318 | 176,549 |
| 6 | 21,029 | 69,768 | 178,547 |

[55] According to the ''FAA Aerospace Medical Certification Services Airman Satisfaction Survey,'' (April 2017), over 60 percent of applicants traveled between 0 and 25 miles one way for an exam with an AME. (Retrieved from: *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201904-2120-007.*)

[56] Department of Transportation. ''The Value of Travel Time Savings: Departmental Guidance for Conducting Economic Evaluations Revision 2 (2016 Update). Available at: *https://www.transportation.gov/office-policy/transportation-policy/revised-departmental-guidance-valuation-travel-time-economic.* This analysis assumes that the value of travel time grows 1% a year. Year 2020: $14.30.

TABLE 3—TOTAL INDUSTRY COST FOR SPECIAL ISSUANCES—Continued

| Year | Total private sector costs for special issuance | | |
|---|---|---|---|
| | Low | Middle | High |
| 7 | 21,949 | 71,221 | 180,547 |
| 8 | 22,870 | 72,675 | 182,549 |
| 9 | 23,793 | 74,130 | 184,552 |
| 10 | 24,717 | 75,588 | 186,557 |
| Present Value at 7% | 140,959 | 479,339 | 1,239,310 |
| Annualized at 7% | 20,069 | 68,247 | 176,450 |
| Present Value at 3% | 173,625 | 586,001 | 1,510,442 |
| Annualized at 3% | 20,354 | 68,697 | 177,070 |

Summary of Total Cost to Industry

The FAA estimates the present value of total cost to industry associated with obtaining a second-class medical certification and special issuances to be $1.6 million to $13.6 million, with a mid-estimate of $5.3 million at a 7 percent discount rate and $1.9 million to $16.6 million, with a mid-estimate of $6.4 million at a 3 percent discount rate. The annualized value of total cost to industry are $0.2 million to $1.9 million with a mid-estimate of $0.8 million at a 7 percent discount rate and $0.2 million to $1.9 million with a mid-estimate of $0.8 million at a 3 percent discount rate. In Table 4 below, the FAA shows these total costs to industry for obtaining a second-class medical certification and special issuances in each year. The low, middle, and high estimates correspond to the range of estimates on the number of affected pilots and costs associated with obtaining medical certification.

TABLE 4—TOTAL INDUSTRY COSTS

| Year | Total cost to industry | | |
|---|---|---|---|
| | Low | Middle | High |
| 1 | $181,053 | $687,902 | $1,854,410 |
| 2 | 191,064 | 703,759 | 1,876,263 |
| 3 | 201,092 | 719,633 | 1,898,133 |
| 4 | 211,151 | 735,554 | 1,920,076 |
| 5 | 221,228 | 751,493 | 1,942,038 |
| 6 | 231,324 | 767,451 | 1,964,018 |
| 7 | 241,438 | 783,427 | 1,986,017 |
| 8 | 251,570 | 799,421 | 2,008,034 |
| 9 | 261,721 | 815,434 | 2,030,070 |
| 10 | 271,891 | 831,466 | 2,052,124 |
| Present Value at 7% | 1,550,549 | 5,272,731 | 13,632,413 |
| Annualized at 7% | 220,763 | 750,718 | 1,940,949 |
| Present Value at 3% | 1,909,876 | 6,446,015 | 16,614,860 |
| Annualized at 3% | 223,896 | 755,670 | 1,947,768 |

Costs to FAA To Implement Requirement for Second-Class Medical Certification for Balloon Pilots

(1) FAA Cost of MedXPress Review and Processing

The FAA would incur costs associated with reviewing and processing applications submitted through MedXPress. Based on internal FAA data on total personnel costs and benefits attributable to labor hours spent on review of airmen medical certification in FY 2019 and FY 2020, the FAA estimates an average cost of $30 to review and process each application. In Table 5 below, the Agency derives the FAA cost to review applications in each year using the estimated range for the number of submissions based on the forecasted number of active balloon pilots in each year.

TABLE 5—FAA COSTS TO REVIEW AND PROCESS APPLICATIONS

| Year | FAA costs for review and processing | | |
|---|---|---|---|
| | Low | Middle | High |
| 1 | $30,489 | $73,737 | $145,786 |
| 2 | 32,147 | 75,394 | 147,444 |
| 3 | 33,805 | 77,052 | 149,102 |
| 4 | 35,462 | 78,710 | 150,759 |
| 5 | 37,120 | 80,367 | 152,417 |
| 6 | 38,778 | 82,025 | 154,075 |
| 7 | 40,435 | 83,683 | 155,732 |
| 8 | 42,093 | 85,340 | 157,390 |
| 9 | 43,751 | 86,998 | 159,048 |

TABLE 5—FAA COSTS TO REVIEW AND PROCESS APPLICATIONS—Continued

| Year | FAA costs for review and processing | | |
|---|---|---|---|
| | Low | Middle | High |
| 10 | 45,408 | 88,656 | 160,705 |
| Present Value at 7% | 260,087 | 563,839 | 1,069,884 |
| Annualized at 7% | 37,031 | 80,278 | 152,327 |
| Present Value at 3% | 320,268 | 689,177 | 1,303,774 |
| Annualized at 3% | 37,545 | 80,793 | 152,842 |

(2) FAA Cost of Special Issuance Review

A MedXPress application that requires a special issuance medical certificate is deferred to the Aerospace Medical Certification Division (AMCD) of Oklahoma City for further consideration. Based on FAA internal data on personnel compensation and benefits attributable to labor hours spent on reviewing and processing special issuance medical certificates in FY 2019 and FY 2020, the FAA estimates an average cost of approximately $126 per special issuance review. The table below displays the FAA cost for special issuance review assuming that 10 percent of the applicants do not initially qualify for second-class medical certification.

TABLE 6—FAA COST OF SPECIAL ISSUANCE REVIEW

| Year | FAA costs for special issuance review | | |
|---|---|---|---|
| | Low | Middle | High |
| 1 | $13,018 | $31,484 | $62,248 |
| 2 | 13,726 | 32,192 | 62,956 |
| 3 | 14,434 | 32,900 | 63,664 |
| 4 | 15,142 | 33,608 | 64,371 |
| 5 | 15,850 | 34,315 | 65,079 |
| 6 | 16,557 | 35,023 | 65,787 |
| 7 | 17,265 | 35,731 | 66,495 |
| 8 | 17,973 | 36,439 | 67,202 |
| 9 | 18,681 | 37,147 | 67,910 |
| 10 | 19,388 | 37,854 | 68,618 |
| Present Value at 7% | 111,052 | 240,749 | 456,820 |
| Annualized at 7% | 15,811 | 34,277 | 65,041 |
| Present Value at 3% | 136,748 | 294,266 | 556,687 |
| Annualized at 3% | 16,031 | 34,497 | 65,261 |

(3) Cost of FAA Review of the National Driver Register (NDR) Reports

Included within the medical certificate application is the applicant's authorization for the FAA to receive NDR data, which provides a report of applicable motor vehicle actions within the preceding three years. Intentional failure to report required drug or alcohol motor vehicle actions is grounds for suspension of a pilot certificate. NDR checks help to identify persons who may have substance abuse or dependence issues. Although the bulk of the process is automated, the FAA estimates there is roughly a 3% return rate that requires additional review and investigation. The FAA estimates that it takes approximately 40 hours of additional review time by a special agent for each applicant that is flagged through the NDR database. Using a special agent hourly wage adjusted for fringe benefits of $60.18 as shown in Table 7 below, the FAA estimates that each submission that requires further investigation would cost $2,407. The total costs to FAA associated with NDR review is estimated in Table 8 using the range of estimated submissions.

TABLE 7—SPECIAL AGENT WAGE WITH FRINGE BENEFITS

| | Yearly | Hourly | Fringe benefits | Total |
|---|---|---|---|---|
| Special Agent | $91,877 | $44.17 | $16.01 | $60.18 |
| Federal Fringe Benefit Factor [1 2 3] | | | 36.25% | |

[1] *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2008/m08-13.pdf.*

[2] Percent of position's basic pay.

[3] Dallas-Fort Worth, TX–OK locality plus fringe benefits, GS–12 Step 4. Retrieved from *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2021/DFW.pdf.*

TABLE 8—FAA COSTS FOR NDR REVIEW

| Year | FAA costs for NDR review | | |
|---|---|---|---|
| | Low | Middle | High |
| 1 | $74,382 | $179,890 | $355,664 |
| 2 | 78,427 | 183,934 | 359,708 |
| 3 | 82,471 | 187,978 | 363,752 |
| 4 | 86,515 | 192,022 | 367,796 |
| 5 | 90,559 | 196,066 | 371,840 |
| 6 | 94,603 | 200,111 | 375,884 |
| 7 | 98,647 | 204,155 | 379,928 |
| 8 | 102,691 | 208,199 | 383,972 |
| 9 | 106,735 | 212,243 | 388,017 |
| 10 | 110,779 | 216,287 | 392,061 |
| Present Value at 7% | 634,516 | 1,375,557 | 2,610,118 |
| Annualized at 7% | 90,341 | 195,848 | 371,622 |
| Present Value at 3% | 781,334 | 1,681,335 | 3,180,721 |
| Annualized at 3% | 91,596 | 197,104 | 372,877 |

Summary of Total Costs to FAA

The total costs to the FAA to implement the requirement for commercial balloon pilots to hold a second-class medical certificate is the sum of the costs for FAA review and processing of MedXPress applications, review of special issuances, and review of NDR information associated with certain applications. The FAA estimates the present value of total costs to the Agency to be $1.0 million to $4.1 million, with a mid-estimate of $2.2 million at a 7 percent discount rate and $1.2 million to $5.0 million, with a mid-estimate of $2.7 million at a 3 percent discount rate. The annualized value of total cost to FAA are $0.1 million to $0.6 million with a mid-estimate of $0.3 million at a 7 percent discount rate and $0.1 million to $0.6 million with a mid-estimate of $0.3 million at a 3 percent discount rate.

These preliminary cost estimates to the FAA are subject to change for the final rule and are not intended to inform future rulemakings or policies involving user fees since these are point-in-time preliminary estimates of additional personnel costs to FAA before the effective date of the final rule. The FAA acknowledges the difficulty in estimating FAA burden and cost after the effective date of this rule given uncertainties in the number of pilot applicants and those pilots that would either receive a second-class medical certification or be granted a special issuance certification.

TABLE 9—TOTAL COSTS TO FAA

| Year | Total cost to FAA | | |
|---|---|---|---|
| | Low | Middle | High |
| 1 | $117,890 | $285,111 | $563,698 |
| 2 | 124,300 | 291,521 | 570,107 |
| 3 | 130,709 | 297,930 | 576,517 |
| 4 | 137,119 | 304,340 | 582,927 |
| 5 | 143,528 | 310,749 | 589,336 |
| 6 | 149,938 | 317,159 | 595,746 |
| 7 | 156,347 | 323,568 | 602,155 |
| 8 | 162,757 | 329,978 | 608,565 |
| 9 | 169,167 | 336,387 | 614,974 |
| 10 | 175,576 | 342,797 | 621,384 |
| Present Value at 7% | 1,005,655 | 2,180,145 | 4,136,823 |
| Annualized at 7% | 143,183 | 310,404 | 588,991 |
| Present Value at 3% | 1,238,350 | 2,664,778 | 5,041,181 |
| Annualized at 3% | 145,172 | 312,393 | 590,980 |

Total Costs of the Rule

The total costs are shown in the table below, which include both costs to industry and to the FAA. The total costs over the ten years include the costs for pilots to obtain their second-class medical certificate, special issuances and costs to the Agency for review of applications, special issuances, and NDR information. The FAA estimates the present value of total costs over ten years is $2.6 million to $17.8 million with a mid-estimate of $7.5 million at a 7 percent discount rate and $3.1 million to $21.7 million with a mid-estimate of $9.1 million at a 3 percent discount rate. The FAA estimates the annualized costs over ten years is $0.4 million to $2.5 million with a mid-estimate of $1.1 million at a 7 percent discount rate and $0.4 million to $2.5 million with a mid-estimate of $1.1 million at a 3 percent discount rate.

As stated previously, in some cases, where the airman's medical condition does not meet the part 67 standard, the airman may still be issued a medical certificate by authorization for special issuance when the Federal Air Surgeon determines the risk associated with the medical condition(s) to be sufficiently mitigated. Based on the rate of special issuance for general aviation, the FAA

assumes that 10% of the commercial balloon pilot applicants would require a special issuance. For purposes of this analysis, the FAA assumes that most applicants would ultimately either receive a second-class medical certification or be granted a special issuance certification and therefore does not quantify costs associated with not meeting the requirements.

However, the FAA expects some applicants who would have otherwise been able to operate as commercial balloon pilots may not meet the requirements of a second-class medical certification nor the requirements for a special issuance. Furthermore, the opportunity cost (including the time and fees) of seeking a second-class medical certification for some pilots may outweigh their private gains from operating commercially, resulting in some pilots opting not to seek medical certification. The FAA does not have sufficient information to predict how the supply of commercial balloon pilots would change as a result of this rule.

While the FAA does not expect a significant decrease in the availability of balloon pilots, changes in supply of balloon pilots could affect prices as well. This analysis does not quantify any potential changes in consumer and producer surplus from changes in supply. If the rule effectively screens out certain individuals for disqualifying medical conditions as intended, any potential adverse effects on individual applicants should be offset by the safety gains to the public. The FAA requests comment on these assumptions and data that would allow the FAA to quantify these potential impacts.

TABLE 10—TOTAL COSTS OF THE RULE

| Year | Total Cost of the Rule | | |
|---|---|---|---|
| | Low | Middle | High |
| 1 | $298,944 | $973,013 | $2,418,108 |
| 2 | 315,364 | 995,280 | 2,446,370 |
| 3 | 331,802 | 1,017,563 | 2,474,650 |
| 4 | 348,270 | 1,039,894 | 2,503,003 |
| 5 | 364,757 | 1,062,242 | 2,531,374 |
| 6 | 381,262 | 1,084,609 | 2,559,764 |
| 7 | 397,785 | 1,106,995 | 2,588,172 |
| 8 | 414,327 | 1,129,399 | 2,616,599 |
| 9 | 430,888 | 1,151,822 | 2,645,044 |
| 10 | 447,467 | 1,174,263 | 2,673,508 |
| Present Value at 7% | 2,556,204 | 7,452,875 | 17,769,236 |
| Annualized at 7% | 363,946 | 1,061,122 | 2,529,939 |
| Present Value at 3% | 3,148,226 | 9,110,792 | 21,656,041 |
| Annualized at 3% | 369,068 | 1,068,063 | 2,538,749 |

Breakeven Analysis

Given the uncertainties and limitations in the available data, the FAA conducted a breakeven analysis to determine the number of averted fatalities necessary to generate benefits equal to costs. The FAA divided the present value of total costs of the rule by the present value of a statistical life to estimate the number of fatalities needed to break even with the costs of the rule over a ten-year time horizon. Using a value of statistical life of $11.6 million and the range of present value of costs presented in Table 10 above, the monetized benefits of this rule will break even with costs if the new medical certification requirement averts between 0.4 to 3.0 fatalities under a 7 percent discount rate and between 0.4 to 2.5 fatalities under a 3 percent discount rate.[57]

[57] Departmental Guidance on Valuation of a Statistical Life in Economic Analysis *https://www.transportation.gov/office-policy/transportation-policy/revised-departmental-guidance-on-valuation-of-a-statistical-life-in-economic-analysis.*

Regulatory Alternatives

The FAA considered one alternative to the proposed rule:

Letter of Authorization (LOA) and *Drug and Alcohol Testing.* With this alternative, the FAA would institute both a medical certificate requirement as well as a requirement for obtaining an LOA from the FAA and mandatory drug and alcohol testing. This alternative would expand the definition of an operator under § 91.147 to include balloons, which would require the commercial balloon operators to obtain an LOA from the FAA in accordance with § 91.147 prior to conducting operations, and implement drug and alcohol testing programs in accordance with 14 CFR part 120. This alternative goes beyond the statutory mandate and would add the additional administrative costs of implementing a drug and alcohol testing program and obtaining a LOA to commercial balloon operators and pilots.

*B. Regulatory Flexibility Act*

The Regulatory Flexibility Act (RFA) of 1980, Public Law 96–354, 94 Stat. 1164 (5 U.S.C. 601–612), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121, 110 Stat. 857, Mar. 29, 1996) and the Small Business Jobs Act of 2010 (Pub. L. 111–240, 124 Stat. 2504 Sept. 27, 2010), requires Federal agencies to consider the effects of the regulatory action on small business and other small entities and to minimize any significant economic impact. The term ''small entities'' comprises small businesses and 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 FAA is publishing this Initial Regulatory Flexibility Analysis (IRFA) to aid the public in commenting on the potential impacts to small entities from this proposal. The FAA invites interested parties to submit data and information regarding the potential economic impact that would result from the proposal. The FAA will consider comments when making a determination or when completing a Final Regulatory Flexibility Analysis.

An IRFA must contain the following:

(1) A description of the reasons why the action by the agency is being considered;

(2) A succinct statement of the objective of, and legal basis for, the proposed rule;

(3) A description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;

(4) A description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record;

(5) An identification, to the extent practicable, of all relevant Federal rules that may duplicate, overlap, or conflict with the proposed rule; and

(6) A description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities.

Description of Reasons the Agency Is Considering the Action

The FAA is publishing this rulemaking to comply with the Commercial Balloon Pilot Safety Act of 2018, which directs the FAA to require commercial balloon pilots conducting operations for compensation or hire to hold a valid second-class medical certificate. Congress introduced this legislation in response to the 2016 Heart of Texas hot air balloon accident and the NTSB finding that (1) the pilot's impairing medical conditions and medications and (2) the FAA's policy to not require a medical certificate for commercial balloon pilots were contributing factors in the accident.

This proposed rule would amend part 61 to require a second-class medical certificate for balloon operations conducted for compensation or hire, other than flight training. As such, a person who holds a commercial pilot certificate with a balloon class rating would be required to hold a valid second-class medical certificate when exercising the privileges of that certificate in a balloon for compensation or hire, unless that person is conducting flight training in accordance with § 61.133(a)(2)(ii).

Statement of the Legal Basis and Objectives

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

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart iii, Section 44701, General Requirements; Section 44702, Issuance of Certificates; and Section 44703, Airman Certificates. Under these sections, the FAA is charged with prescribing regulations and minimum standards for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. The FAA is also authorized to issue certificates, including airman certificates and medical certificates, to qualified individuals. This rulemaking proposal is within the scope of that authority.

Further, this rulemaking is issued under section 318 of the FAA Reauthorization Act of 2018, Public Law 115–254, (''Commercial Balloon Pilot Safety Act of 2018''). Section 318 directed the FAA to ''revise section 61.3(c) of title 14, Code of Federal Regulations (relating to second-class medical certificates), to apply to an operator of an air balloon to the same extent such regulations apply to a pilot flight crewmember of other aircraft.'' While the statute specifically directs the FAA to revise § 61.3(c), the FAA notes that § 61.23, Medical certificates: Requirement and duration establishes the requirements and exceptions for medical certificates based on certain types of operations. The FAA proposes to amend § 61.23 in addition to § 61.3(c) for purposes of implementing the statutory requirement.

Description of the Recordkeeping and Other Compliance Requirements

The FAA proposes that airmen hold a valid second-class medical certificate when exercising the privileges of a commercial pilot certificate in a balloon for compensation or hire. A medical certificate would not be required for commercial pilots conducting flight training in a balloon. As determined by a physical examination and review of medical history, airmen must meet the applicable medical standards of part 67 in order to receive an unrestricted medical certificate. In cases where the airman's medical condition does not meet the part 67 standard, the airman may still be issued a medical certificate by authorization for special issuance or SODA when the Federal Air Surgeon had determined that the risk associated with the medical condition(s) is sufficiently mitigated.

A person obtains a medical certificate by completing an online application (FAA form 8500–8, Application for Medical Certificate) using the FAA's medical certificate application tool, MedXPress,[58] and undergoing a physical examination with an FAA-designated AME. An AME may defer an applicant to the FAA for further review (which may include further examination and testing by a specialist physician) when there is information indicating the existence or potential of an adverse medical finding that may warrant further FAA medical evaluation and oversight. Second-class medical certificates held for any operations requiring a commercial pilot certificate (including the second-class medical certificates that would be required for balloon operations under this proposal) expire at the end of the last day of the 12th month after the month of the date of examination shown on the medical certificate.

All Federal Rules That May Duplicate, Overlap, or Conflict

There are no relevant Federal rules that may duplicate, overlap, or conflict with the proposed rule.

Description and an Estimated Number of Small Entities Impacted

The proposed rule would affect commercial balloon pilots and establishments involved in commercial balloon operations. The FAA does not maintain a database of commercial balloon operators actively operating in the United States. Using commercial sources, the FAA estimates that number to be about 356 [59] companies. Approximately 4,870 commercial pilots hold balloon ratings, and approximately 4,940 balloons are registered with the FAA. The commercial balloon industry estimates that 100,000 to 250,000 passenger rides are conducted annually, as well as aerial advertising and other commercial activities.

Businesses affected by this rule would be classified using the 2017 North American Industry Classification System [60] under NAICS code 487990 ''Scenic and Sightseeing Transportation, Other.'' This industry comprises establishments primarily engaged in providing scenic and sightseeing transportation (except on land and water). The U.S. Small Business Administration (SBA) defines entities in this industry as ''small'' using an average annual revenue threshold of $8 million.[61] With limited information and

[58] *https://medxpress.faa.gov/.*

[59] *http://www.blastvalve.com/Balloon_Rides/USA/index.shtml.*

[60] *https://www.census.gov/naics/?input=487990&year=2017&details=487990.*

[61] *https://www.sba.gov/sites/default/files/2019-08/SBA%20Table%20of%20Size%20Standards_Effective%20Aug%2019%2C%202019_Rev.pdf.*

data on sales revenues for each of the affected commercial balloon operators, the FAA has uncertainty as to how many entities would meet the SBA's small-entity criteria.[62] Furthermore, the FAA has uncertainty as to how the burden associated with the proposed rule would be distributed across commercial balloon companies versus individual balloon pilots employed by an operator. The FAA requests comment and data on the average annual sales revenues for the affected small businesses and to what extent the costs of obtaining a second-class medical certification would be considered an ''out-of-pocket'' cost incurred by commercial balloon pilots rather than a cost to the commercial balloon operator. As previously described, the FAA estimates the cost per pilot to obtain a second-class medical certificate would be between $160 and $685 annually, depending on whether a special issuance would be necessary.

For purposes of this initial regulatory flexibility analysis, the FAA assumes that the private sector costs of this rule (*i.e.,* the cost to obtain a second-class medical certification or special issuance) fall entirely on commercial balloon operators. In the absence of data on annual receipts specific to the commercial balloon industry, the FAA relies on the most recent data available on average revenues for all businesses, including commercial balloon operators, classified under NAICS 487990 ''Scenic and Sightseeing Transportation, Other'' from the 2017 Census Bureau's Statistics of U.S. Businesses (SUSB)[63] to inform the analysis. Note that the total number of firms identified for this industry is less than the FAA estimated number of commercial balloon operators. In this analysis, the FAA uses the SUSB data to estimate the proportion of balloon companies for each size category by annual receipts.

The table below summarizes the total number of firms, employment, and estimated annual receipts by annual receipt category for the entire industry classified under NAICS 487990 ''Scenic and Sightseeing Transportation, Other'' for the year 2017. Note that blanks in the table below reflect data that the Census Bureau withheld to avoid disclosing data for individual companies, but are included in the higher level totals. After adjusting the 2017 dollar values to constant 2020 dollars using the GDP deflator,[64] the FAA estimates that approximately 93 percent of companies (or about 331 balloon operators extrapolating from this percentage) may be considered small entities under the SBA definition.

To compare the compliance costs of the rule to the average revenues of small entities, for each receipt size category the FAA multiplies the proportion of total employment by the annualized private sector costs of the rule and divides by the estimated annual receipts in 2020 dollars.[65] Assuming that costs are proportional to employment size, which may be reasonable given that costs are driven by the number of pilots requiring a second-class medical certification, the FAA estimates that the costs of the proposed rule would constitute 0.07% to 0.42% of average annual revenues for small entities. Given the currency and level of aggregation of the data available, the FAA requests comment on accuracy of these estimates and any other information or data that would be relevant for estimating the effects of the rule on small entities.

TABLE 11—NUMBER OF FIRMS, ESTABLISHMENTS, EMPLOYMENT, AND ESTIMATED RECEIPTS BY ENTERPRISE RECEIPT SIZES FOR THE UNITED STATES, NAICS 487900: 2017 (CENSUS STATISTICS OF U.S. BUSINESSES)

| Enterprise receipt size [a] | Number of firms [b] | Percentage of firms | Employment | Percentage of total employment | Estimated receipts ($1,000) | Cost for all firms in size category ($1,000) | Cost as a percentage of receipts |
|---|---|---|---|---|---|---|---|
| <$100,000 | 53 | 17 | 48 | 1 | 2,255 | 10 | 0.42 |
| $100,000–499,999 | 119 | 39 | 192 | 5 | 29,644 | 40 | 0.13 |
| $500,000–999,999 | 47 | 15 | 237 | 7 | 32,765 | 49 | 0.14 |
| $1,000,000–2,499,999 | 43 | 14 | 365 | 10 | 63,134 | 76 | 0.11 |
| $2,500,000–4,999,999 | 18 | 6 | 323 | 9 | 65,788 | 67 | 0.10 |
| $5,000,000–7,499,999 | 6 | 2 | 106 | 3 | 29,465 | 22 | 0.07 |
| $7,500,000–9,999,999 | 5 | 2 | 213 | 6 | 41,585 | 44 | 0.10 |
| $10,000,000–14,999,999 | 4 | 1.3 | 196 | 5 | 50,270 | 41 | 0.08 |
| $20,000,000–24,999,999 | | | | | | | |
| $25,000,000–29,999,999 | 3 | 1.0 | 93 | 3 | 19,490 | 19 | 0.09 |
| $30,000,000–34,999,999 | | | | | | | |
| $35,000,000–39,999,999 | | | | | | | |
| $50,000,000–74,999,999 | | | | | | | |
| $100,000,000+ | 4 | 1 | 1,044 | 29 | 251,871 | 217 | 0.08 |
| Total | 309 | 100 | 3,611 | 100 | 762,426 | 751 | 0.09 |

[a] Using the Gross Domestic Product (GDP) deflator, the FAA finds that $7.49 million in 2017 dollars would be approximately $7.97 million in 2020 dollars. Therefore, the FAA assumes firms with receipts of less than $7.49 million in 2017 dollars would be considered small.

[b] The FAA notes that the number of firms in NAICS 487900 is lower than FAA's estimate of the number of balloon operators. For purposes of this analysis, the SUSB data is used to estimate the percentage of small entities and the distribution of costs relative to revenues.

## Alternatives Considered To Minimize Any Significant Economic Impact on Small Entities

The FAA has not identified any significant alternative that would minimize any significant economic impact on small entities which do not conflict with the statutory mandate. The FAA solicits comment on potential alternative approaches that could minimize the burden on small entities while still accomplishing the objectives of the proposal.

[62] Rainbow Ryders is one of the larger Commercial Balloon companies and are under the Small Business Administration small-entity criteria. Therefore, the FAA estimates that all of the Commercial balloon companies are a small entity. *It's Been a Year of Growth for Rainbow Ryders, https://www.abqjournal.com/1095655/its-been-a-growth-year-for-rainbow-ryders.html,* September 9, 2019.

[63] Available at: *https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html,* retrieved on August 15, 2021.

[64] Available at: *https://www.whitehouse.gov/omb/historical-tables/,* retrieved on January 15, 2020.

[65] For this calculation, the FAA uses the mid-estimate of $750,718 for the total private sector costs annualized at a 7 percent discount rate.

*C. International Trade Impact Assessment*

The Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these Acts, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. The FAA has assessed the potential effect of this proposed rule and determined that it will not create unnecessary obstacles to the foreign commerce of the United States.

*D. Unfunded Mandates Assessment*

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (in 1995 dollars) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a ''significant regulatory action.'' The FAA uses an inflation-adjusted value of $158.0 million in lieu of $100 million. This proposed rule does not contain such a mandate; therefore, the requirements of Title II of the Act do not apply.

*E. Paperwork Reduction Act*

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the FAA consider the impact of paperwork and other information collection burdens imposed on the public.

According to the 1995 amendments to the Paperwork Reduction Act (5 CFR 1320.8(b)(2)(vi)), an agency may not collect or sponsor the collection of information, nor may it impose an information collection requirement unless it displays a currently valid Office of Management and Budget (OMB) control number.

This NPRM contains the following proposed amendments to the existing information collection requirements previously approved under OMB Control No. 2120–0034. In the analysis below, the FAA describes the incremental changes in the number of respondents, annual burden, and monetized costs of the existing information collection requirement previously approved under OMB Control No. 2120–0034. As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the FAA submitted the proposed information collection requirements to OMB for its review. Review for the renewal of OMB Control No. 2120–0034 was completed on May 29, 2020.

Requirements To Hold a Second-Class Medical Certificate

The proposed rule would require airmen to hold a valid second-class medical certificate when exercising the privileges of a commercial pilot certificate in a balloon for compensation or hire. To obtain a medical certificate, an airmen would complete an online application (FAA form 8500–8, Application for Medical Certificate) using the FAA's medical certificate application tool, MedXPress and undergo a physical examination with an FAA-designated Aviation Medical Examiner (AME).

In Table 12 below, the FAA shows the incremental burden of this rule to the approved information collection under OMB Control No. 2120–0034. Additional details on assumptions and calculations used in this section are presented elsewhere in the Regulatory Evaluation section of this document.

Estimates of the Hour Burden of the Collection of Information

The mid estimate of the number of applicants in the first year is 2,491.

TABLE 12—BURDEN HOURS ASSOCIATED WITH MEDXPRESS FORM 8500–8

| Form No. | Number of applicants | Hours per applicant | Total hours |
|---|---|---|---|
| 8500–8 | 2,491 | 1.5 | 3,737 |

Estimate of the Total Annual Cost Burden to Respondents or Record Keepers Resulting From the Collection of Information

Once the information on FAA Form 8500–8 is collected, respondents must receive a medical examination in order to be certificated to exercise commercial balloon pilot privileges. The average fee for a basic medical examination is estimated at $150. The total cost for medical exams in the first year is as follows:

$150 × 2,491 submissions of Form 8500–8 = $373,650

Estimates of Annualized Costs to the Federal Government

The estimated annualized cost to the Federal Government is between $143,183 and $588,991, with a mid-estimate of $310,404 at a 7 percent discount rate. The FAA would incur costs associated with reviewing and processing applications submitted through MedXPress. It costs about $30 per medical certification review using the primary estimate for the number of applications in the first year, the FAA estimates a total cost of $73,747 (= $30 per application × 2,491) in the first year.

Currently, a MedXPress application that requires a special issuance medical certificate is deferred to the AMCD of Oklahoma City for further consideration. The FAA assumes that 10 percent of the applicants do not initially qualify for second-class medical certification and therefore would require special issuance. The average cost to FAA for each medical certificate special issuance review is approximately $126.

The total annualized costs for the FAA to review and process MedXPress applications from commercial balloon applicants and costs for the FAA to conduct Special Issuance Review for commercial balloon applicants is between $90,341 and $371,622, with a mid-estimate of $195,848 at a 7 percent discount rate over ten years.

Individuals and organizations may send comments on the information collection requirement to the address listed in the **ADDRESSES** section at the beginning of this preamble by January 18, 2022. Comments should be submitted to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Desk Officer for FAA, New Executive Office Building, Room 10202, 725 17th Street NW, Washington DC 20053.

*F. International Compatibility*

In keeping with U.S. obligations under the Convention on International

Civil Aviation, it is FAA policy to conform to International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has reviewed the corresponding ICAO Standards and Recommended Practices and has identified no differences with these proposed regulations.

*G. Environmental Analysis*

FAA Order 1050.1F identifies FAA actions that are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act in the absence of extraordinary circumstances. The FAA has determined this rulemaking action qualifies for the categorical exclusion identified in paragraph 5–6.6 and involves no extraordinary circumstances.

## VI. Executive Order Determination

*A. Executive Order 13132, Federalism*

The FAA has analyzed this rulemaking under the principles and criteria of Executive Order 13132, Federalism. The agency has determined that this action would not have a substantial direct effect on the States, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government, and, therefore, would not have federalism implications.

*B. Executive Order 13211, Regulations that Significantly Affect Energy Supply, Distribution, or Use*

The FAA analyzed this rulemaking under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). The Agency has determined that it would not be a ''significant energy action'' under the executive order and would not be likely to have a significant adverse effect on the supply, distribution, or use of energy.

*C. Executive Order 13609, International Cooperation*

Executive Order 13609, Promoting International Regulatory Cooperation, (77 FR 26413, May 4, 2012) promotes international regulatory cooperation to meet shared challenges involving health, safety, labor, security, environmental, and other issues and to reduce, eliminate, or prevent unnecessary differences in regulatory requirements. The FAA has analyzed this action under the policies and agency responsibilities of Executive Order 13609, and has determined that this action would reduce differences between U.S. aviation standards and those of other civil aviation authorities by bringing U.S. regulatory requirements partially into compliance with International Civil Aviation Organization (ICAO) standards for medical certification.[66]

## VII. Additional Information

*A. Comments Invited*

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. The Agency also invites comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time.

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

Confidential Business Information: Confidential Business Information (CBI) is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this document. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

*B. Electronic Access and Filing*

A copy of this notice of proposed rulemaking, all comments received, any final rule, and all background material may be viewed online at *https://www.regulations.gov* using the docket number listed above. A copy of this rulemaking will be placed in the docket. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded from the Office of the Federal Register's website at *https://www.federalregister.gov* and the Government Publishing Office's website at *https://www.govinfo.gov.* A copy may also be found at the FAA's Regulations and Policies website at *https://www.faa.gov/regulations_policies.*

Copies may also be obtained by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW, Washington, DC 20591, or by calling (202) 267–9677. Commenters must identify the docket or notice number of this rulemaking.

All documents the FAA considered in developing this proposed rule, including economic analyses and technical reports, may be accessed in the electronic docket for this rulemaking.

## List of Subjects

*14 CFR Part 61*

Aircraft, Airmen, Alcohol abuse, Aviation safety, Drug abuse, Flight instruction, Medical certification, Recreation and recreation areas, Reporting and recordkeeping requirements, Security measures, Teachers.

*14 CFR Part 68*

Aircraft, Airmen, Health, Reporting and recordkeeping requirements.

## The Proposed Amendment

For the reasons discussed in the preamble, the Federal Aviation Administration proposes to amend chapter I of title 14, Code of Federal Regulations as follows:

[66] The 12th edition of the Annex 1 to the Convention on International Civil Aviation, Personnel Licensing, (July 2018), specifies that a person exercising the privileges of a Free Balloon Pilot License must hold a Class 2 medical. *See* 2.10.1.5.

## PART 61—CERTIFICATION: PILOTS, FLIGHT INSTRUCTORS, AND GROUND INSTRUCTORS

■ 1. The authority citation for part 61 is revised to read as follows:

**Authority:** 49 U.S.C. 106(f), 106(g), 40113, 44701–44703, 44703 note, 44707, 44709–44711, 44729, 44903, 45102–45103, 45301–45302.

■ 2. Amend § 61.3 by revising paragraphs (c)(2)(vi), (xiii), and (xiv) and adding paragraph (c)(2)(xv) to read as follows:

**§ 61.3 Requirement for certificates, ratings, and authorizations.**

* * * * *

(c) * * *

(2) * * *

(vi) Is holding a pilot certificate with a balloon class rating and that person—

(A) Is exercising the privileges of a private pilot certificate in a balloon; or

(B) Is providing flight training in a balloon in accordance with § 61.133(a)(2)(ii);

* * * * *

(xiii) Is exercising the privileges of a student, recreational or private pilot certificate for operations conducted under the conditions and limitations set forth in § 61.113(i) and holds a U.S. driver's license;

(xiv) Is exercising the privileges of a flight instructor certificate and acting as pilot in command or a required flightcrew member for operations conducted under the conditions and limitations set forth in § 61.113(i) and holds a U.S. driver's license; or

(xv) Is exercising the privileges of a student pilot certificate or higher while acting as pilot in command on a medical flight test authorized under part 67 of this chapter.

* * * * *

■ 3. Amend § 61.23 by:

■ a. Revising paragraphs (a)(2)(i) and (ii);

■ b. Adding paragraph (a)(2)(iii);

■ c. Revising paragraph (b)(3);

■ d. Redesignating paragraphs (b)(4) through (9) as paragraphs (b)(6) through (11);

■ e. Adding new paragraphs (b)(4) and (5);

■ f. Removing the word ''or'' at the end of paragraph (b)(10);

■ g. Revising newly redesignated paragraph (b)(11)(ii);

■ h. Adding paragraph (b)(12); and

■ i. Revising paragraphs (c)(3)(i)(C), (D), and (E), (d)(1)(iii), and (d)(2)(i).

The revisions and additions read as follows:

**§ 61.23 Medical certificates: Requirement and duration.**

(a) * * *

(2) * * *

(i) Second-in-command privileges of an airline transport pilot certificate in part 121 of this chapter (other than operations specified in paragraph (a)(1)(ii) of this section);

(ii) Privileges of a commercial pilot certificate in an aircraft other than a balloon or glider; or

(iii) Except as provided in paragraph (b)(5) of this section, privileges of a commercial pilot certificate with a balloon class rating in a balloon for compensation or hire; or

* * * * *

(b) * * *

(3) When exercising the privileges of a pilot certificate with a glider category rating in a glider;

(4) When exercising the privileges of a private pilot certificate with a balloon class rating in a balloon;

(5) When exercising the privileges of a commercial pilot certificate with a balloon class rating in a balloon if the person is providing flight training in accordance with § 61.133(a)(2)(ii);

* * * * *

(11) * * *

(ii) The flight conducted is a domestic flight operation within U.S. airspace; or

(12) When exercising the privileges of a student pilot certificate or higher while acting as pilot in command on a medical flight test authorized under part 67 of this chapter.

(c) * * *

(3) * * *

(i) * * *

(C) Complete the medical education course set forth in § 68.3 of this chapter during the 24 calendar months before acting as pilot in command or serving as a required flightcrew member in an operation conducted under § 61.113(i) and retain a certification of course completion in accordance with § 68.3(b)(1) of this chapter;

(D) Receive a comprehensive medical examination from a State-licensed physician during the 48 months before acting as pilot in command or serving as a required flightcrew member of an operation conducted under § 61.113(i) and that medical examination is conducted in accordance with the requirements in part 68 of this chapter; and

(E) If the individual has been diagnosed with any medical condition that may impact the ability of the individual to fly, be under the care and treatment of a State-licensed physician when acting as pilot in command or serving as a required flightcrew member of an operation conducted under § 61.113(i).

* * * * *

(d) * * *

| If you hold | And on the date of examination for your most recent medical certificate you were | And you are conducting an operation requiring | Then your medical certificate expires, for that operation, at the end of the last day of the |
|---|---|---|---|
| * | * | * | * |
| ..... | (iii) Any age ..... | a commercial pilot certificate (other than a commercial pilot certificate with a balloon rating when conducting flight training), a flight engineer certificate, or an air traffic control tower operator certificate. | 12th month after the month of the date of examination shown on the medical certificate. |
| * | * | * | * |
| (2) * | * | * | * |
| ..... | (i) Any age ..... | an airline transport pilot certificate for second-in-command privileges (other than the operations specified in paragraph (d)(1) of this section), a commercial pilot certificate (other than a commercial pilot certificate with a balloon rating when conducting flight training), a flight engineer certificate, or an air traffic control tower operator certificate. | 12th month after the month of the date of examination shown on the medical certificate. |

| If you hold | And on the date of examination for your most recent medical certificate you were | And you are conducting an operation requiring | Then your medical certificate expires, for that operation, at the end of the last day of the |
|---|---|---|---|
| * | * | * | * |

■ 4. In § 61.113, revise the introductory text of paragraph (i) to read as follows:

**§ 61.113 Private pilot privileges and limitations: Pilot in command.**

* * * * *

(i) A private pilot may act as pilot in command or serve as a required flightcrew member of an aircraft without holding a medical certificate issued under part 67 of this chapter provided the pilot holds a valid U.S. driver's license, meets the requirements of § 61.23(c)(3), and complies with this section and all of the following conditions and limitations:

* * * * *

## PART 68—REQUIREMENTS FOR OPERATING CERTAIN SMALL AIRCRAFT WITHOUT A MEDICAL CERTIFICATE

■ 5. The authority citation for part 68 continues to read as follows:

**Authority:** 49 U.S.C. 106(f), 44701–44703; sec. 2307 of Pub. L. 114–190, 130 Stat. 615 (49 U.S.C. 44703 note).

■ 6. Amend § 68.3 by revising paragraphs (a) introductory text and (b) introductory text to read as follows:

**§ 68.3 Medical education course requirements.**

(a) The medical education course required to act as pilot in command or serve as a required flightcrew member in an operation under § 61.113(i) of this chapter must—

* * * * *

(b) Upon successful completion of the medical education course, the following items must be electronically provided to the individual seeking to act as pilot in command or serve as a required flightcrew member under the conditions and limitations of § 61.113(i) of this chapter and transmitted to the FAA—

* * * * *

■ 7. In § 68.9, revise the introductory text of paragraph (a) to read as follows:

**§ 68.9 Special Issuance process.**

(a) *General.* An individual who has met the qualifications to operate an aircraft under § 61.113(i) of this chapter and is seeking to act as a pilot in command or serve as a required flightcrew member under that section must have completed the process for obtaining an Authorization for Special Issuance of a Medical Certificate for each of the following:

* * * * *

Issued in Washington, DC, under authority provided by 49 U.S.C. 106(f), 44701, 44702, and 44703, and section 318 of Public Law 115–254 on or about November 1, 2021.

**Robert Ruiz,**

*Acting Deputy Executive Director, Flight Standards Service.*

[FR Doc. 2021–24141 Filed 11–17–21; 8:45 am]

BILLING CODE 4910–13–P

## DEPARTMENT OF THE TREASURY

### Office of Investment Security

### 31 CFR Parts 800 and 802

### Proposed Regulations Pertaining to Certain Investments in the United States by Foreign Persons and Proposed Regulations Pertaining to Certain Transactions by Foreign Persons Involving Real Estate in the United States

*Correction*

In proposed rule document 2021–24597, appearing on pages 62978–62980 in the issue of Monday, November 15, 2021, make the following correction:

On page 24597, in the third column, on the second line of the **DATES** section, ''December 15, 2021'' is corrected to read ''December 10, 2021''.

[FR Doc. C1–2021–24597 Filed 11–17–21; 8:45 am]

BILLING CODE 0099–10–P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

**[EPA–R10–OAR–2021–0750, FRL–9189–01–R10]**

### Air Plan Approval; Washington; Update to the Yakima Regional Clean Air Agency Wood Heater and Burn Ban Regulations

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing to approve submitted revisions to the Yakima Regional Clean Air Agency (YRCAA) regulations designed to control particulate matter from residential wood heaters, such as woodstoves and fireplaces. The updated YRCAA regulations set fine particulate matter trigger levels for impaired air quality burn bans, consistent with statutory changes enacted by the Washington State Legislature. The submission also contains updates to improve the clarity of the language and align with the statewide solid fuel burning device regulations already applicable in YRCAA's jurisdiction. We are proposing to approve these changes because they meet the requirements of the Clean Air Act and strengthen the Washington SIP.

**DATES:** Comments must be received on or before December 20, 2021.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA–R10–OAR–2021–0750 at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

**FOR FURTHER INFORMATION CONTACT:** Jeff Hunt, EPA Region 10, 1200 Sixth Avenue—Suite 155, Seattle, WA 98101, at (206) 553–0256, or *hunt.jeff@epa.gov.*

**SUPPLEMENTARY INFORMATION:** Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, it is intended to refer to the EPA.

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II. Summary of SIP Revision
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## I. Background

On July 1, 1987, the EPA published revised National Ambient Air Quality Standards (NAAQS) for particulate matter focused on inhalable coarse particles ($PM_{10}$) that are 10 micrometers in diameter or smaller (52 FR 24634). The $PM_{10}$ standard most relevant to Washington was the 24-hour $PM_{10}$ NAAQS.[1] The EPA set the 24-hour $PM_{10}$ NAAQS at 150 micrograms per cubic meter (μg/m³), not to be exceeded more than once per year on average over a three-year period. On August 7, 1987, the EPA identified the Yakima area as a $PM_{10}$ ''Group I'' area of concern, *i.e.,* an area with a 95% or greater likelihood of violating the $PM_{10}$ NAAQS (52 FR 29383). The U.S. Congress subsequently designated the Yakima area as a moderate $PM_{10}$ nonattainment area upon enactment of the Clean Air Act Amendments of 1990 (November 15, 1990).[2] On March 24, 1989, the Washington Department of Ecology (Ecology) submitted a plan for attaining the 24-hour $PM_{10}$ NAAQS, amended with additional submissions between 1992 and 1995. The EPA approved the plan on February 2, 1998 (63 FR 5269). One element of the approved $PM_{10}$ attainment plan was the residential wood smoke curtailment program codified in local regulation at YRCAA, Article IX, *Woodstove and Fireplaces.* On February 8, 2005, the EPA redesignated the Yakima area to attainment for $PM_{10}$ based on the existing set of control measures contained in the attainment plan (70 FR 6591).[3]

On July 18, 1997, the EPA published a revision to the particulate matter standards to establish the fine particulate matter ($PM_{2.5}$) NAAQS for particles that are 2.5 micrometers in diameter or smaller, based on significant evidence and numerous health studies demonstrating that serious health effects are associated with exposures to $PM_{2.5}$ (62 FR 38652). The EPA's revised 1997 particulate matter standards included a 24-hour NAAQS of 65 μg/m³ for $PM_{2.5}$, based on a three-year average of the 98th percentile of 24-hour concentrations. On October 17, 2006, the EPA published a revision to the $PM_{2.5}$ 24-hour NAAQS, lowering the level from 65 μg/m³ to 35 μg/m³, based on additional evidence and health studies (71 FR 61144).

On February 2, 1998, the EPA approved Article IX, *Woodstoves and Fireplaces,* adopted by YRCAA in 1993 and 1995 (63 FR 5269). This set of adopted regulations predated the EPA's promulgation of the 1997 and 2006 $PM_{2.5}$ NAAQS and focused on the 1987 $PM_{10}$ NAAQS for residential woodstove curtailment. In a series of amendments beginning in 2005, the Washington State Legislature revised the underlying statutory authority contained in Chapter 70.94[4] Revised Code of Washington (RCW) (Washington Clean Air Act) regarding residential wood smoke curtailment programs to focus on the more recent 24-hour $PM_{2.5}$ NAAQS. In a SIP revision approved by the EPA on May 9, 2014, Ecology provided an analysis covering former $PM_{10}$ nonattainment areas in both Western and Eastern Washington, including the Yakima area, to demonstrate that wood smoke curtailment programs focused on the more recent 24-hour $PM_{2.5}$ NAAQS will provide continued maintenance of the 24-hour $PM_{10}$ NAAQS (79 FR 26628). The EPA agreed with Ecology's analysis and approved revisions to the statewide regulations contained in Chapter 173–433 Washington Administrative Code (WAC) *Solid Fuel Burning Devices* (May 9, 2014, 79 FR 26628). These revisions removed the $PM_{10}$ burn ban trigger levels and replaced them with $PM_{2.5}$ trigger levels, consistent with the changes to RCW 70.94.473[5] of the Washington Clean Air Act.[6]

## II. Summary of SIP Revision

In the October 14, 2021 submission that is the subject of this action, Ecology and YRCAA requested that the EPA approve changes to *Regulation 1,* sections 3.04 *Wood Heaters* and 3.05 *Burn Bans,* adopted by YRCAA on October 8, 2020, to replace the outdated 1993 and 1995 Article IX provisions previously approved into the SIP.[7] The submitted revisions, state effective on November 9, 2020, align the YRCAA wood heater and impaired air quality burn ban regulations with the Washington Clean Air Act statutory changes discussed above, as well as the EPA-approved changes to Ecology's statewide solid fuel burning device regulations. The definition of ''wood heater'' in Regulation 1, section 3.04 is consistent with the term ''solid fuel burning device'' in the Washington Clean Air Act. Specifically, section 3.04(B) *Applicability* states, ''This section applies to any solid fuel burning device which, as defined by RCW 70A.15.3510, burns wood, wood products, or other nongaseous or non-liquid fuels, including those rated less than one million British thermal unit (Btu) per hour.'' Aside from this difference in terminology, the YRCAA regulations generally mirror and cite to the statewide Chapter 173–433 WAC provisions already applicable in YRCAA's jurisdiction. An analysis of the YRCAA regulations is included in the docket for this action.

We note that the former Article IX regulations adopted in 1993 and 1995 included a ''Woodsmoke Control Zone,'' which imposed impaired air quality burn ban requirements on a portion of Yakima County generally corresponding to the boundaries of the northern half of the county which encompassed the former $PM_{10}$ nonattainment area.[8] YRCAA's current regulations expand applicability of impaired air quality burn bans to all of Yakima County, except for lands located within the external boundaries of the Yakama Indian Reservation. Because this revision strengthens the SIP by expanding the geographic scope of the curtailment program, we are proposing to approve YRCAA's elimination of the Woodsmoke Control Zone from the regulations.

## III. Proposed Action

The EPA is proposing to approve and incorporate by reference *Regulation 1,* sections 3.04 *Wood Heaters* and 3.05 *Burn Bans,* adopted by YRCAA effective November 9, 2020. These revisions strengthen the SIP in several ways, including by revising burn ban trigger

[1] No areas in Washington violated the annual $PM_{10}$ NAAQS, which the EPA subsequently revoked on October 17, 2006 (71 FR 61144).

[2] See 40 CFR 81.348 for legal description and current designation.

[3] Ibid.

[4] This statute was re-codified on June 11, 2020, to Chapter 70A.15 RCW. There were no substantive changes to the statutory text except updated cross references.

[5] Re-codified to RCW 70A.15.3580 with no substantive changes to the statutory text.

[6] YRCAA continues to operate a $PM_{10}$ monitor, in addition to the collocated $PM_{2.5}$ monitor, to verify compliance with both the $PM_{10}$ and $PM_{2.5}$ NAAQS (Yakima-4th Ave S, monitor ID #530770009). Ecology's 2014 analysis, based on these collocated monitors, determined that $PM_{2.5}$ concentrations would need to reach 62 μg/m³ before triggering the former $PM_{10}$ level for a stage 1 impaired air quality burn ban. Therefore, the current trigger level established under Chapter 70A.15.3580 of the Washington Clean Air Act (forecasted to reach or exceed $PM_{2.5}$ concentrations of 30 μg/m³) is the controlling standard. Similarly, $PM_{2.5}$ concentrations would need to reach 76 μg/m³ to exceed the former $PM_{10}$ trigger level for a stage 2 impaired air quality burn ban. See 79 FR 26628 (May 9, 2014).

[7] We note that the October 14, 2021 submission also includes outdoor burning regulations and other general air quality regulations which the EPA will address in separate actions.

[8] See 40 CFR 81.348 for legal description and current designation.

levels to align with the Washington State Legislature's statutory changes focused on the more recent 24-hour $PM_{2.5}$ NAAQS and expanding the burn ban applicability beyond the former Woodsmoke Control Zone. The EPA is also proposing to determine that *Regulation 1,* sections 3.04 *Wood Heaters* and 3.05 *Burn Bans,* adopted by YRCAA effective November 9, 2020 are consistent with section 110 of the Clean Air Act. The EPA is soliciting public comments on YRCAA *Regulation 1,* sections 3.04 *Wood Heaters* and 3.05 *Burn Bans* which will be considered before taking final action. We are also proposing to remove from the SIP the outdated 1993 and 1995 Article IX provisions *Woodstoves and Fireplaces,* which are replaced by sections 3.04 and 3.05. We note that the October 14, 2021 submission also includes outdoor burning regulations and other general air quality regulations which the EPA will address in separate actions.

## IV. Incorporation by Reference

In this document, the EPA is proposing to include in a final rule, regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference YRCAA *Regulation 1,* sections 3.04 and 3.05 discussed in section III of this preamble and remove from the incorporation by reference YRCAA Regulation 1, Article IX which is replaced by sections 3.04 and 3.05. The EPA has made, and will continue to make, these documents generally available through *https://www.regulations.gov* and at the EPA Region 10 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

## V. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Clean Air Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve State choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this proposed action merely approves State law as meeting Federal requirements and does not impose additional requirements beyond those imposed by State law. For that reason, this proposed action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of the requirements would be inconsistent with the Clean Air Act; and
- Does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this proposed action would not apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). Consistent with EPA policy, the EPA provided an opportunity to request consultation to the Confederated Tribes and Bands of the Yakama Nation in a letter dated April 5, 2021.

## List of Subjects in 40 CFR Part 52

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

Dated: November 9, 2021.

**Michelle L. Pirzadeh,**

*Acting Regional Administrator, Region 10.*

[FR Doc. 2021–25042 Filed 11–17–21; 8:45 am]

**BILLING CODE 6560–50–P**

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## FEDERAL COMMUNICATIONS COMMISSION

## 47 CFR Part 64

**[CG Docket No. 03–123; RM–11820; FCC 21–95; FR ID 57163]**

## Internet Protocol Relay Service Compensation Methodology

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** In this document, the Federal Communications Commission (FCC or Commission) proposes to modify the methodology for determining compensation for the provision of internet Protocol Relay (IP Relay) service and seeks comments on modifying the formula for determining the per-minute compensation for providers of IP Relay to ensure Interstate TRS Fund support is sufficient to sustain a functionally equivalent telephone service.

**DATES:** Comments are due December 20, 2021; reply comments are due January 18, 2022.

**ADDRESSES:** You may submit comments, identified by CG Docket No. 03–123 and RM–11820, by either of the following methods:

- *Federal Communications Commission's Website: https://www.fcc.gov/ecfs/filings.* Follow the instructions for submitting comments.
- *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. Currently, the Commission does not accept any hand delivered or messenger delivered filings as a temporary measure taken to help protect the health and safety of individuals, and to mitigate the transmission of COVID–19. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

For detailed instructions on submitting comments and additional information on the rulemaking process, see document FCC 21–95 at: *https://docs.fcc.gov/public/attachments/FCC-21-95A1.pdf.*

**FOR FURTHER INFORMATION CONTACT:** William Wallace, Consumer and

Governmental Affairs Bureau, at 202–418–2716, or *William.Wallace@fcc.gov.*

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's Notice of Proposed Rulemaking (Notice), document FCC 21–95, adopted on August 5, 2021, released on August 6, 2021, in CG Docket No. 03–123 and RM–11820. The full text of document FCC 21–95 is available for public inspection and copying via the Commission's Electronic Comment Filing System (ECFS).

To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at (202) 418–0530.

This proceeding shall be treated as a ''permit-but-disclose'' proceeding in accordance with the Commission's *ex parte* rules. 47 CFR 1.1200 *et seq.* Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with § 1.1206(b). In proceedings governed by § 1.49(f) or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.,* .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules.

**Initial Paperwork Reduction Act of 1995 Analysis**

The Notice in document FCC 21–95 seeks comment on proposed rule amendments to the compensation methodology that may result in modified information collection requirements. If the Commission adopts any modified information collection requirements, the Commission will publish another document in the **Federal Register** inviting the public to comment on the requirements, as required by the Paperwork Reduction Act. Public Law 104–13; 44 U.S.C. 3501–3520.

In addition, pursuant to the Small Business Paperwork Relief Act of 2002, the Commission seeks comment on how it might further reduce the information collection burden for small business concerns with fewer than 25 employees. Public Law 107–198; 44 U.S.C. 3506(c)(4).

**Synopsis**

1. In document FCC 21–95, the Commission proposes to modify the methodology for setting compensation for IP Relay, a form of Telecommunications Relay Service (TRS).

2. With IP Relay, an individual with a hearing or speech disability can communicate with voice telephone users by transmitting text via the internet. The text transmission is delivered to an IP Relay call center, where a communications assistant (CA) converts the user's text to speech for the hearing party and converts that party's speech to text for the IP Relay user.

3. IP Relay is supported by the TRS Fund in accordance with a methodology approved by the Commission in 2007. A base level of per-minute compensation is approved based on the weighted average of providers' reasonable costs and remains effective for a three-year period. In addition, an adjustment factor is set to be applied to the base amount to determine per-minute compensation for the second and third years, which reflects an increase due to inflation, offset by a decrease due to cost efficiencies. The base compensation amount also is subject to upward adjustment to account for exogenous costs, *i.e.,* those costs beyond the control of the IP Relay providers that are not reflected in the inflation adjustment. At the end of each three-year period, the base compensation level is reset based on average provider costs. The current compensation period runs from July 1, 2019, to June 30, 2022.

4. Since 2007, there have been substantial changes in the circumstances relevant to TRS Fund support of IP Relay. In 2013 and 2014, four of the five IP Relay providers exited the market, and IP Relay demand declined precipitously. After November 2014, Sprint Corporation (now T-Mobile USA, Inc.) was the sole provider of IP Relay service, and demand stabilized.

5. In response to these developments, the Consumer and Governmental Affairs Bureau (CGB or Bureau) has taken a number of steps to ensure that TRS Fund support for IP Relay was sufficient to sustain the service and allow the remaining provider to ascertain and meet the needs of consumers relying on it for functionally equivalent telephone service.

6. In 2016, the Bureau partially waived the Commission rule prohibiting TRS Fund support of IP Relay provider-directed outreach activities to allow T-Mobile to effectively educate deafblind consumers about its service and solicit feedback on how to improve it. The Bureau renewed this waiver in subsequent years.

7. In 2019, the Bureau allowed recovery of an operating margin, determined as a percentage of annual expenses, in lieu of the rate of return on capital investment previously allowed. In renewing the previously granted waiver permitting provider recovery of expenses for outreach to the deafblind community, the Bureau expanded the scope of that waiver to include outreach to other potential users of this service.

8. In November 2018, Sprint (now T-Mobile) filed a petition for rulemaking requesting a new compensation methodology. The company proposed that the Commission adopt a new approach based substantially on the Multi-State Average Rate Structure (MARS) compensation plan for TTY-based TRS offered through state TRS programs.

9. The Commission proposes to amend the compensation rules for IP Relay to take account of the changed environment in which this service is provided. The Commission believes it should continue the practice of periodically re-setting the compensation level based on determinations of reasonable provider cost. As the Commission explained last year when setting compensation for internet Protocol Captioned Telephone Service (IP CTS) in the *IP CTS Compensation Methodology Order,* published at 85 FR 64971, October 14, 2020, over a long period ''the Commission has developed a consistent approach to determining

the reasonable costs of providing TRS, which can be applied without imposing undue administrative burdens on either providers or the Commission.'' Further, ''[a]lthough any ratemaking method is subject to imprecision, provider cost data, which is subject to audit, has been reasonably reliable and consistent,'' and ''the Commission's determinations regarding allowability of costs are solidly reasoned and have been upheld on judicial review.'' The Commission seeks comment on whether these general observations continue to hold true for IP Relay.

10. The Commission proposes to continue setting the compensation level for a multi-year period, subject to annual adjustment based on predetermined factors. The Commission proposes a number of changes in how reasonable costs are determined, and seeks comment on whether to change the specific duration of the compensation period and on the appropriate criteria for annual adjustment of the compensation level, as well as other aspects of the methodology. The Commission seeks comment on which specific aspects of the cost-based approach have been problematic in the IP Relay context and how they could be improved. The Commission seeks additional comment on the MARS-based alternative proposed in T-Mobile's petition for rulemaking, and invites commenters to suggest additional alternative compensation methodologies.

**Benefits of IP Relay**

11. The Commission seeks granular information on which segments of the TRS-eligible population primarily use and benefit from this service. How many deafblind individuals use IP Relay and how many minutes of use do they represent? The Commission seeks comment on the best way to determine or estimate these numbers. What features of IP Relay are critical for this customer segment? What proportion of IP Relay users represent people who became deaf or hard of hearing early in life, and are unable to use VRS because they do not know ASL? To what extent is IP Relay used to make 911 calls, and what advantages does it offer in this regard? To what extent do other forms of TRS (or other communications services, such as real-time text) provide an effective substitute to IP Relay for individuals who might otherwise rely on the service as their sole or primary means of telephone communication? To what extent do people who lose hearing later in life find IP Relay beneficial, despite the availability of other options, such as IP CTS? Would a person with close to 100% hearing loss find IP Relay preferable to IP CTS? Would such a preference depend on how much an individual's speech is affected, or other factors? The Commission seeks comment on whether there has been enough outreach and education to the deafblind community by the Commission and TRS providers and whether more is needed. Would increased outreach and education to the deafblind community regarding the availability and merits of each type of TRS increase legitimate demand for IP Relay?

**Allowable Expenses**

12. The Commission has made a number of determinations, both for TRS generally and for specific relay services, as to whether various categories of costs are allowable for recovery from the TRS Fund as reasonable costs of providing TRS. The Commission seeks comment on possible amendments to the allowable cost rules.

13. *Outreach.* The Commission proposes to rescind the current prohibition on outreach recovery by IP Relay providers and seeks comment on this proposal, its costs and benefits, and the underlying rationale stated below.

14. First, CGB has found that in the absence of competition, providing economic incentive for outreach and education by the sole service provider may be critical to effectively educate consumers—including consumers who are deafblind and others—regarding the availability of and improvements to the service. The Commission invites comment on the extent to which outreach for this purpose continues to be needed and the resulting benefits.

15. Second, with only one IP Relay provider, the Commission believes that provider outreach expenditures in this context are more likely to be focused appropriately on educating existing and potential IP Relay users about the service rather than on encouraging or preventing ''churn'' among existing customers, would therefore be more effective for their intended purpose than when the outreach ban was adopted, and would not likely duplicate other outreach efforts. Finally, a review of the outreach reports submitted by T-Mobile in response to the resumption of compensated outreach activity has not shown that they are misdirected toward ineligible users. Therefore, the Commission does not believe such efforts would contribute to a recurrence of the kind of misuse of IP Relay that occurred prior to 2015. The Commission seeks comment on these assumptions.

16. The Commission seeks comment on whether to limit allowable outreach expenses to a specified percentage or amount, and, if so, what percentage or amount should be allowed. How should the Commission measure the effectiveness of outreach efforts—based on the number of new users or on some other basis? Should the Commission continue to require the filing of regular reports to ensure that outreach expenses are beneficial and effectively educating consumers about IP Relay service, and if so, on what schedule? Should the Commission continue to require separate reporting of general and deafblind outreach activities and the associated costs?

17. *Indirect Overhead.* The Commission seeks comment on whether to modify, with respect to IP Relay, the Commission's rule allowing recovery for only those overhead costs directly related to and directly supporting the provision of relay service and whether there is a continuing need for this rule in the IP Relay context.

18. First, is the current rule effectively mandated by section 225 of the Communications Act of 1934, as amended? 47 U.S.C. 225. Given that only some current providers of TRS are common carriers, does the Commission have more flexibility in determining what costs are reasonable?

19. Second, the Commission seeks comment on the cost-effectiveness of the current rule, relative to alternatives, notably allowing a reasonable contribution toward overhead costs. To what extent is it feasible for a multi-service provider to track administrative costs directly, to the extent they are attributable to the provision of TRS? Is it unduly burdensome to require a demonstration of cost causation for such costs, *e.g.,* by maintaining time records for staff time attributable to IP Relay? What specific kinds of administrative costs that are not currently recoverable would be recovered if allocation of overhead were permitted? The Commission seeks comment on whether there are circumstances specific to the current context of IP Relay, such as the presence of only one provider, that make the rule more burdensome or less appropriate for application to this service, compared to other forms of TRS? How much would allowing support for such costs increase per-minute IP Relay compensation? Is there any risk T-Mobile would abandon TRS if it continued to receive no contribution to overheads but continued to be fully compensated for all costs attributed to TRS?

20. If the Commission were to allow recovery of overhead costs, *i.e.,* administrative costs not directly attributable to TRS, how should such

costs be allocated—based on the percentage of total revenues derived from IP Relay, percentage of total company costs, or by some other method? How could the Commission or Fund administrator effectively audit such allocations?

21. *Other Allowable Costs.* Are there other costs incurred in the provision of IP Relay that the Commission's methodology should allow?

**Operating Margin**

22. The Commission proposes to amend its compensation rules to affirm that the IP Relay compensation level should include an operating margin—*i.e.,* an allowance for recovery of a designated percentage of allowed expenses, in lieu of return on investment. The Commission seeks comment on this proposal and its cost-effectiveness.

23. The Commission seeks comment on what percentage of allowable expenses constitutes a reasonable operating margin for IP Relay. By what criteria should the allowed operating margin be determined? Is business risk assessment an appropriate measure for setting the operating margin for IP Relay? Due to the level of business risk, or for other reasons, should the operating margin for IP Relay be different from that for other forms of TRS? Is the operating margin of 12.35%, determined by the Bureau in 2019, a reasonable margin going forward, or should a different allowed margin be selected? Have there been recent changes in capital markets that would support increasing or decreasing this margin? The Commission seeks comment on whether future determinations of an operating margin for IP Relay should be made by the Commission itself or could be delegated to the Bureau.

**Projected Versus Historical Costs**

24. The Commission proposes to return to the pre-2019 practice of using only projected costs and demand as the basis for calculating the base compensation level for IP Relay and seeks comment on this proposal and its cost-effectiveness relative to other approaches. The Commission invites the submission of evidence regarding the likelihood that the current level of cost increases in IP Relay are likely to continue or to prove to be a temporary phenomenon.

**Compensation Period and Adjustments**

25. *Duration of Compensation Period.* The Commission proposes to continue setting IP Relay compensation for a multi-year period and seeks comment on this proposal and whether it will provide benefits in the IP Relay context.

26. Assuming that the Commission continues setting compensation for a multi-year period, should the duration continue to be three years? A longer compensation period, such as four or five years, would potentially offer a provider greater certainty for the purpose of long-term planning and allow retention of a larger portion of any profits produced by efficiency improvements—as well as reducing the administrative burden for the provider and the Commission. Would these benefits outweigh the risks posed by the potential for unpredicted cost increases or fall-off in demand? Alternatively, would a shorter period be preferable, to address cost predictability concerns, while retaining some of the benefit of a multi-year plan? The Commission seeks comment on the extent to which a compensation period of longer than three years would make a material difference to such firms' capacity to provide and improve IP Relay service. Recognizing that, if over a given compensation period, costs were to rise substantially, and providers would have strong incentives to present a robust petition explaining their need, and thus obtain relief, to what extent would any benefits of a longer compensation period justify the risks of overcompensation that would occur if costs were to fall significantly over the period?

27. Are IP Relay costs sufficiently predictable to warrant setting a base compensation amount for a multi-year period? Alternatively, is the variability in IP Relay costs sufficiently unpredictable that the Commission should reassess the IP Relay compensation level annually? The Commission seeks comment on the cost-effectiveness of this alternative approach relative to the current approach or other alternative approaches. Would the resulting year-to-year uncertainty and reduced incentives for efficiency and innovation be outweighed by the greater flexibility to ensure full cost recovery in response to unpredicted cost and demand changes? Are there net benefits of this alternative that would outweigh any increased administrative burden on the provider and the Commission?

28. The Commission also seeks comment on whether compensation decisions based on cost determinations, whether made annually or at longer intervals, should be made by the full Commission, or by the Bureau under delegated authority. Further, should other decisions—*e.g.,* approval of annual changes based on preset adjustment factors, determinations regarding exogenous cost claims, and grant or denial of requests for waiver of compensation rules—be made at the Commission or Bureau level?

29. *Compensation Adjustments During a Multi-Year Period.* If the Commission continues setting IP Relay compensation for a multi-year period, it seeks comment on whether to continue the current practice of adjusting the compensation level in subsequent years of the cycle, and if so, whether to modify the criteria for such adjustments.

30. *Inflation Adjustment.* Should the Commission continue to apply an annual inflation adjustment to the base compensation level, and if so, how should the adjustment be determined? The current methodology uses an inflation factor based on the Gross Domestic Product—Price Index (GDP–PI) to adjust the compensation level upward. Is the GDP–PI a reasonably accurate predictor of inflation in IP Relay costs? Would another price index provide a better measure? For example, because IP Relay is currently a labor-intensive service, should the Commission select a measure from the Bureau of Labor Statistics' (BLS) Employment Cost Index: Historical Listing Volume III (April 2021), available at *https://www.bls.gov/web/eci/echistrynaics.pdf,* which tracks measures of labor cost for various industry segments—for example, the seasonally-adjusted ''office and administrative support,'' ''service-providing industries,'' ''other services except public administration,'' or the non-seasonally-adjusted ''office and administrative support,'' indices? Which measure or measures of inflation in this index would be most appropriate for IP Relay? Is there another general or sector-specific cost index that would more accurately predict changes in IP Relay cost?

31. *Efficiency Adjustment.* The Commission also established an efficiency factor, used to adjust the compensation level in a downward direction to reflect expected productivity improvements. The Commission seeks comment on how best to measure expected efficiency gains for this particular service. What are the potential sources of annual efficiency gains in IP Relay, and how should the extent of annual efficiency gains be estimated? Alternatively, should the Commission eliminate the efficiency factor?

32. *Exogenous Costs.* The IP Relay base compensation level can be adjusted upward to permit recovery of exogenous costs, which are ''costs beyond the control of the IP Relay providers that are

not reflected in the inflation adjustment,'' such as a new service requirement adopted by the Commission. Should the Commission retain this aspect of the methodology? If so, are there other types of exogenous costs that warrant inclusion? Should the Commission broaden the definition of exogenous costs? Should the Commission apply the allowable cost criteria adopted in the *2017 VRS Compensation Order,* published at 82 FR 39673, August 22, 2017, which allow upward compensation adjustment for well-documented exogenous costs that (1) belong to a category of costs that the Commission has deemed allowable, (2) result from new TRS requirements or other causes beyond the provider's control, (3) are new costs that were not factored into the applicable compensation rates, and (4) if unrecovered, would cause a provider's current allowable-expenses-plus-operating margin to exceed its revenues?

33. *Other Adjustments.* In addition to adjustments for inflation, efficiency, and exogenous costs, are there other types of adjustments to the IP Relay compensation level that the Commission should be making in subsequent years of a multi-year rate cycle?

**Alternative Compensation Methodologies**

34. *Hybrid MARS Approach.* T-Mobile proposes that in setting a new IP Relay compensation level, the Commission should take as a starting point the per-minute compensation for interstate TTY-based TRS, which is currently set using the MARS method. The Commission would multiply the average per-minute rate of TTY-based TRS compensation by the projected number of IP Relay minutes, subtract those provider costs that are incurred only in providing TTY-based TRS, and add costs that are incurred only in providing IP Relay. The resulting funding requirement would be divided by projected IP Relay demand to determine the per-minute compensation level.

35. The Commission invites advocates of this approach to identify the specific categories of costs they believe would be appropriate to add and subtract to achieve an appropriate per-minute compensation level using such a hybrid MARS methodology. Which categories of TTY-based TRS costs, specifically, are not incurred to provide IP Relay, which categories of IP Relay costs are not incurred to provide TTY-based TRS, and what are the estimated current costs in each of those categories?

36. The Commission is unpersuaded that it would be appropriate to use a MARS compensation approach as a starting point for setting IP Relay compensation, and believes that attempting to revert to a version of the MARS methodology would likely result in significant overcompensation for IP Relay, wasting TRS funds. The Commission also is not persuaded that T-Mobile's proposed methodology would be any less difficult to apply or subject to inaccuracy than the current methodology, and T-Mobile's proposal appears inconsistent with recent Commission precedent. The Commission seeks comment on the concerns stated above. Are there other factors that merit consideration of T-Mobile's proposal? Would the hybrid MARS approach better serve the compensation-setting policy goals articulated above?

37. *Other Methodologies.* Are there other compensation methodologies that the Commission should consider for IP Relay to achieve its policy goals?

**Initial Regulatory Flexibility Analysis**

38. As required by the Regulatory Flexibility Act of 1980, as amended (RFA), the Commission has prepared this Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on a substantial number of small entities by the policies and rules proposed in the Notice. Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadline for comments on the Notice provided in the item. The Commission will send a copy of the entire Notice, including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA).

*Need for, and Objectives of the Proposed Rules*

39. In the Notice, the Commission proposes to reform the compensation methodology for IP Relay. To develop a complete record, the Commission seeks comment on whether and how to modify the process for setting projected-cost-based IP Relay compensation, including whether certain costs that are currently not allowed should be compensable, the methodology for calculating the compensation amount, and alternative approaches. The Commission takes these steps to allow recovery of reasonable provider costs and ensure that functionally equivalent IP Relay is provided in the most efficient manner.

*Legal Basis*

40. The authority for this proposed rulemaking is contained in sections 1, 2, and 225 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 225.

*Small Entities Impacted*

41. The proposals in the document FCC 21–95 will affect the obligations of IP Relay providers. These services can be included within the broad economic category of All Other Telecommunications.

*Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements*

42. The proposed compensation methodology will not create new reporting, recordkeeping, or other compliance requirements.

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

43. Throughout the Notice, the Commission is (1) taking steps to minimize the impact on small entities by proposing reforms to the IP Relay compensation methodology that would ensure that providers of IP Relay are fairly compensated for the provision of IP Relay, including considering significant alternatives by identifying and seeking comment on multiple methodologies for compensation; and (2) considering various options to determine the best compensation methodology for ensuring functionally equivalent service and maintaining an efficient IP Relay market over the long term in accordance with the Commission's statutory obligations. The Notice seeks comment on the effect these proposals will have on all entities that have the potential to provide IP Relay, including small entities.

44. The Notice seeks comment from all interested parties. Small entities are encouraged to bring to the Commission's attention any specific concerns they may have with the proposals outlined in the Notice. The Commission expects to consider the economic impact on small entities, as identified in comments filed in response to the Notice, in reaching its final conclusions and acting in this proceeding.

*Federal Rules Which Duplicate, Overlap, or Conflict With, the Commission's Proposals*

45. None.

Federal Communications Commission.

**Marlene Dortch,**

*Secretary, Office of the Secretary.*

[FR Doc. 2021–24945 Filed 11–17–21; 8:45 am]

**BILLING CODE 6712–01–P**

# Notices

Federal Register

Vol. 86, No. 220

Thursday, November 18, 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

### Request for Information: Center for WIC Modernization and Delivery

**AGENCY:** Food and Nutrition Service (FNS), USDA.

**ACTION:** Notice, correction.

**SUMMARY:** The Food and Nutrition Service published a document in the **Federal Register** of November 8, 2021, concerning a Request for Information about establishing a resource center that supports State and local Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) agencies in improving the WIC application and certification journey. The document is missing a contact email. To avoid any confusion, we are re-publishing the notice in its entirety with the missing email information:

The Food and Nutrition Service (FNS) is issuing this Request for Information (RFI) to gain insights from interested parties about establishing a resource center that supports State and local Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) agencies in improving the WIC application and certification journey.

This is a request for information that may inform a future cooperative agreement. It is not a solicitation for proposals or proposal abstracts. The purpose of this notice is to:

1. Determine the level of interest that exists for the proposed service;
2. Obtain information about the approach to providing the service, including needs, capabilities, and requirements; and
3. Gather information on the potential constraints and risks associated with this approach. Information gathered through this RFI may be used to inform potential strategies for supporting and improving State and local WIC operations. FNS welcomes comments from all stakeholders.

**DATES:** Written comments must be received on or before December 8, 2021.

**ADDRESSES:** FNS is seeking information from a broad array of stakeholders—such as nonprofits, WIC State agencies, WIC local agencies, and others—about the Center for WIC Modernization and Delivery, the capabilities necessary to complete this work, relevant examples or case studies, and the capacity needed to support State and local WIC agencies. Responses to this RFI may be submitted by a single party or by a team.

USDA invites submission of the requested information through one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Email:* FNS will accept electronic submissions emailed to *SM.FNCS.WIC.Innovation@usda.gov.* The email should contain the subject line, ''Response to RFI: Center for WIC Modernization and Delivery.''

All comments submitted in response to this RFI will be included in the record and will be made available to the public. Please be advised that the substance of the comments and the identity of the individuals or entities submitting the comments will be subject to public disclosure. USDA will make the comments publicly available via *http://www.regulations.gov.*

*Response to this RFI is voluntary.* Respondents should respond to this RFI in a Microsoft Word document attached to email. This document should contain the following:

- *Three clearly delineated sections:* (1) Cover page with company name and contact information; (2) approach, no more than 10 single-spaced pages in length; and (3) business information.
- 1-inch margins (top, bottom, and sides).
- Times New Roman and 12 point font.

*Privacy Note:* All comments received from members of the public will be available for public viewing on *regulations.gov.*

In accordance with FAR 15.202(3), responses to this notice are not offers and cannot be accepted by the Government to form a binding contract. Responders are solely responsible for all expenses associated with responding to this RFI.

**FOR FURTHER INFORMATION CONTACT:** Sarah Widor, Director, Supplemental Food Programs Division at (703) 305–2746, *sarah.widor@usda.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background

The American Rescue Plan Act of 2021 (ARPA; Pub. L. 117–2) provided $390 million in funding for WIC to carry out outreach, innovation, and program modernization efforts to increase WIC participation and redemption of benefits. See ARPA section 1106. Despite clear evidence that WIC drives better health outcomes, only about 57% of WIC-eligible mothers and children participated in the program in 2018. The funding provided through ARPA is a critical opportunity for WIC to undertake a range of high-impact projects to increase WIC's participation rate through an improved enrollment and participant experience, and to reduce disparities in program delivery.

Given this unprecedented opportunity to invest in programmatic innovations, FNS solicited input from a diverse range of stakeholders. FNS convened 27 listening sessions representing different stakeholder perspectives, interests, and geographies on ways to increase program participation and retention, improve the participant experience, streamline benefit delivery, and reduce disparities in program delivery. FNS also partnered with the U.S. Digital Service (USDS) to conduct research on how to improve the WIC certification process. This RFI is seeking information to build on that research.

FNS would like to partner with one or more organizations to create a Center for WIC Modernization and Delivery that will leverage human-centered design (HCD), modern technology practices, and data to improve the certification journey for WIC participants. This Center will be a resource for the 89 WIC State agencies (States, DC, territories, and Indian Tribal Organizations), and potentially WIC local agencies, to access cross-functional delivery capabilities to support digital transformation and service design initiatives. These capabilities might include data science, design, engineering, procurement, product management, and research expertise that states can leverage to develop and implement solutions aimed at improving WIC certification processes. The Center will work closely

with FNS and USDS to define its approach and ensure solutions are practical, integrated into clinic practices, and drive towards a better participant journey through the WIC program and improved outcomes. FNS expects the Center to support WIC State agencies in improving enrollment and service delivery through a variety of ways, such as:

- Supporting State and local agencies in developing project ideas and proposals aimed at improving the participant journey and program outcomes;
- Helping State and local agencies use HCD, technology, and data more effectively in their clinic operations to increase enrollment and reduce disparities in program delivery;
- Assisting State and local agencies in addressing technical and/or service gaps; and
- Working with State and local agencies to implement holistic technology solutions and process changes. This might include helping them prototype, test, and iterate on potential solutions; and evaluating existing products or developing new ones for adoption by agencies. The Center might assist State and local agencies in procuring or implementing these solutions and measuring their impact on enrollment and retention.

Examples of solutions aimed at improving the applicant and participant experience may include:

- Participant-facing technology tools such as online schedulers, document uploaders, and participant portals;
- Data matching, interoperability, and/or cross-enrollment projects to reduce the documentation burden on participants;
- Technology platforms, which allow applicants to choose video, phone, text, or other voice applications to connect with WIC clinics;
- Content updates, such as content strategy or plain language updates to websites, forms, or notices;
- Data analytics tools; and
- Process improvements.

In addition to providing direct support to State and local agencies, FNS expects the Center to identify, evaluate, develop, and disseminate effective solutions and technical standards across States, and help WIC State agencies leverage their data to improve the WIC customer experience. It will also facilitate collaboration between WIC State agencies to address common operational issues.

FNS anticipates that the Center will support multiple WIC State agencies at once. The Center should have quick access to talent covering a spectrum of potential needs, and must be agile and capable of meeting shifting goals and objectives as they learn more about the problem space.

## II. Responses

FNS is seeking information from stakeholders on the following questions. Responses should be limited to 10 single-spaced pages that follow the formatting guidelines above. Respondents should not include proprietary information or concepts in their responses.

FNS requests the following information:

(1) What capabilities should the Center have to effectively support State and local WIC agencies in implementing new technology solutions and process changes?

(2) How should the Center evaluate WIC State agency needs and prioritize projects?

(3) How should the Center work with State and local WIC agencies to help them modernize their WIC programs and improve the participant journey through WIC?

(4) How should the Center share and promote the reuse of best practices, solutions, code, reference implementations, and other resources among WIC State agencies to help them address common operational issues that impact the customer experience?

(5) How would you define and measure success for the Center?

(6) What risks do you foresee in establishing a Center to support WIC State agencies? How would you mitigate those risks?

(7) Do you have any other feedback or suggestions on this Center-based approach? Please describe in detail.

**Cynthia Long,**

*Administrator, Food and Nutrition Service.*

[FR Doc. 2021–25145 Filed 11–17–21; 8:45 am]

**BILLING CODE 3410–30–P**

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## DEPARTMENT OF AGRICULTURE

### Forest Service

### Del Norte County Resource Advisory Committee

**AGENCY:** Forest Service, Agriculture (USDA).

**ACTION:** Notice of meeting.

**SUMMARY:** The Del Norte County Resource Advisory Committee (RAC) will hold two virtual meetings. 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 Six Rivers National Forest within Del Norte County, consistent with the Federal Lands Recreation Enhancement Act. RAC information can be found at the following website: *https://www.fs.usda.gov/main/srnf/workingtogether/advisorycommittees.*

**DATES:** The meetings will be held on:

- December 7, 2021, 4:00 p.m.–8:00 p.m., Pacific Standard Time; and
- December 8, 2021, 4:00 p.m.–8:00 p.m., Pacific Standard Time.

All RAC meetings are subject to cancellation. For status of the meetings prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

**ADDRESSES:** The meetings will be held with virtual attendance only (with call-in option). For virtual meeting information, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

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 at the Gasquet Ranger District, 10600 Highway 199, Gasquet, CA 95543. Please call ahead to facilitate entry into the building.

**FOR FURTHER INFORMATION CONTACT:** Kathy Allen, Designated Federal Officer (DFO), by phone at 707–457–3860 or via email at *kathy.allen@usda.gov.*

Individuals who use telecommunication devices for the deaf/hard-of-hearing (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339, 24 hours per day, ever day of the year, including holidays.

**SUPPLEMENTARY INFORMATION:** The purpose of the meetings are to:

1. Provide updates regarding the status of the Secure Rural Schools Program and Title II funding; and
2. Review and recommend existing potential projects eligible for funding.

The meetings are open to the public. The agendas 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 seven days before the meeting 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 meetings. Written comments and requests for time to make oral comments must be sent to Kathy Allen, DFO, Gasquet Ranger District, 10600 Highway 199, Gasquet, CA 95543, by email to *kathy.allen@usda.gov,* or via facsimile to 707–457–3860.

*Meeting Accommodations:* Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodation. For access to 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.

Equal opportunity practices, in line with USDA policies, will be followed in all membership appointments to the RAC. To help ensure that recommendations of the RAC have taken into account the needs of the diverse groups served by the Department, membership shall include, to the extent practicable, individuals with demonstrated ability to represent minorities, women, and persons with disabilities.

The USDA prohibits discrimination in all of its programs and activities on the basis of race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, political beliefs, income derived from a public assistance program, or reprisal or retaliation for prior civil rights activity in any program or activity conducted or funded by USDA (not all bases apply to all programs).

Dated: November 12, 2021.

**Cikena Reid,**

*USDA Committee Management Officer.*

[FR Doc. 2021–25106 Filed 11–17–21; 8:45 am]

**BILLING CODE 3411–15–P**

## DEPARTMENT OF AGRICULTURE

### Forest Service

### Tri-County Resource Advisory Committee

**AGENCY:** Forest Service, Agriculture (USDA).

**ACTION:** Notice of meeting.

**SUMMARY:** The Tri-County Resource Advisory Committee (RAC) will hold two 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 as well as to make recommendations on recreation fee proposals for sites on the Beaverhead-Deerlodge National Forest within Deer Lodge, Granite, and Powell 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/bdnf/workingtogether/advisorycommittees.*

**DATES:** The meetings will be held on:

- December 15, 2021, 9:00 a.m.–12:00 p.m., Mountain Standard Time; and
- December 16, 2021, 9:00 a.m.–12:00 p.m., Mountain Standard Time;

All RAC meetings are subject to cancellation. For status of the 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 conference. Details on how members of the public can join the meeting can be found at the website link in the above **SUMMARY**.

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:** Cheri Ford, Designated Federal Officer (DFO), by phone at 406–683–3973 or email at *cheri.ford@usda.gov* or Jeanne Dawson, RAC Coordinator, at 406–683–3987 or email at *jeanne.dawson@usda.gov.*

Individuals who use telecommunication devices for the deaf/hard-of-hearing (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339, 24 hours a day, every day of the year, including holidays.

**SUPPLEMENTARY INFORMATION:** The purpose of the meetings are to:

1. Hear from Title II project proponents and discuss Title II project proposals;

2. Make funding recommendations on Title II projects;

3. Discuss recreation fee proposals for developed recreation sites; and

4. Make recommendations on fees for the recreation fee proposals.

The meetings are 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 make a request in writing by Wednesday, December 1, 2021, to be scheduled on the agenda for a 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 Jeanne Dawson, RAC Coordinator, 420 Barrett Street, Dillon, MT 59725 or by email to *jeanne.dawson@usda.gov.*

*Meeting Accommodations:* Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodation. For access to 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.

Equal opportunity practices, in line with USDA policies, will be followed in all membership appointments to the RAC. To help ensure that recommendations of the RAC have taken into account the needs of the diverse groups served by the Department, membership shall include, to the extent practicable, individuals with demonstrated ability to represent minorities, women, and persons with disabilities.

The USDA prohibits discrimination in all of its programs and activities on the basis of race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, political beliefs, income derived from a public assistance program, or reprisal or retaliation for prior civil rights activity in any program or activity conducted or funded by USDA (not all bases apply to all programs).

Dated: November 12, 2021.

**Cikena Reid,**

*USDA Committee Management Officer.*

[FR Doc. 2021–25108 Filed 11–17–21; 8:45 am]

**BILLING CODE 3411–15–P**

## DEPARTMENT OF AGRICULTURE

### Forest Service

### Southwest Montana Resource Advisory Committee

**AGENCY:** Forest Service, Agriculture (USDA).

**ACTION:** Notice of meeting.

**SUMMARY:** The Southwest Montana Resource Advisory Committee (RAC) will hold two 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 to make recommendations on recreation fee proposals for sites on the Beaverhead-Deerlodge National Forest within Beaverhead, Jefferson, Madison, and Silver Bow 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/bdnf/workingtogether/advisorycommittees.*

**DATES:** The virtual meetings will be held on:

- December 13, 2021, 9:00 a.m.–12:00 p.m., Mountain Standard Time; and
- December 14, 2021, 9:00 a.m.–12:00 p.m., Mountain Standard Time.

All RAC meetings are subject to cancellation. For status of the 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 conference. Details on how members of the public can join the meetings can be found at the website link in the above **SUMMARY**.

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:** Cheri Ford, Designated Federal Officer (DFO), by phone at 406–683–3973 or email at *cheri.ford@usda.gov* or Jeanne Dawson, RAC Coordinartor, at 406–683–3987 or email at *jeanne.dawson@usda.gov.*

Individuals who use telecommunication devices for the deaf/hard-of-hearing (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339, 24 hours a day, every day of the year, including holidays.

**SUPPLEMENTARY INFORMATION:** The purpose of the meetings are to:

1. Hear from Title II project proponents and discuss Title II project proposals;
2. Make funding recommendations on Title II projects;
3. Discuss recreation fee proposals for developed recreation sites; and
4. Make recommendations on fees for the recreation fee proposals.

The meetings are 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 make a request in writing by Monday, November 29, 2021, to be scheduled on the agenda for a 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 Jeanne Dawson, RAC Coordinator, 420 Barrett Street, Dillon, MT 59725 or by email to *jeanne.dawson@usda.gov.*

*Meeting Accommodations:* Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodation. For access to 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.

Equal opportunity practices, in line with USDA policies, will be followed in all membership appointments to the RAC. To help ensure that recommendations of the RAC have taken into account the needs of the diverse groups served by the Department, membership shall include, to the extent practicable, individuals with demonstrated ability to represent minorities, women, and persons with disabilities.

The USDA prohibits discrimination in all of its programs and activities on the basis of race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, political beliefs, income derived from a public assistance program, or reprisal or retaliation for prior civil rights activity in any program or activity conducted or funded by USDA (not all bases apply to all programs).

Dated: November 12, 2021.

**Cikena Reid,**

*USDA Committee Management Officer.*

[FR Doc. 2021–25107 Filed 11–17–21; 8:45 am]

**BILLING CODE 3411–15–P**

## DEPARTMENT OF COMMERCE

**[Docket No. 210923–0194]**

### Privacy Act of 1974; System of Records

**AGENCY:** Department of Commerce, Office of the Secretary.

**ACTION:** Notice of a new system of records.

**SUMMARY:** This notice announces the Department of Commerce's (Department) proposal to establish a new system of records entitled ''COMMERCE/DEPT–31, Public Health Emergency Records of Employees, Visitors, and Other Individuals at Department Locations'' under the Privacy Act of 1974, and the Office of Management and Budget (OMB) Circular A–108, ''Federal Agency Responsibilities for Review, Reporting, and Publication under the Privacy Act''. This system of records describes the Department's collection, use, and maintenance of records on individuals associated with the Department and its facilities during a public health emergency or similar health and safety incident. This newly established system will be included in the Department's inventory of record systems. We invite public comment on the new system announced in this publication.

**DATES:** This new system of records will become effective upon publication, subject to a 30-day comment period in which to comment on the routine uses, described below. Please submit any comments by December 20, 2021.

**ADDRESSES:** You may submit written comments to Tahira Murphy, Acting Program Director for Privacy Act Compliance, *tmurphy2@doc.gov.*

**FOR FURTHER INFORMATION CONTACT:** Tahira Murphy, Acting Program Director for Privacy Act Compliance, (202) 482–8075.

**SUPPLEMENTARY INFORMATION:** The Department of Commerce must ensure the safety of its workforce and the public, including when the Secretary of Health and Human Services (HHS) or other designated official determines and declares that a public health emergency exists or when a similar health and safety emergency or incident occurs. Responses to public health emergencies or similar health and safety incidents

depend on the nature of the emergency or incident, but in the context of an infectious disease outbreak, or a pandemic or epidemic that can cause widespread harm to the health of individuals, the Department of Commerce may collect information on Department personnel (including employees, detailees, guest researchers, affiliates, interns, and volunteers), contractors, long-term trainees, mission support individuals, and visitors at or on Department locations (including buildings, grounds, ships, aircraft, vehicles, or properties that are owned or leased by the Department; otherwise used by the Department for meetings, conferences, events, or other official business; or contractor or subcontractor workplace locations and individuals in those locations working on or in connection with a Federal Government contract or contract-like instrument) in order to ensure a safe and secure work environment. The information collected may include names and contact information; individual circumstances and dates of suspected exposure; testing results, symptoms, and treatments; health status information, and other information related to the public health emergency. For federal employees, in certain instances, depending on the type of record collected and maintained, this information will also be maintained and covered by OPM/GOVT–10, Employee Medical File System Records, 75 FR 35099 (June 21, 2010), and modified at 80 FR 74815 (Nov. 30, 2015). However, any collection and use of records covered by COMMERCE/DEPT–31, Public Health Emergency Records of Employees, Visitors, and Other Individuals at Department Locations, is only permitted during times of a public health emergency or similar health and safety incident and when the circumstances permit the Department to collect and maintain such information on the various categories of Department personnel, contractors, long-term trainees, mission support individuals, and visitors at Department locations.

The circumstances must be examined in conjunction with all applicable laws, including the U.S. Constitution, federal privacy laws, federal labor and employment laws, and federal workforce health and safety laws. Different laws may apply depending upon the type of information at issue, who the information pertains to, who collected the information, and how the information is collected, maintained, and used by the Department.

For instance, when collecting information on Department employees, there are several employment laws that govern the collection, dissemination, and retention of employee medical information. These employment laws include the Americans with Disabilities Act of 1990, as amended (ADA), the Rehabilitation Act of 1973 (Rehab Act), and the Occupational Safety and Health Act of 1970 (OSH Act). Generally, under federal employment laws, medical information pertaining to employees is confidential and may be obtained by an employer only for certain reasons and only at certain points in the employment relationship. During a public health emergency, an employer may be permitted to collect certain employee medical information that it would not otherwise be permitted to collect depending upon the circumstances. Whether an employer is permitted to collect otherwise confidential employee medical information during a public health emergency depends upon whether an employee or a potential employee poses a ''direct threat'' to others within the meaning of the ADA and the Rehab Act. Again, this system of records will apply if it is determined that the circumstances permit the Department to legally collect the employee medical information at issue in the first instance.

Information stored in this system of records may be shared with other Department components that have a need to know the information to carry out their mission essential functions, but only if it is first determined that the information may be shared under all other applicable laws and Department policies.

In addition, the Department may share information with appropriate federal, state, local, tribal, territorial, foreign, or international government agencies consistent with the routine uses set forth in this system of records notice, but, again, only if it is first determined that the information may be shared under all other applicable laws and Department policies.

This newly established system will be included in the Department's inventory of record systems.

## Privacy Act

The Privacy Act embodies fair information practice principles in a statutory framework governing the means by which federal government agencies collect, maintain, use, and disseminate individuals' records. The Privacy Act applies to information that is maintained in a ''system of records.'' A ''system of records'' is a group of any records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined to encompass U.S. citizens and lawful permanent residents. Additionally, the Judicial Redress Act (JRA) provides covered persons with a statutory right to make requests for access and amendment to covered records, as defined by the JRA, along with judicial review for denials of such requests. In addition, the JRA prohibits disclosures of covered records, except as otherwise permitted by the Privacy Act.

Below is the description of the COMMERCE/DEPT–31, Public Health Emergency Records of Employees, Visitors, and Other Individuals at Department Locations, system of records.

In accordance with 5 U.S.C. 552a(r), the Department has provided a report of this system of records to the Office of Management and Budget and to Congress.

**SYSTEM NAME AND NUMBER:**

COMMERCE/DEPT–31, Public Health Emergency Records of Employees, Visitors, and Other Individuals at Department Locations.

**SECURITY CLASSIFICATION:**

Controlled Unclassified Information.

**SYSTEM LOCATION:**

Records are maintained at the Department of Commerce (Department) Headquarters, component offices, field offices, and contractor-owned and operated facilities.

**SYSTEM MANAGER AND ADDRESS:**

Director, Office of Privacy and Open Government, U.S. Department of Commerce, 1401 Constitution Ave. NW, Room 61025, Washington, DC 20230.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 319 of the Public Health Service (PHS) Act (42 U.S.C. 247d); Coronavirus Aid, Relief, and Economic Security (CARES) Act, Public Law 116–136, Div. B., Title VIII, sec. 18115, 134 Stat. 574 (codified in 42 U.S.C. 247d note); 21 U.S.C. 360bbb–3; Rehabilitation Act, 29 U.S.C. 701 et. seq.; Americans with Disabilities Act of 1990, as amended, 102(d), 42 U.S.C. 12112(d); 29 CFR part 1602; 29 CFR part 1630; Medical Examinations for Fitness for Duty Requirements, including 5 CFR part 339; Workforce safety federal requirements, including the Occupational Safety and Health Act of 1970, Executive Order 12196, 5 U.S.C. 7902; 29 U.S.C. chapter 15 (*e.g.,* 29 U.S.C. 668), 29 CFR part 1904, 29 CFR part 1910, and 29 CFR part 1960; and the Genetic Information Nondiscrimination Act of 2008, 42

U.S.C. 2000ff to ff–11, and 29 CFR part 1635; and other federal laws, regulations, Executive orders, or guidance related to the specific public health emergency or similar health and safety incident, including guidance issued by the Office of Management and Budget, the Centers for Disease Control and Prevention, or other appropriate agency or entity, as applicable.

**PURPOSE(S) OF THE SYSTEM:**

The purpose of this system is to maintain records to protect the Department's workforce and other individuals at or on ''Department locations''—which is defined to include buildings, grounds, ships, aircraft, vehicles, or properties that are owned or leased by the Department; otherwise used by the Department for meetings, conferences, events, or other official business; or contractor or subcontractor workplace locations and individuals in those locations working on or in connection with a Federal Government contract or contract-like instrument—and respond to or mitigate a public health emergency or similar health and safety incident. For instance, the Department may use the information collected to conduct contact tracing (*i.e.,* the subsequent identification, monitoring, and support of a confirmed or probable case's close contacts who have been exposed to, and possibly infected with, a disease or illness at or on Department locations); institute preventative testing or other measures to permit entry to Department locations to minimize exposure; and fulfill testing reporting requirements, to the extent permitted by law.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Department personnel (including employees, detailees, guest researchers, affiliates, interns, and volunteers), long-term trainees (such as Honors graduates, Pathways employees, Temporary, Not-to-Exceed (NTE) employees, Knauss Fellows, etc.), contractors, mission support individuals, visitors (such as all other federal employees, applicants, and members of the public) at or on Department locations, and potentially affected individuals otherwise present during official Department business. For example, individuals covered by this system may include those who are suspected or confirmed to have a disease or illness that is the subject of a public health emergency, may have been or could have been exposed to someone who is suspected or confirmed to have a disease or illness that is the subject of a public health emergency, or who must undergo preventative testing or treatment (*e.g.,* vaccines) for a disease or illness that is the subject of a public health emergency. Mission support individuals include those individuals who are assigned from other federal, state, local, or private agencies to support Department missions and operations at Department locations. The system also covers individuals listed as emergency contacts for such individuals.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

The records in this system include information related to the public health emergency or similar health and safety incident that is relevant and necessary to achieve the purpose of this system or records, which may vary depending on the nature of the specific emergency or incident. For Department personnel, long-term trainees, contractors, and mission support individuals, the information collected may include, for example: Individual's full name; Preferred phone number(s); Department duty location, facility, and specific work space accessed; Preferred email address(es); Individual's supervisor's name, address, and contact information, and/or the contractor's supervisor/contracting officer representative name, address, and contact information; Date(s) and circumstances of the individual's suspected or actual exposure to disease or illness including symptoms, as well as locations within the Department workplace where an individual may have contracted or been exposed to the disease or illness, and names and contact information of other employees, long-term trainees, contractors, mission support individuals, or visitors that the individual interacted with at or on a Department location during time the individual was suspected to or had contracted the disease or illness; Work status of the individual (*e.g.,* administrative leave, sick leave, teleworking, in the office, deployed to the field) and affiliated leave status information; Emergency contact information; Other individual information directly related to the disease or illness, such as vaccination status, testing results/information, symptoms, source of potential exposure, or prior infection status; Other information for identification verification purposes when disclosing testing results or other health emergency data to third-parties; and Information collected in accordance with CARES Act reporting requirements or other statutory, regulatory, and administrative reporting requirements. For visitors at Department locations, the information collected may include, for example: Full name; Preferred phone number(s); Preferred email address(es); Date(s) and time(s) of entrance and exit from Department workspaces, ships, aircraft, facilities, and grounds; Name(s) of all individuals encountered while in or at Department locations; Public-health emergency-related data, such as vaccination status, testing results/information, symptoms, source of potential exposure, or prior infection status; Emergency contact information; and Information indicating plans on entering a Department location in the near future.

**RECORD SOURCE CATEGORIES:**

When permitted by applicable law, records may be obtained from Department personnel, long-term trainees, contractors, mission support individuals, and visitors at or on Department locations; their family members; federal, state, local, tribal, territorial, and foreign government agencies; employers; and other entities and individuals who may provide relevant information on a suspected or confirmed disease or illness that is the subject of a public health emergency. Records in this system may also be obtained from security systems or other systems of records, such as OPM/GOVT–10.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:**

In the event the Department's Senior Agency Official for Privacy or other senior Department privacy official determines, in consultation with the Office of the General Counsel, that disclosure of a record contained in this system is not prohibited by the Rehabilitation Act or other applicable laws, regulations, or policies, that record may be disclosed as generally permitted by the Privacy Act and for the following routine uses pursuant to 5 U.S.C. 552a(b)(3):

1. In the event that a system of records maintained by the Department to carry out its functions indicates a violation or potential violation of law or contract, whether civil, criminal or regulatory in nature and whether arising by general statute or particular program statute or contract, or rule, regulation, or order issued pursuant thereto, or the necessity to protect an interest of the Department, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether federal, state, local or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute or contract, or rule, regulation, or

order issued pursuant thereto, or protecting the interest of the Department.

2. A record from this system of records may be disclosed, as a routine use, to a federal, state, or local agency maintaining civil, criminal, or other relevant enforcement information or other pertinent information, such as current licenses, if necessary to obtain information relevant to the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant or other benefit.

3. A record from this system of records may be disclosed, as a routine use, to a federal, state, local, or international agency, in response to its request, in connection with the issuance of a security clearance, the reporting of an investigation of an individual, the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

4. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate or administrative tribunal, including disclosures to duly-authorized investigators or opposing counsel in the course of discovery or settlement negotiations.

5. A record in this system of records may be disclosed, as routine use, to a Member of Congress submitting a request involving an individual when the individual has requested assistance from the Member with respect to the subject matter of the record.

6. A record in this system of records which contains medical information may be disclosed, as a routine use, to the medical advisor of any individual submitting a request for access to the record under the Act and 15 CFR part 4, subpart B if, in the sole judgment of the Department, disclosure directly to the individual could have an adverse effect upon the individual, under the provision of 5 U.S.C. 552a(f)(3) and implementing regulations at 15 CFR 4.26.

7. (Reserved)

8. A record in this system of records may be disclosed, as a routine use, to the Office of Management and Budget in connection with the review of private relief legislation as set forth in OMB Circular No. A–19 at any stage of the legislative coordination and clearance process as set forth in that Circular.

9. A record in this system of records may be disclosed, as a routine use, to the Department of Justice in connection with determining whether disclosure thereof is required by the Freedom of Information Act (5 U.S.C. 552).

10. A record in this system of records may be disclosed, as a routine use, to a contractor of the Department having need for the information in the performance of the contract, but not operating a system of records within the meaning of 5 U.S.C. 552a(m).

11. (Reserved)

12. A record in this system may be transferred, as a routine use, to the Office of Personnel Management: For personnel research purposes; as a data source for management information; for the production of summary descriptive statistics and analytical studies in support of the function for which the records are collected and maintained; or for related manpower studies.

13. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services Administration (GSA), or his designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.,* GSA or Department of Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

14. A record in this system of records may be disclosed to appropriate agencies, entities, and persons when (1) the Department suspects or has confirmed that there has been a breach of the system of records; (2) the Department has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the Department (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 Department's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

15. A record in this system of records may be disclosed to another Federal agency or Federal entity, when the Department 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.

16. A record in this system of records may be disclosed to student volunteers, individuals working under a personal services contract, and other workers who technically do not have the status of Federal employees, when they are performing work for the Department and/or its operating units, as authorized by law, as needed to perform their assigned functions.

17. A record in this system may be disclosed to the Department of Treasury for the purpose of reporting and recouping delinquent debts owed the United States pursuant to the Debt Collection Improvement Act of 1996.

18. A record in this system may be disclosed to an agency or organization for the purpose of performing audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function.

19. A record in this system of records may be disclosed to appropriate federal, state, local, tribal, or foreign governmental agencies or multilateral governmental organizations for the purpose of protecting the vital interests of a data subject or other persons, including to assist such agencies or organizations in preventing exposure to or transmission of a communicable or quarantinable disease, to combat other significant public health threats, or to identify mission critical personnel appropriate for potential early vaccination or other treatment options.

20. A record in this system of records may be disclosed to such recipients and under such circumstances and procedures as are mandated by Federal statute or treaty.

21. A record in this system of records may be disclosed to Federal agencies such as the Department of Health and Human Services (HHS), State and local health departments, and other public health or cooperating medical authorities in connection with program activities and related collaborative efforts to deal more effectively with exposures to communicable diseases, and to satisfy mandatory reporting requirements when applicable.

22. A record in this system of records may be disclosed to a potentially affected individual's emergency contact for purposes of locating the individual to communicate that they may have been exposed to a public health emergency contaminant in a Department location, while otherwise present during official Department business, or at contractor or subcontractor workplace

locations where individuals in those locations were working on or in connection with a Federal Government contract or contract-like instrument.

23. A record in this system of records may be disclosed to affected individuals or potentially affected individuals, or, when needed, to the (potentially) affected individual's employer, grantee organization, federal agency to whom the individual is contracted, or other similar designated external points of contact, to the extent the information is necessary for contact tracing.

**POLICIES AND PRACTICES FOR STORAGE OF RECORDS:**

Records in this system of records are stored electronically or on paper in secure facilities. Electronic records are stored on a secure network. Records are protected from unauthorized access and improper use through administrative, technical, and physical security measures. Medical information collected is maintained on separate forms and in separate medical files and is treated as a confidential medical record.

**POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:**

The Department may retrieve records by any of the categories of records, including name, location, date of vaccination, date of potential exposure, or work status.

**POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:**

All records are retained and disposed of in accordance with National Archive and Records Administration regulations (36 CFR chapter XII, subchapter B—Records Management); Departmental directives and comprehensive records schedules; and, to the extent applicable, NOAA Administrative Order 205–01 or other directives issued by a Departmental component. To the extent applicable, to ensure compliance with the Americans with Disabilities Act (ADA), the Rehabilitation Act, and the Genetic Information Nondiscrimination Act of 2008 (GINA), medical information must be maintained on separate forms and in separate medical files and be treated as a confidential medical record. 42 U.S.C. 12112(d)(3)(B); 42 U.S.C. 2000ff–5(a); 29 CFR 1630.14(b)(1), (c)(1), (d)(4)(i); and 29 CFR 1635.9(a). This means that medical information and documents must be stored separately from other personnel records. As such, the Department must keep medical records for at least one year from creation date. 29 CFR 1602.14. Further, any records compiled under this system and incorporated into an occupational individual medical case record pursuant to the OSH Act must be maintained in accordance with 5 CFR 293.511(b) and 29 CFR 1910.1020(d), and must be destroyed 30 years after employee separation or when the Official Personnel Folder (OPF) is destroyed, whichever is longer, in accordance with NARA General Records Schedule (GRS) 2.7, Item 60, and NARA records retention schedule DAA–GRS–2017–0010–0009, to the extent applicable. Visitor processing records are covered by GRS 5.6, Items 110 and 111, and must be destroyed when either two or five years old, depending on security level, but may be retained longer if required for business use, pursuant to DAA–GRS–2017–0006–0014 and –0015.

**ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:**

The system of records is stored in buildings with doors that are locked during and after business hours. Visitors to the facility must register with security guards and must be accompanied by Federal personnel at all times. Records are stored in a locked room and/or a locked file cabinet. Electronic records containing Privacy Act information are protected by a user identification/password. The user identification/password is issued to those individuals who have a need to access the records for the performance of their official duties and who have appropriate clearances or permissions. Technical security safeguards include restrictions on computer access to authorized individuals who have a legitimate need to know the information; required use of strong passwords that are frequently changed; multi-factor authentication for remote access; use of encryption for certain data types and transfers; firewalls and intrusion detection applications; and regular review of security procedures and best practices to enhance security. Physical safeguards include restrictions on building access to authorized individuals and storage of records in locked offices and filing cabinets.

All electronic information disseminated by the Department adheres to the standards set out in Appendix III, Security of Automated Information Resources, OMB Circular A–130; the Computer Security Act (15 U.S.C. 278g–3 and 278g–4); and the Government Information Security Reform Act, Public Law 106–398; and follows NIST SP 800–18, Guide for Developing Security Plans for Federal Information Systems; NIST SP 800–26, Security Self-Assessment Guide for Information Technology Systems; and NIST SP 800–53, Recommended Security Controls for Federal Information Systems.

**RECORD ACCESS PROCEDURES:**

Requests from individuals should be addressed to: Chief Privacy Officer, U.S. Department of Commerce, Office of Privacy and Open Government, 1401 Constitution Ave. NW, Room 61025, Washington, DC 20230, pursuant to 15 CFR part 4, subpart B.

**CONTESTING RECORD PROCEDURES:**

The Department's rules for access, contesting contents, and appealing initial determinations by the individual concerned appear in 15 CFR part 4, subpart B. Use address cited in Record Access Procedures above.

**NOTIFICATION PROCEDURES:**

Requests for notification of the existence of records pertaining to the requester should be submitted pursuant to the inquiry provisions of the Department's rules which appear in 15 CFR part 4, subpart B. Use address cited in Record Access Procedures above.

**EXEMPTIONS CLAIMED FOR THE SYSTEM:**

None.

**HISTORY:**

No history.

*Notice of New System of Record.*

**Jennifer Goode,**

*Department of Commerce, Acting Chief Privacy Officer and Director, Office of Privacy and Open Government.*

[FR Doc. 2021–25136 Filed 11–17–21; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF COMMERCE

### Foreign-Trade Zones Board

**[B–55–2021]**

### Foreign-Trade Zone (FTZ) 22—Chicago, Illinois; Authorization of Production Activity AbbVie, Inc. (Pharmaceutical Products) North Chicago and Lake County, Illinois

On July 16, 2021, AbbVie, Inc., submitted a notification of proposed production activity to the FTZ Board for its facilities within Subzone 22S, in North Chicago and Lake County, Illinois.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (86 FR 41008, July 30, 2021). On November 15, 2021, the applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time.

The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board's regulations, including Section 400.14.

Dated: November 15, 2021.

**Camille Evans,**

*Acting Executive Secretary.*

[FR Doc. 2021–25186 Filed 11–17–21; 8:45 am]

**BILLING CODE 3510–DS–P**

## DEPARTMENT OF COMMERCE

### International Trade Administration

**[A–570–827]**

### Certain Cased Pencils From the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2019–2020

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** The Department of Commerce (Commerce) has completed its administrative review of the antidumping duty order on certain cased pencils (cased pencils) from the People's Republic of China (China) for the period of review (POR) December 1, 2019, through November 30, 2020. We continue to find that Wah Yuen Stationery Co. Ltd. and Shandong Wah Yuen Stationery Co. Ltd. (collectively, Wah Yuen) had no shipments of cased pencils during the POR. We also continue to find that Tianjin Tonghe Stationery Co., Ltd. (Tianjin Tonghe) and Ningbo Homey Union Co., Ltd. (Ningbo Homey) are not eligible for a separate rate and should be treated as part of the China-wide entity.

**DATES:** Applicable November 18, 2021.

**FOR FURTHER INFORMATION CONTACT:** Sergio Balbontin or Brian Smith, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC, 20230; telephone: 202–482–6478 or 202–482–1766, respectively.

**SUPPLEMENTARY INFORMATION:**

#### Background

On September 7, 2021, Commerce published the *Preliminary Results* in the **Federal Register**.[1] We invited interested parties to comment on the *Preliminary Results*; however, no interested parties submitted comments. Accordingly, we made no changes to the *Preliminary Results.*

#### Scope of the Order [2]

The merchandise covered by the *Order* is certain cased pencils of any shape or dimension (except as described below) which are writing and/or drawing instruments that feature cores of graphite or other materials, encased in wood and/or man-made materials, whether or not decorated and whether or not tipped (*e.g.,* with erasers, etc.) in any fashion, and either sharpened or unsharpened. The pencils subject to the *Order* are currently classifiable under subheading 9609.10.00 of the Harmonized Tariff Schedule of the United States (HTSUS). Specifically excluded from the scope of the *Order* are mechanical pencils, cosmetic pencils, pens, non-cased crayons (wax), pastels, charcoals, chalks, and pencils produced under U.S. patent number 6,217,242, from paper infused with scents by the means covered in the above-referenced patent, thereby having odors distinct from those that may emanate from pencils lacking the scent infusion. Also excluded from the scope of the *Order* are pencils with all of the following physical characteristics: (1) Length: 13.5 or more inches; (2) sheath diameter: not less than one-and-one quarter inches at any point (before sharpening); and (3) core length: not more than 15 percent of the length of the pencil.

In addition, pencils with all of the following physical characteristics are excluded from the scope of the *Order:* Novelty jumbo pencils that are octagonal in shape, approximately ten inches long, one inch in diameter before sharpening, and three-and-one eighth inches in circumference, composed of turned wood encasing one-and-one half inches of sharpened lead on one end and a rubber eraser on the other end.

Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the merchandise covered by the scope of the *Order* is dispositive.

#### Final Determination of No Shipments

In the *Preliminary Results,* Commerce determined that Wah Yuen [3] had no shipments of cased pencils during the POR, based on our analysis of U.S. Customs and Border Protection (CBP) entry documentation and Wah Yuen's questionnaire responses.[4] We received no comments on our preliminary finding. As there is no information on the record that calls into question this preliminary finding, we continue to find in the final results of this review that Wah Yuen had no shipments of subject merchandise during the POR.

#### China-Wide Entity

With the exception of Wah Yuen, we find all other companies for which a review was requested to be part of the China-wide entity, because they did not file no-shipment statements, separate rate applications, or separate rate certifications. Accordingly, Tianjin Tonghe and Ningbo Homey are part of the China-wide entity. Because no party requested a review of the China-wide entity, and Commerce no longer considers the China-wide entity as an exporter, conditionally subject to administrative reviews, we did not conduct a review of the China-wide entity.[5] The rate previously established for the China-wide entity is 114.90 percent and is not subject to change as a result of this review.[6]

#### Assessment Rates

Commerce shall determine, and CBP shall assess, antidumping duties on all appropriate entries in accordance with section 751(a)(2)(C) of the Tariff Act of 1930, as amended, (the Act) and 19 CFR 351.212(b). Because we determined that Tianjin Tonghe and Ningbo Homey are not eligible for a separate rate and are part of the China-wide entity, we intend to instruct CBP to apply an *ad valorem* assessment rate of 114.90 percent (*i.e.,*

[1] *See Certain Cased Pencils from the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2019–2020,* 86 FR 50023 (September 7, 2021) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *See Certain Cased Pencils from the People's Republic of China: Continuation of Antidumping Duty Order,* 82 FR 41608 (September 1, 2017); and *Antidumping Duty Order: Certain Cased Pencils from the People's Republic of China,* 59 FR 66909 (December 28, 1994) (collectively, *Order*).

[3] Commerce determined that Wah Yuen Stationery Co. Ltd. and Shandong Wah Yuen Stationery Co. Ltd. are affiliated and should be treated as a single entity in the *Preliminary Results* and prior administrative reviews. *See Preliminary Results* PDM at 1, n.2; *see also Certain Cased Pencils from the People's Republic of China: Preliminary Results of Antidumping Duty New Shipper Review; 2014–2015,* 81 FR 37573 (June 10, 2016), and accompanying PDM at 9–10, unchanged in *Certain Cased Pencils from the People's Republic of China: Final Results of Antidumping Duty New Shipper Review; 2014–2015,* 81 FR 74764 (October 27, 2016). We received no comments regarding our treatment of these companies as a single entity and therefore continue to collapse them for the final results of this administrative review.

[4] *See* Wah Yuen's Letter, ''Certain Cased Pencils from the People's Republic of China: Section A Questionnaire Response,'' dated May 18, 2021; *see also* Memorandum, ''Entry Summary Documentation,'' dated June 30, 2021.

[5] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013).

[6] *See Certain Cased Pencils from the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2012–2013,* 80 FR 26897 (May 11, 2015).

the China-wide entity rate) to all entries of subject merchandise during the POR that were exported by these companies. In addition, as Commerce continues to find that Wah Yuen did not have any shipments of subject merchandise during the POR, we will instruct CBP to assess any suspended entries of subject merchandise associated with Wah Yuen at the China-wide rate.

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of these final results of review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

**Cash Deposit Requirements**

The following cash deposit requirements will be effective for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) Wah Yuen's cash deposit rate will continue to be its existing exporter-producer specific rate, 30.55 percent; [7] (2) for previously investigated or reviewed Chinese and non-Chinese exporters for which a review was not requested and that received a separate rate in a prior segment of this proceeding, the cash deposit rate will continue to be the existing exporter-specific rate published for the most recently-completed period; (3) for all Chinese exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be the rate for the China-wide entity; and (4) for all non-Chinese exporters of subject merchandise that have not received their own rate, the cash deposit rate will be the rate applicable to the Chinese exporter that supplied that non-Chinese exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

**Notification to Importers Regarding the Reimbursement of Duties**

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 Regarding Administrative Protective Order**

This notice also serves as a final reminder to parties subject to administrative protective orders (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

**Notification to Interested Parties**

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) and 19 CFR 351.221(b)(5).

Dated: November 10, 2021.

**Ryan Majerus,**

*Deputy Assistant Secretary for Policy and Negotiations, Performing the Non-Exclusive Functions and Duties of the Assistant Secretary for Enforcement and Compliance.*

[FR Doc. 2021–25187 Filed 11–17–21; 8:45 am]

BILLING CODE 3510–DS–P

[7] *See Certain Cased Pencils from the People's Republic of China: Amended Final Results of Antidumping Duty New Shipper Review; 2014–2015,* 81 FR 92784 (December 20, 2016).

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**[RTID 0648–XB519]**

### Fisheries of the Gulf of Mexico; 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 75 life history topical working group data scoping webinar for Gulf of Mexico gray snapper.

**SUMMARY:** The SEDAR 75 assessment of Gulf of Mexico gray snapper will consist of a series of assessment webinars. See **SUPPLEMENTARY INFORMATION**.

**DATES:** The SEDAR 75 data scoping webinar for the life history topical working group will be held December 9, 2021, from 1 p.m. until 3 p.m. Eastern. The established times may be adjusted as necessary to accommodate the timely completion of discussion relevant to the assessment process. Such adjustments may result in the meeting being extended from or completed prior to the time established by this notice.

**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 multi-step 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.

The items of discussion in the data scoping webinar are as follows:

Participants will discuss what data may be available for use in the assessment of Gulf of Mexico gray snapper.

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: November 15, 2021.

**Tracey L. Thompson,**

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

[FR Doc. 2021–25165 Filed 11–17–21; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**[RTID 0648–XB591]**

### Gulf of Mexico Fishery Management Council; Public Meeting

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

**ACTION:** Notice of a public meeting.

**SUMMARY:** The Gulf of Mexico Fishery Management Council will hold a two-day in-person and virtual meeting (hybrid) of its Shrimp Advisory Panel (AP).

**DATES:** The meeting will convene Tuesday, December 7, 2021, 9 a.m.–5 p.m. and Wednesday, December 8, 2021, 9 a.m.–5 p.m., EST. For agenda details, see **SUPPLEMENTARY INFORMATION**.

**ADDRESSES:** Those who prefer to attend the meeting in-person may do so at the Gulf Council office. If you are unable or do not wish to travel, you may participate in the meeting via webinar. Registration information will be available on the Council's website by visiting *www.gulfcouncil.org* and clicking on the Shrimp AP meeting on the calendar.

*Council address:* Gulf of Mexico Fishery Management Council, 4107 W. Spruce Street, Suite 200, Tampa, FL 33607; telephone: (813) 348–1630.

**FOR FURTHER INFORMATION CONTACT:** Dr. Matt Freeman, Economist, Gulf of Mexico Fishery Management Council; *matt.freeman@gulfcouncil.org,* telephone: (813) 348–1630.

**SUPPLEMENTARY INFORMATION:** The following items are on the agenda, though agenda items may be addressed out of order (changes will be noted on the Council's website when possible).

**Tuesday, December 7, 2021; 9 a.m.–5 p.m. EST (8 a.m.–4 p.m. CST)**

Meeting will begin with Introduction of Members, Election of Chair and Vice Chair, Adoption of Agenda, Approval of Minutes from March 23, 2021 meeting and Scope of Work. The AP will review Council Actions in Response to Motions from the March 2021 *Shrimp* AP Meeting and October 2021 Council Meeting Motions.

The AP will review and discuss an Update on Vessel Position Data Collection, which will include an overview of current cellular electronic logbook (cELB) units' programming and implementation, a presentation on elements of data from current cELB units, a presentation on the Gulf States Marine Fishery Commission process for data receival, security, and storage, and discussion of a comparison table on current vessel monitoring system technical specifications and proposed technical specifications. The AP will also receive a presentation on a Case Study of South Atlantic *Rock Shrimp* VMS data inputted into the *Gulf Shrimp* effort algorithm for illustration of compatibility, the Summary of October 2021 *Shrimp* Focus Group Meeting, and a Review of Draft *Shrimp* Framework Action.

**Wednesday, December 8, 2021; 9 a.m.–5 p.m. EST (8 a.m.–4 p.m. CST)**

The AP will reconvene and review a Draft Plan for Pilot Testing of VMS Units on *Gulf Shrimp* Vessels, receive an update from the Bureau of Ocean Energy Management on Wind Energy Development in the Gulf, hold a discussion on *Shark* Depredation, review the Recent *Shrimp* Biological Opinion, and receive an Update on Aquaculture Opportunity Areas.

Lastly, the AP will receive any public testimony and discuss other business items.

— Meeting Adjourns

The in-person meeting will be broadcast via webinar. You may register by visiting *www.gulfcouncil.org* and clicking on the Shrimp Advisory Panel meeting on the calendar.

The Agenda is subject to change, and the latest version along with other meeting materials will be posted on *www.gulfcouncil.org* as they become available.

Although other non-emergency issues not on the agenda may come before the Advisory Panel for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), those issues may not be the subject of formal action during this meeting. Actions 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 Act, provided the public has been notified of the Council's intent to take-action to address the emergency at least 5 working days prior to the meeting.

**Special Accommodations**

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid or accommodations should be directed to Kathy Pereira, *kathy.pereira@gulfcouncil.org,* at least 5 days prior to the meeting date.

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

Dated: November 15, 2021.

**Tracey L. Thompson,**

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

[FR Doc. 2021–25155 Filed 11–17–21; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**[RTID 0648–XB593]**

### New England Fishery Management Council; Public Meeting

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

**ACTION:** Notice of public meeting.

**SUMMARY:** The New England Fishery Management Council (Council, NEFMC) will hold a three-day meeting to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Due to ongoing public safety considerations related to COVID–19, this meeting will be conducted entirely by webinar.

**DATES:** The webinar meeting will be held on Tuesday, Wednesday, and Thursday, December 7, 8, and 9, 2021, beginning at 9:30 a.m. on Tuesday and 9 a.m. on Wednesday and Thursday.

**ADDRESSES:** All meeting participants and interested parties can register to join the webinar at *https://attendee.gotowebinar.com/register/3955600152224819215.*

*Council address:* New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950; telephone (978) 465–0492; *www.nefmc.org.*

**FOR FURTHER INFORMATION CONTACT:** Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492, ext. 113.

**SUPPLEMENTARY INFORMATION:**

## Agenda

*Tuesday, December 7, 2021*

After introductions and brief announcements, the Council will receive reports on recent activities from its Chair and Executive Director, the Greater Atlantic Regional Fisheries Office (GARFO) Regional Administrator, the Northeast Fisheries Science Center (NEFSC) Director, the NOAA Office of General Counsel, the Mid-Atlantic Fishery Management Council liaison, staff from the Atlantic States Marine Fisheries Commission (ASMFC), and representatives from the U.S. Coast Guard and NOAA's Office of Law Enforcement. Next, the Council will receive a briefing from NOAA General Council on disclosure of financial interests and voting recusal regulations for Regional Fishery Management Council members.

Following the lunch break, the Council will go into the Habitat Committee report and: (1) Approve a revised Council policy on wind energy; and (2) receive an update on other ongoing habitat-related work. The Council also will receive a presentation from the Bureau of Ocean Energy Management (BOEM) on Atlantic offshore wind leasing activity and have an opportunity to ask questions. The Spiny Dogfish Committee report will be next. The Council will review results of recent spiny dogfish meetings and consider appropriate actions, including: (1) Committee and Mid-Atlantic Council recommendations to increase the federal trip limit to 7,500 pounds; and (2) potentially prioritizing a 2022 framework action to consider additional trip limit changes pending the results of the Spiny Dogfish Research Track Assessment. Then, the Council will receive a progress report on work being done by the Council Coordination Committee (CCC) Subcommittee on Area-Based Management to assist the CCC in responding to the 30x30 initiative in the draft White House report titled ''Conserving and Restoring America the Beautiful.'' The Council will close out the day by reviewing and approving a Council comment letter responding to NOAA's request for input on the ''Conserving and Restoring America the Beautiful'' report.

*Wednesday, December 8, 2021*

The Council will begin with a presentation from GARFO on the NOAA Fisheries outreach process for development of bycatch reduction measures to reduce takes of sea turtles in trawl fisheries. Next, the Northeast Fisheries Science Center will present an overview of the 2021 Management Track Stock Assessments Peer Review for Gulf of Maine cod and Georges Bank cod. The Scientific and Statistical Committee (SSC) report will follow. The Council will receive SSC recommendations on overfishing limits (OFLs) and acceptable biological catches (ABCs) for: (1) Atlantic sea scallops for fishing years 2022 and defaults for 2023; (2) Georges Bank cod and Gulf of Maine cod for fishing years 2022–24; (3) Gulf of Maine and Georges Bank haddock for 2022; and (4) white hake for fishing year 2022. The Council then will receive a report on the Transboundary Management Guidance Committee's November 4, 2021 intersessional meeting. After that, members of the public will have the opportunity to speak during an open comment period on issues that relate to Council business but are not included on the published agenda for this meeting. The Council asks the public to limit remarks to 3–5 minutes. These comments will be received through the webinar. A guide for how to publicly comment through the webinar is available on the Council website at *https://s3.amazonaws.com/nefmc.org/NEFMC-meeting-remote-participation_generic.pdf.*

Following the lunch break, the Council will receive the Groundfish Committee report, which will focus on final action for Framework Adjustment 63 to the Northeast Multispecies (Groundfish) Fishery Management Plan (FMP). This framework includes: (1) 2022 total allowable catches for U.S./Canada shared resources on Georges Bank (GB), which the Council approved during its September 2021 meeting; (2) 2022–23 specifications for Georges Bank yellowtail flounder; (3) 2022–24 specifications for Georges Bank cod and Gulf of Maine cod; (4) possible adjustment of 2022 specifications for Georges Bank and Gulf of Maine haddock; (5) adjustment of 2022 specifications for white hake based on rebuilding plan; (6) additional measures to promote stock rebuilding; and (7) alternatives for setting groundfish default specifications. The Council then will adjourn for the day.

*Thursday, December 9, 2021*

The Council will begin the third day of its meeting with the Scallop Committee report. The Council will take final action on Framework Adjustment 34 to the Atlantic Sea Scallop FMP, which includes 2022 fishery specifications, 2023 default specifications, and the inclusion of measures that are expected to be available under Amendment 21 to the FMP, which currently is under review by NOAA Fisheries. Additionally, the Council will receive: (1) A draft report on the evaluation of the scallop fishery's rotational area management program; and (2) an update on the Scallop Survey Working Group's activities. Following the conclusion of scallop business, the Council will hear remarks from NOAA Fisheries Assistant Administrator Janet Coit, who will introduce herself to the Council in her new role as head of the National Marine Fisheries Service and provide the Council with an opportunity to ask questions.

After the lunch break, the Council will discuss and take final action on 2022 Council Priorities for all fishery management plans and other Council responsibilities. After this discussion, the Council will close out the meeting with other business.

Although non-emergency issues not contained on this agenda may come before the Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded.

Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

**Special Accommodations**

This meeting is being conducted entirely by webinar. Requests for auxiliary aids should be directed to Thomas A. Nies (see **ADDRESSES**) at least 5 days prior to the meeting date.

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

Dated: November 15, 2021.

**Tracey L. Thompson,**

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

[FR Doc. 2021–25156 Filed 11–17–21; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**[RTID 0648–XB589]**

### Marine Mammals; File No. 22187

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

**ACTION:** Notice; receipt of application for permit amendment.

**SUMMARY:** Notice is hereby given that Heather E. Liwanag, Ph.D., 1 Grand Avenue, San Luis Obispo, CA 93407–0401, has applied for an amendment to Scientific Research Permit No. 22187–01.

**DATES:** Written, telefaxed, or email comments must be received on or before December 20, 2021.

**ADDRESSES:** The application and related documents are available for review by selecting ''Records Open for Public Comment'' from the ''Features'' box on the Applications and Permits for Protected Species (APPS) home page, *https://apps.nmfs.noaa.gov,* and then selecting File No. 22187 from the list of available applications. These documents are also available upon written request via email to *NMFS.Pr1Comments@noaa.gov.*

Written comments on this application should be submitted via email to *NMFS.Pr1Comments@noaa.gov.* Please include File No. 22187 in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request via email to *NMFS.Pr1Comments@noaa.gov.* The request should set forth the specific reasons why a hearing on this application would be appropriate.

**FOR FURTHER INFORMATION CONTACT:** Sara Young or Shasta McClenahan, Ph.D., (301) 427–8401.

**SUPPLEMENTARY INFORMATION:** The subject amendment to Permit No. 22187–01 is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*) and the regulations governing the taking and importing of marine mammals (50 CFR part 216).

Permit No. 22187–01, issued on January 28, 2020, authorizes the permit holder to conduct research to establish a catalog of known individual northern elephant (*Mirounga angustirostris*) seals along the California coast. Types of authorized takes include behavioral observations, measurements, bioacoustic recordings, acoustic playbacks, marking, flipper tagging, capture, and non-invasive physiological sampling. The permit holder is requesting the permit be amended to include authorization for 20 additional takes of northern elephant seals per year, two takes per year for 10 individuals. These animals will be captured by hand or net, sedated, fitted with satellite transmitters, swabbed, imaged with an ultrasound, weighed, and recaptured approximately three months later to remove the instruments. An additional five takes are requested for animals that are captured and released because they are not appropriate candidates for the study. The permit would remain valid until March 31, 2024.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of this application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: November 15, 2021.

**Julia M. Harrison,**

*Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.*

[FR Doc. 2021–25151 Filed 11–17–21; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**[RTID 0648–XB504]**

### 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 77 Highly Migratory Species (HMS) Hammerhead Sharks Data Workshop.

**SUMMARY:** The SEDAR 77 assessment of the Atlantic stock of hammerhead sharks will consist of a stock identification (ID) process, data webinars/workshop, a series of assessment webinars, and a review workshop. A SEDAR 77 Data Workshop has been scheduled via webinar for December 13–17, 2021. See **SUPPLEMENTARY INFORMATION.**

**DATES:** The SEDAR 77 HMS Hammerhead Sharks Data Workshop has been scheduled for December 13–16 from 9:30 a.m. until 5 p.m. Eastern and December 17 from 9:30 a.m. until 1 p.m. Eastern. The established times may be adjusted as necessary to accommodate the timely completion of discussion relevant to the assessment process. Such adjustments may result in the meeting being extended from or completed prior to the time established by this notice.

**ADDRESSES:**

*Meeting address:* The meeting will be held via webinar. The webinar is open to members of the public. Registration for the main plenary webinar and the working groups is available by contacting the SEDAR coordinator via email at *Kathleen.Howington@safmc.net.*

*SEDAR address:* South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N. Charleston, SC 29405; *www.sedarweb.org.*

**FOR FURTHER INFORMATION CONTACT:** Kathleen Howington, SEDAR Coordinator, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405; phone: (843) 571–4371; email: *Kathleen.Howington@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 three-step process including: (1) Data Workshop; (2) Assessment Process utilizing webinars; and (3) Review Workshop. The product of the Data Workshop is a data report which 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 which 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, Highly Migratory Species 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 non-governmental organizations (NGOs); international experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion at the SEDAR 77 HMS Hammerhead Shark Data Workshop are as follows: Participants will evaluate all available data and select appropriate sources for providing information on life history characteristics, catch statistics, discard estimates, length and age composition, and fishery independent and fishery dependent measures of stock abundance, as specified in the Terms of Reference for the workshop, to develop an assessment data set and associated documentation.

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**

This meeting is accessible to people with disabilities. Requests for auxiliary aids should be directed to the South Atlantic Fishery Management Council office (see **ADDRESSES**) at least 5 business 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: November 15, 2021.

**Tracey L. Thompson,**

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

[FR Doc. 2021–25164 Filed 11–17–21; 8:45 am]

**BILLING CODE 3510–22–P**

## CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

### Privacy Act of 1974; System of Records

**AGENCY:** Corporation for National and Community Service.

**ACTION:** Notice of a new system of records (SORN).

**SUMMARY:** In accordance with the Privacy Act of 1974, as amended, the Corporation for National and Community Service (CNCS, operating as AmeriCorps) is issuing a public notice of its intent to create the AmeriCorps Privacy Act system of records ''Personal Health and Religious Information.'' This system of records maintains personal health and religious information collected in response to (1) medical-based and religious-based reasonable accommodation requests; (2) public health emergency or similar health and safety incidents, such as a pandemic, epidemic, or man-made emergency; and/or (3) any other lawful collection of health-related information that is necessary to ensure a safe and healthy environment for individuals who are occupying AmeriCorps facilities, attending AmeriCorps-sponsored events, participating in AmeriCorps programs, or otherwise engaged in official business on behalf of the agency. The system of records will assist the agency in the collection, storing, dissemination, and disposal of personal health and religious information collected and maintained by the agency.

**DATES:** This new system will be effective upon publication. New or modified routine uses will be effective December 20, 2021. Submit comments on or before December 20, 2021.

**ADDRESSES:** Commenters are strongly encouraged to submit public comments electronically. AmeriCorps expects to have limited personnel available to process public comments that are submitted on paper through mail. Until further notice, any comments submitted on paper will be considered only to the extent practicable. All submissions must include the agency's name (AmeriCorps) and reference this notice. You may submit comments, identified by system name and number via any of the following methods:

1. Electronically through *regulations.gov*. Once you access *regulations.gov*, locate the web page for this System of Records Notice (SORN) by searching for *CNCS-10-CEO-PHRI-Personal Health and Religious Information.* If you upload any files, please make sure they include your first name, last name, and the name of the proposed SORN.
2. By email at *privacy@cns.gov*.
3. By mail: AmeriCorps, Attn: Chief Privacy Officer, OIT, 250 E Street SW, Washington, DC 20525.
4. By hand delivery or courier to AmeriCorps at the address for mail between 9:00 a.m. and 4:00 p.m. Eastern Standard Time, Monday through Friday, except for Federal holidays.

Please note that all submissions received may be posted without change to the agency's website and to *regulations.gov*, including any personal information.

**FOR FURTHER INFORMATION CONTACT:** Ayanna McKinnon, Office of General Counsel, 202–914–8966, *amckinnon@cns.gov* or Bilal Razzaq, Chief Privacy Officer and Chief Information Security Officer, 202–948–9711, *brazzaq@cns.gov.* If you have general questions about the system of record, you may email them to *privacy@cns.gov* or mail them to the address in the **ADDRESSES** section above. Please include the system of record's name and number.

**SUPPLEMENTARY INFORMATION:** Additional information about AmeriCorps is available at *https://americorps.gov/.*

**I. Background**

AmeriCorps will maintain the ''Personal Health and Religious Information'' system of records. AmeriCorps is committed to providing all employees (including political appointees, career employees, detailees, and interns), applicants and candidates for employment, contractors, national service members, volunteers, applicants and candidates for AmeriCorps national service programs, and occupants of, and visitors to, its facilities, with a safe and healthy environment. To ensure and maintain the safety of all parties during standard operations and public health

emergencies or similar health and safety incidents, such as a pandemic, epidemic, or man-made emergency, AmeriCorps may develop and institute additional safety measures that require the collection of personal health or religious information, as applicable.

AmeriCorps is committed to providing medical-based reasonable accommodation to qualified AmeriCorps employees and applicants for employment, pursuant to section 501 of the Rehabilitation Act of 1973, as amended, unless doing so would cause undue hardship. AmeriCorps is also committed to complying with Executive 14043, *Requiring Coronavirus Disease 2019 Vaccination,* which requires Federal agencies to collect employee health information related to the Coronavirus 2019 (hereafter ''COVID–19). AmeriCorps may develop and institute additional measures that require the collection of personal health information.

Additionally, AmeriCorps is committed to ensuring grantee and sponsor compliance in providing reasonable accommodation to qualified AmeriCorps national service applicants, candidates, members and volunteers, unless doing so would cause undue hardship, pursuant to section 504 of the Rehabilitation Act of 1973, as amended, and section 175 of the National and Community Service Act of 1990, as amended, and section 417 of the Domestic Volunteer Service Act of 1973, as amended.

Moreover, pursuant to Title VII of the Civil Rights Act of 1964, as amended, AmeriCorps is committed to providing reasonable accommodation to AmeriCorps employees (including political appointees, career employees, detailees, interns, and applicants and candidates for employment) based on religion or religious belief, unless doing so would cause undue hardship. Also, AmeriCorps is committed to ensuring grantee and sponsor compliance in providing religious-based reasonable accommodation to AmeriCorps national service applicants, candidates, members and volunteers, unless doing so would cause undue hardship, pursuant to section 175 of the National and Community Service Act of 1990, as amended, and section 417 of the Domestic Volunteer Service Act of 1973, as amended.

AmeriCorps may collect medical-based and religious-based reasonable accommodation requests for AmeriCorps employees (including political appointees, career employees, detailees, and interns), applicants and candidates for employment, contractors, national service members and volunteers, and applicants and candidates for AmeriCorps national service programs.

In addition, in response to public health emergencies, including a pandemic or epidemic, AmeriCorps may collect health related information (including but not limited to vaccination status and proof of vaccination status) for AmeriCorps employees (including political appointees, career employees, detailees, and interns), applicants and candidates for employment, contractors, national service members, volunteers, applicants and candidates for AmeriCorps national service programs, and visitors to AmeriCorps facilities, as necessary to ensure a safe and healthy work environment.

Information will be collected, maintained, and disclosed in accordance with applicable law, regulations, and statutes, including, but not limited to, the Rehabilitation Act, the Genetic Information Nondiscrimination Act, the Executive Order 14043, and regulations and guidance published by the U.S. Occupational Safety and Health Administration, the U.S. Equal Employment Opportunity Commission, and the U.S. Centers for Disease Control and Prevention, the Office of Management and Budget, Safer Federal Workforce Taskforce, or other relevant entities. This newly established system will be included in the AmeriCorps inventory of record systems.

A report of this system of records has been sent to Congress and the Office of Management and Budget.

## II. Privacy Act

The Privacy Act of 1974, as amended, embodies fair information practice principles in a statutory framework governing how Federal agencies collect, maintain, use, and disseminate individuals' records. The Privacy Act applies to records about individuals that are maintained in a ''system of records.'' A ''system of records'' is a group of any records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. The Privacy Act defines an individual as a United States citizen or lawful permanent resident. Individuals may request access to their own records that are maintained in a system of records in the possession or under the control of AmeriCorps by complying with Privacy Act regulations at 43 CFR part 2, subpart K, and following the procedures outlined in the Records Access, Contesting Record, and Notification Procedures sections of this notice.

The Privacy Act requires each agency to publish in the **Federal Register** a description denoting the existence and character of each system of records that the agency maintains, and the routine uses of each system. The ''Personal Health and Religious Information'' system of records notice is published in its entirety below. In accordance with 5 U.S.C. 552a(r), AmeriCorps has provided a report of this system of records to the Office of Management and Budget and to Congress.

## III. Public Participation

You should be aware your entire comment including your personally identifiable information, such as your address, phone number, email address, or any other personal information in your comment, may be made publicly available at any time. While you may request to withhold your personally identifiable information from public review, we cannot guarantee we will be able to do so.

**SYSTEM NAME AND NUMBER:**

CNCS–10–CEO–PHRI, Personal Health and Religious Information (PHRI).

**SECURITY CLASSIFICATION:**

Unclassified.

**SYSTEM LOCATION:**

CEO Immediate Office, Corporation for National and Community Service, 250 E Street SW, Suite 300, Washington, DC 20525.

**SYSTEM MANAGER(S):**

CEO Immediate Office, Corporation for National and Community Service, 250 E Street SW, Suite 300, Washington, DC 20525.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

The authority to collect this information derives from Title VII of the Civil Rights Act of 1964, as amended, sections 501 and 504 of the Rehabilitation Act of 1973, as amended, section 175 of the National and Community Service Act of 1990, as amended, and section 417 of the Domestic Volunteer Service Act of 1973, as amended. The substantive standards of the Americans with Disabilities Act of 1990, as amended (42 U.S.C. 12101 *et seq.*) apply to the Federal Government through the Rehabilitation Act. (29 U.S.C. 791 *et seq.*). Additional authority is derived from 5 U.S.C. chapters 11 and 79, and in discharging the functions directed under Executive Order 14043, Requiring Coronavirus Disease 2019 Vaccination for Federal Employees

(Sept. 9, 2021), Executive Order 14042, Ensuring Adequate COVID Safety Protocols for Federal Contractors (Sept. 2, 2021), Executive Order 13163, Increasing Opportunity for Individuals With Disabilities To Be Employed in the Federal Government (Jul. 26, 2000), and Executive Order 13164, Requiring Federal Agencies to Establish Procedures to Facilitate the Provision of Reasonable Accommodation (Jul. 26, 2000).

**PURPOSE(S) OF THE SYSTEM:**

AmeriCorps' Equal Employment Opportunity Program (EEOP) proposes to collect this information to maintain personal health and religious information collected in response to (1) medical-based and religious-based reasonable accommodation requests; (2) public health emergency or similar health and safety incidents, such as a pandemic, epidemic, or man-made emergency; and/or (3) any other lawful collection of health-related information that is necessary to ensure a safe and healthy environment for individuals who are occupying AmeriCorps facilities, attending AmeriCorps-sponsored events, participating in AmeriCorps programs, or otherwise engaged in official business on behalf of the agency. The system will assist the agency in the collection, storing, dissemination, and disposal of personal health and religious information collected and maintained by the agency.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Individuals covered by the system include all AmeriCorps employees (including political appointees, career employees, detailees, and interns), applicants and candidates for employment, contractors, national service members, volunteers, applicants and candidates for AmeriCorps national service programs, and visitors to AmeriCorps facilities. This includes authorized individuals or representatives who file a request for a reasonable accommodation on behalf of any of the above-referenced parties.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

The personal health and religious information records system may contain some or all of the following information: General personal information including, but not limited to, the name, address, social security number, maiden name, place of birth, financial information, alias, gender, telephone number, military service, age, email address, physical characteristics, race/ethnicity, education, other contact information, and medical information including vaccination status; reasonable accommodation requests, including requestor's name and contact information (if different than the employee/service member who needs an accommodation); date request was initiated; information concerning the nature of the disability and the need for accommodation, including appropriate medical documentation and other supporting documents; information concerning religious affiliation, the nature of the sincerely held religious belief, practice, or observance, and the need for accommodation, including any appropriate documentation; details of the accommodation requests, such as: Type of accommodation requested, how the requested accommodation would assist the individual in the performance of their job, essential duties of the position, information relating to an individual's capability to satisfactorily perform the duties of the position currently held, estimated cost of accommodation, action by deciding official, and other supporting documents relating to reasonable accommodation, the sources of technical assistance consulted in trying to identify alternative reasonable accommodation, any additional information provided by the requestor related to the processing of the request, and whether the request was approved or denied, and whether the accommodation was approved for a trial period; and notification(s) to the employee/service member and his/her supervisor(s) regarding the accommodation. These records may also contain work-related data, including but not limited to service information, occupation, telephone number, salary, job title, email address, work history, work address, business associates, and/or program office to which the employee is assigned.

**RECORD SOURCE CATEGORIES:**

Records in this system are obtained directly from employees (including political appointees, career employees, detailees, and interns), applicants and candidates for employment, contractors, national service members, volunteers, applicants and candidates for AmeriCorps national service programs, or any family member, health professional, or other person responding to an information request as a representative of any of the above-referenced parties, or visitors when obtaining necessary health information; therefore, the accuracy is ensured by collecting the information from the source who may be required to certify under penalty of perjury that the information is true and accurate to the best of their knowledge.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside AmeriCorps as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. A record from this system of records may be disclosed as a routine use to a prospective employer of a Government employee. Upon transfer of the employee to another Federal agency, the information is transferred to such agency.

B. A record from this system of records may be disclosed as a routine use to provide information to the OPM and/or MSPB for review, audit, or reporting purposes.

C. To the appropriate Federal, State, or local agency responsible for investigating, prosecuting, enforcing, or implementing a statute, rule, regulation, or order where the record, either alone or in conjunction with other information, indicates a violation or potential violation of a civil or criminal law or regulation.

D. To other federal agencies if required to operate a jointly managed national service program and manage those members.

E. To the Office of the President, a Member of Congress, or their personnel in response to a request made on behalf of, and at the request of, the individual who is the subject of the record. These advocates will receive the same records that individuals would have received if they filed their own request.

F. To another Federal agency or a party in litigation before a court or in an administrative proceeding being conducted by a Federal agency, when the Government is a party to the judicial or administrative proceeding, and such information is the subject of a court order directing disclosure or deemed by AmeriCorps to be relevant and necessary to the litigation.

G. To NARA's Office of Government Information Services so that it may review agency compliance with the Freedom of Information Act of 1967, as amended, (FOIA) provide mediation services to resolve FOIA disputes, and identify policies and procedures for improving FOIA compliance, and to the extent necessary to fulfill its responsibilities as required by 5 U.S.C. 552(h)(2)(A–B) and (3).

H. By AmeriCorps, in the production of summary descriptive statistics and

analytical studies in support of the function for which the records are collected and maintained, or for related workforce studies. While published statistics and studies do not contain individual identifiers, in some instances, the selection of elements of data included in the study may be structured in such a way as to make the data individually identifiable by inference.

I. A record from this system of records may be disclosed as a routine use to provide information to the OPM and/or MSPB for review, audit, or reporting purposes.

J. A record from this system of records may be disclosed as a routine use to AmeriCorps-paid experts or consultants, and those under contract with the AmeriCorps on a ''need-to-know'' basis for a purpose within the scope of the pertinent AmeriCorps task. This access will be granted to an AmeriCorps contractor or employee of such contractor by a system manager only after satisfactory justification has been provided to the system manager.

K. The United States, when AmeriCorps determines that litigation is likely to affect AmeriCorps 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 AmeriCorps is deemed by AmeriCorps to be relevant and necessary to the litigation.

L. To disclose information to officials of the Merit Systems Protection Board or the Office of the Special Counsel, when requested in connection with appeals, special studies of the civil service and other merit systems, review of OPM rules and regulations, investigations of alleged or possible prohibited personnel practices, and such other functions as promulgated in 5 U.S.C. 1205 and 1206, or as may be authorized by law.

M. To disclose information to the U.S. Equal Employment Opportunity Commission when requested in connection with investigations into alleged or possible discrimination practices in the Federal sector, examination of Federal affirmative employment programs, compliance by Federal agencies with the Uniform Guidelines of Employee Selection Procedures, or other functions vested in the Commission.

N. To disclose information to the Federal Labor Relations Authority or its General Counsel when requested in connection with investigations of allegations of unfair labor practices of matters before the Federal Service Impasses Panel.

O. To disclose information to the Office of Management and Budget at any stage of the legislative coordination and clearance process in connection with private relief legislation as set forth in OMB circular No. A–19.

P. To provide authorized AmeriCorps officials, vendors or staff members information needed in the performance of official duties related to succession planning, workforce analysis, skills gap closure, training and development, or recruitment and retention.

Q. To authorized contractors, vendors, grantees, or volunteers performing or working on a contract, service, grant, cooperative agreement, or job for AmeriCorps or the Federal government that is in the performance of a Federal duty to which the information is deemed relevant.

R. To disclose to a requesting Federal agency, information in connection with the hiring, retention, separation, or retirement of an employee; the issuance of a security clearance; the reporting of an investigation of an employee; the letting of a contract; the classification of a job; or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that AmeriCorps determines that the information is relevant and necessary to the requesting party's decision on the matter.

S. To an appeal, grievance, hearing, or complaints examiner; an equal opportunity investigator, arbitrator, or mediator; and an exclusive representative or other person authorized to investigate or settle a grievance, complaint, or appeal filed by an individual who is the subject of the record.

T. For Data Breach and Mitigation Response to provide information to appropriate agencies, entities, and persons when:

a. AmeriCorps suspects or has confirmed that there has been a breach of the system of records.

b. AmeriCorps has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, AmeriCorps (including its information systems, programs, and operations), the Federal Government, or national security, and

c. The disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with AmeriCorps' efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

U. To provide information to another Federal agency or Federal entity, when AmeriCorps 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:**

Paper records are stored in locked rooms, file cabinets, and desks. Electronic records and backups are stored on secure servers and encrypted media to include computers and network drives.

**POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:**

Information covered by this system of records notice may be retrieved by the name of the individual.

**POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:**

All records in the system will be retained until their retention and disposal schedule is approved by NARA, then retained and disposed according to the applicable schedule.

**ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:**

AmeriCorps has established security and privacy protocols that meet the required security and privacy standards issued by the National Institute of Standards and Technology (NIST). Records are maintained in a secure, password protected electronic system that utilizes security hardware and software to include multiple firewalls, active intruder detection, and role-based access controls. AmeriCorps has adopted appropriate administrative, technical, and physical controls in accordance with its security program to protect the confidentiality, integrity, and availability of the information, and to ensure that records are not disclosed to or accessed by unauthorized individuals. Electronic records are stored on computer networks, which may include cloud-based systems, and protected by controlled access with either Personal Identity Verification (PIV) cards or by assigning user accounts to individuals needing access to the records passwords set by authorized users that must be changed periodically. Paper records are maintained in locked rooms, file cabinets, and desks when not in use.

**RECORD ACCESS PROCEDURES:**

Individuals requesting access to their individual records should follow the Notification Procedure below.

**CONTESTING RECORD PROCEDURES:**

Individuals contesting the content of records about themselves contained in this system of records should follow the Notification Procedure below.

**NOTIFICATION PROCEDURES:**

Individuals requesting notification of the existence of records on themselves or requesting access to their individual records must send a signed, written inquiry that includes their name, address, date of birth, and verification of identity to Gina Cross, Senior Agency Official for Privacy, Corporation for National and Community Service, 250 E Street SW, Suite 300, Washington, DC 20525, or email *gcross@cns.gov.* The request envelope (or subject line) and letter should both be clearly marked ''PRIVACY ACT INQUIRY.'' A request for notification must meet the requirements of 43 CFR 2.235.

**EXEMPTIONS PROMULGATED FOR THE SYSTEM:**

None.

**HISTORY:**

None.

Dated: November 8, 2021.

**Ndiogou Cisse,**

*Chief Information Officer.*

[FR Doc. 2021–24868 Filed 11–17–21; 8:45 am]

**BILLING CODE 6050–28–P**

## DEPARTMENT OF EDUCATION

**[Docket No.: ED–2021–SCC–0104]**

### Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; 21st Century Community Learning Centers Annual Performance Report

**AGENCY:** Office of Elementary and Secondary Education (OESE), Department of Education (ED).

**ACTION:** Notice.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, ED is proposing a revision of a currently approved collection.

**DATES:** Interested persons are invited to submit comments on or before December 20, 2021.

**ADDRESSES:** Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this information collection request by selecting ''Department of Education'' under ''Currently Under Review,'' then check ''Only Show ICR for Public Comment'' checkbox. Comments may also be sent to *ICDocketmgr@ed.gov.*

**FOR FURTHER INFORMATION CONTACT:** For specific questions related to collection activities, please contact Daryn Hedlund, (202) 401–3008.

**SUPPLEMENTARY INFORMATION:** The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

*Title of Collection:* 21st Century Community Learning Centers Annual Performance Report.

*OMB Control Number:* 1810–0668.

*Type of Review:* Revision of a currently approved collection.

*Respondents/Affected Public:* State, Local, and Tribal Governments.

*Total Estimated Number of Annual Responses:* 1,357.

*Total Estimated Number of Annual Burden Hours:* 39,447.

*Abstract:* The purpose of the 21st Century Community Learning Centers (21st CCLC) program, as authorized under Title IV, Part B, of the Elementary and Secondary Education Act, as amended by the Every Student Succeeds Act (ESSA) (20 U.S.C. 7171–7176) is to create community learning centers that provide academic enrichment opportunities for children, particularly students who attend high poverty and low-performing schools, to meet State and local student standards in core academic subjects, to offer students a broad array of enrichment activities that can complement their regular academic programs, and to offer literacy and other educational services to the families of participating children. Present in all 50 states, the District of Columbia, Puerto Rico, U.S. Virgin Islands, and the Bureau of Indian Education, academic enrichment and youth development programs are designed to enhance participants' well-being and academic success. The Department of Education (ED) is requesting authorization for a revision to collect data for 21st CCLC programs. The core purpose is to collect information on the Government Performance and Results Act (GPRA) performance indicators associated with the 21st CCLC program to report to Congress annually on the implementation and progress of 21st CCLC projects. All elements collected serve to meet the reporting requirements of the GPRAs. These metrics delivered in the form of an Annual Performance Report (APR) are the primary way the federal government determines the success and progress of the 21st CCLC program based on the statutory requirements.

Dated: November 15, 2021.

**Juliana Pearson,**

*PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.*

[FR Doc. 2021–25148 Filed 11–17–21; 8:45 am]

**BILLING CODE 4000–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. ER22–385–000]**

### Innovative Owner 43, 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 Innovative Owner 43, 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 December 2, 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 TTY, (202) 502–8659.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2021–25176 Filed 11–17–21; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. ER22–381–000]**

### Dunns Bridge Solar Center, 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 Dunns Bridge Solar Center, 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 December 2, 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: November 12, 2021.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2021–25175 Filed 11–17–21; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. RM21–17–000]**

### Building for the Future Through Electric Regional Transmission Planning and Cost Allocation and Generator Interconnection; Further Supplemental Notice of Technical Conference

As first announced in the Notice of Technical Conference issued in this proceeding on September 16, 2021, the Federal Energy Regulatory Commission (Commission) will convene a staff-led technical conference in the above-referenced proceeding on Monday, November 15, 2021, from 10:00 a.m. to 4:30 p.m. Eastern Time. The conference will be held electronically. Attached to this Further Supplemental Notice is the final agenda for the technical conference.

Discussions at the conference may involve issues raised in proceedings that are currently pending before the Commission. These proceedings include, but are not limited to:

| | Docket No. |
|---|---|
| Duke Energy Florida v. Florida Power and Light, et al | EL21–93–000 |
| NYISO | ER21–1647–002, EL21–66–001 |
| Neptune Regional Transmission System, LLC and Long Island Power Authority v. PJM | EL21–39–000 |
| PPL Electric Utilities Corporation & PJM Interconnection, LLC | ER21–2282–001 |

| | Docket No. |
|---|---|
| SOO Green HVDC Link Project Co, LLC v. PJM Interconnection, LLC | EL21–85–000 |
| California Independent System Operator Corporation | ER21–2530–000 |
| NextEra Energy Seabrook, LLC | EL21–3–000 |
| NECEC Transmission LLC and Avangrid, Inc. v. NextEra Energy Resources, LLC | EL21–6–000 |
| ISO New England Inc | EL21–94–000 |

The conference will be open for the public to attend electronically. There is no fee for attendance. Registration for the conference is not required. Information on this technical conference, including a link to the webcast, will be posted on the conference's event page on the Commission's website, *https://www.ferc.gov/news-events/events/technical-conference-building-future-through-electric-regional-transmission,* prior to the event.

The conference will be transcribed. Transcripts of the conference will be available for a fee from Ace-Federal Reporters, Inc. (202) 347–3700.

Commission conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations, please send an email to *accessibility@ferc.gov,* call toll free (866) 208–3372 (voice) or (202) 208–8659 (TTY), or send a fax to (202) 208–2106 with the required accommodations. This notice is issued and published in accordance with 18 CFR 2.1.

For more information about this technical conference, please contact:

David Tobenkin (Technical Information), Office of Energy Policy and Innovation, (202) 502–6445, *david.tobenkin@ferc.gov*

Lina Naik (Legal Information), Office of General Counsel, (202) 502–8882, *Lina.Naik@ferc.gov*

Sarah McKinley (Logistical Information), Office of External Affairs, (202) 502–8004, *Sarah.Mckinley@ferc.gov*

Dated: November 12, 2021.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2021–25177 Filed 11–17–21; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket Nos. CP21–465–000, CP21–465–001, CP21–465–002]**

### Driftwood Pipeline LLC; Notice of Amendment to Application and Establishing Intervention Deadline

Take notice that on October 29, 2021, Driftwood Pipeline LLC (Driftwood), 1201 Louisiana Street, Suite 3100, Houston, TX 77002, filed a second amendment to its application proposing the Line 200 and Line 300 Project that was filed on June 17, 2021 in Docket No. CP21–465–000 and noticed in the **Federal Register** on July 7, 2021.[1] [2]

This amendment, filed in Docket No. CP21–465–002, proposes to increase capacity on the Line 200 and Line 300 Project from the originally proposed nominal capacity of 4.6 billion cubic feet per day Bcf/d to a nominal capacity of 5.4 Bcf/d, with a maximum seasonal capacity of 5.7 Bcf/d, all as more fully set forth in the application which is on file with the Commission and open for public inspection.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://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.

Any questions regarding Driftwood's application may be directed to Joey Mahmoud, Driftwood Pipeline LLC, 1201 Louisiana Street, Suite 3100, Houston, TX 77002, 832–962–4000, *joey.mahmoud@tellurianinc.com;* or Lisa M. Tonery, Partner, Orrick, Herrington & Sutcliffe LLP, 51 West 52nd Street, New York, N.Y. 10019–6142, 212 506–3710, *ltonery@orrick.com.*

Pursuant to Section 157.9 of the Commission's Rules of Practice and Procedure,[3] within 90 days of this Notice the Commission staff will either: complete its environmental review and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or environmental assessment (EA) for this proposal. The filing of an EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

**Public Participation**

There are three ways to become involved in the Commission's review of this project: You can file a protest to the project, you can file a motion to intervene in the proceeding, and you can file comments on the project. There is no fee or cost for filing protests, motions to intervene, or comments. The deadline for filing protests, motions to intervene, and comments is 5:00 p.m. Eastern Time on December 3, 2021. How to file comments and motions to intervene is explained below.

[1] 86 FR 35776.

[2] On October 13, 2021, Driftwood filed its first amendment in Docket No. CP21–465–001 regarding the Line 200 and Line 300 Project to address various project modifications that are largely the result of relocating the proposed Indian Bayou Compressor Station. The deadline for filing protests, motions to intervene, and comments in Docket No. CP21–465–001 ended November 10, 2021.

[3] 18 CFR (Code of Federal Regulations) § 157.9.

*Comments*

Any person wishing to comment on the project may do so. The Commission considers all comments received about the project in determining the appropriate action to be taken. To ensure that your comments are timely and properly recorded, please submit your comments on or before December 3, 2021. However, the filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding.

Persons who comment on the environmental review of this project will be placed on the Commission's environmental mailing list, and will receive notification when the environmental documents (EA or EIS) are issued for this project and will be notified of meetings associated with the Commission's environmental review process.

*Interventions*

Any person, which includes individuals, organizations, businesses, municipalities, and other entities,[4] has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure[5] and the regulations under the NGA[6] by the intervention deadline for the project, which is December 3, 2021. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. [For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene.] For more information about motions to intervene, refer to the FERC website at *https://www.ferc.gov/resources/guides/how-to/intervene.asp.*

All timely, unopposed motions to intervene are automatically granted by operation of Rule 214(c)(1). Motions to intervene that are filed after the intervention deadline are untimely and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations. A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

*How To File Comments and Interventions*

There are two ways to submit your comments and motions to intervene to the Commission. In all instances, please reference the Project docket number, CP21–465–002, in your submission. The Commission encourages electronic filing of submissions.

(1) You may file your comments or motions to intervene electronically by using the eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select ''General'' and then select ''Comment on a Filing'' or ''Intervention''; or

(2) You can file a paper copy of your comments by mailing them to the following address below. Your written comments must reference the Project docket number (CP21–465–002).

To mail via USPS, use the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426

To mail via any other courier, use the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852

Motions to intervene must be served on the applicants either by mail or email (with a link to the document) at: Joey Mahmoud, Driftwood Pipeline LLC, 1201 Louisiana Street Suite 3100, Houston, TX 77002, *joey.mahmoud@tellurianinc.com;* or Lisa M. Tonery, Partner, Orrick, Herrington & Sutcliffe LLP, 51 West 52nd Street, New York, N.Y. 10019–6142, *ltonery@orrick.com.* Any subsequent submissions by an intervenor must be served on the applicants and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online. Service can be via email with a link to the document.

All timely, unopposed[7] motions to intervene are automatically granted by operation of Rule 214(c)(1).[8] Motions to intervene that are filed after the intervention deadline are untimely, and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations.[9] A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

**Tracking the Proceeding**

Throughout the proceeding, additional information about the projects will be available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the ''eLibrary'' link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to *www.ferc.gov/docs-filing/esubscription.asp.*

*Intervention Deadline:* 5:00 p.m. Eastern Time on December 3, 2021.

Dated: November 12, 2021.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2021–25178 Filed 11–17–21; 8:45 am]

**BILLING CODE 6717–01–P**

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## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

### Combined Notice of Filings #1

November 12, 2021.

Take notice that the Commission received the following electric rate filings:

[4] 18 CFR 385.102(d).

[5] 18 CFR 385.214.

[6] 18 CFR 157.10.

[7] The applicant has 15 days from the submittal of a motion to intervene to file a written objection to the intervention.

[8] 18 CFR 385.214(c)(1).

[9] 18 CFR 385.214(b)(3) and (d).

*Docket Numbers:* ER14–2498–012; ER14–2500–012; ER16–2462–012; ER17–2364–006; ER19–106–005; ER21–445–002; ER16–2643–004.

*Applicants:* Potomac Energy Center, LLC, Hill Top Energy Center LLC, Birdsboro Power LLC, St. Joseph Energy Center, LLC, Oregon Clean Energy, LLC, Newark Energy Center, LLC, EIF Newark, LLC.

*Description:* Notice of Non-Material Change in Status of EIF Newark, LLC, et al.

*Filed Date:* 11/12/21.

*Accession Number:* 20211112–5237.

*Comment Date:* 5 p.m. ET 12/3/21.

*Docket Numbers:* ER21–2652–000.

*Applicants:* Caddo Wind, LLC.

*Description:* Report Filing: Third Supplement to Application for Market-Based Rate Authority to be effective N/A.

*Filed Date:* 11/12/21.

*Accession Number:* 20211112–5222.

*Comment Date:* 5 p.m. ET 11/19/21.

*Docket Numbers:* ER22–384–000.

*Applicants:* ITC Midwest LLC.

*Description:* § 205(d) Rate Filing: Filing of a Construction Agreement and Joint Use Agreement to be effective 1/10/2022.

*Filed Date:* 11/10/21.

*Accession Number:* 20211110–5195.

*Comment Date:* 5 p.m. ET 12/1/21.

*Docket Numbers:* ER22–385–000.

*Applicants:* Innovative Owner 43, LLC.

*Description:* Baseline eTariff Filing: Innovative Owner 43, LLC—Application for Market-Based Rate Authority to be effective 11/11/2021.

*Filed Date:* 11/10/21.

*Accession Number:* 20211110–5241.

*Comment Date:* 5 p.m. ET 12/1/21.

*Docket Numbers:* ER22–386–000.

*Applicants:* Portland General Electric Company.

*Description:* Tariff Amendment: Portland General Electric Company submits tariff filing per 35.15: NorthernGrid Funding Agreement Termination to be effective 12/31/2021.

*Filed Date:* 11/12/21.

*Accession Number:* 20211112–5001.

*Comment Date:* 5 p.m. ET 12/3/21.

*Docket Numbers:* ER22–387–000.

*Applicants:* Crescent Ridge LLC.

*Description:* Baseline eTariff Filing: Reactive Power Compensation Filing to be effective 12/13/2021.

*Filed Date:* 11/12/21.

*Accession Number:* 20211112–5013.

*Comment Date:* 5 p.m. ET 12/3/21.

*Docket Numbers:* ER22–388–000.

*Applicants:* Public Service Company of Colorado.

*Description:* § 205(d) Rate Filing: 2021–11–11 PSCoES-Provisional LGIA–657–0.0.0 to be effective 11/12/2021.

*Filed Date:* 11/12/21.

*Accession Number:* 20211112–5019.

*Comment Date:* 5 p.m. ET 12/3/21.

*Docket Numbers:* ER22–389–000.

*Applicants:* Public Service Company of Colorado.

*Description:* § 205(d) Rate Filing: 2011–11–11 PSCoES-Provisional LGIA–658–0.0.0 to be effective 11/12/2021.

*Filed Date:* 11/12/21.

*Accession Number:* 20211112–5024.

*Comment Date:* 5 p.m. ET 12/3/21.

*Docket Numbers:* ER22–390–000.

*Applicants:* Duke Energy Carolinas, LLC.

*Description:* § 205(d) Rate Filing: DEC–BREMC—Revised NITSA SA No. 367 to be effective 1/1/2022.

*Filed Date:* 11/12/21.

*Accession Number:* 20211112–5031.

*Comment Date:* 5 p.m. ET 12/3/21.

*Docket Numbers:* ER22–391–000.

*Applicants:* ISO New England Inc.

*Description:* ISO New England Inc submits its informational filing for qualification in the Forward Capacity Market under 2025–2026 Capacity Commitment Period.

*Filed Date:* 11/9/21.

*Accession Number:* 20211109–5228.

*Comment Date:* 5 p.m. ET 11/24/21.

*Docket Numbers:* ER22–392–000.

*Applicants:* El Paso Electric Company.

*Description:* Compliance filing: EPE Order No. 864 Compliance Filing to be effective N/A.

*Filed Date:* 11/12/21.

*Accession Number:* 20211112–5115.

*Comment Date:* 5 p.m. ET 12/3/21.

*Docket Numbers:* ER22–393–000.

*Applicants:* Hardin Solar Holdings LLC.

*Description:* Tariff Amendment: Notice of Cancellation of Market-Based Rate Tariff to be effective 1/12/2022.

*Filed Date:* 11/12/21.

*Accession Number:* 20211112–5155.

*Comment Date:* 5 p.m. ET 12/3/21.

*Docket Numbers:* ER22–394–000.

*Applicants:* Southwest Power Pool, Inc.

*Description:* § 205(d) Rate Filing: 2888R5 Arkansas Electric Cooperative Corp NITSA NOA to be effective 11/1/2021.

*Filed Date:* 11/12/21.

*Accession Number:* 20211112–5156.

*Comment Date:* 5 p.m. ET 12/3/21.

*Docket Numbers:* ER22–395–000.

*Applicants:* PJM Interconnection, L.L.C.

*Description:* § 205(d) Rate Filing: Original WMPA, Service Agreement No. 6229; Queue No. AG1–213 to be effective 11/1/2021.

*Filed Date:* 11/12/21.

*Accession Number:* 20211112–5158.

*Comment Date:* 5 p.m. ET 12/3/21.

*Docket Numbers:* ER22–396–000.

*Applicants:* Equilon Enterprises LLC.

*Description:* Tariff Amendment: Notice of Cancellation to be effective 11/13/2021.

*Filed Date:* 11/12/21.

*Accession Number:* 20211112–5215.

*Comment Date:* 5 p.m. ET 12/3/21.

*Docket Numbers:* ER22–397–000.

*Applicants:* PJM Interconnection, L.L.C.

*Description:* § 205(d) Rate Filing: WMPA Second Amendment to Service Agreement No. 5589; Queue No. AE2–115 to be effective 1/8/2020.

*Filed Date:* 11/12/21.

*Accession Number:* 20211112–5238.

*Comment Date:* 5 p.m. ET 12/3/21.

*Docket Numbers:* ER22–398–000.

*Applicants:* Mesa Wind Power LLC.

*Description:* Compliance filing: Notice of Succession and Revised Market-Based Rate Tariff to be effective 11/13/2021.

*Filed Date:* 11/12/21.

*Accession Number:* 20211112–5240.

*Comment Date:* 5 p.m. ET 12/3/21.

*Docket Numbers:* ER22–399–000.

*Applicants:* Meadow Lake Solar Park LLC.

*Description:* Baseline eTariff Filing: Market-Based Rate Application to be effective 1/12/2022.

*Filed Date:* 11/12/21.

*Accession Number:* 20211112–5249.

*Comment Date:* 5 p.m. ET 12/3/21.

*Docket Numbers:* ER22–400–000.

*Applicants:* ISO New England Inc., New England Power Pool Participants Committee.

*Description:* § 205(d) Rate Filing: ISO New England Inc. submits tariff filing per 35.13(a)(2)(iii: ISO–NE and NEPOOL; Attachment K Resource Assumption Changes to be effective 1/11/2022.

*Filed Date:* 11/12/21.

*Accession Number:* 20211112–5251.

*Comment Date:* 5 p.m. ET 12/3/21.

*Docket Numbers:* ER22–401–000.

*Applicants:* Florey Knob Energy LLC.

*Description:* Tariff Amendment: Florey Knob Energy LLC Cancellation of MBR Tariff to be effective 11/13/2021.

*Filed Date:* 11/12/21.

*Accession Number:* 20211112–5277.

*Comment Date:* 5 p.m. ET 12/3/21.

*Docket Numbers:* ER22–402–000.

*Applicants:* Idaho Power Company.

*Description:* § 205(d) Rate Filing: Section 4—Sliding Yearly Option to be effective 12/15/2021.

*Filed Date:* 11/12/21.

*Accession Number:* 20211112–5296.

*Comment Date:* 5 p.m. ET 12/3/21.

*Docket Numbers:* ER22–403–000.

*Applicants:* Public Service Company of New Mexico.

*Description:* § 205(d) Rate Filing: First Revised Incremental Transmission Service Agreements to be effective 12/1/2021.

*Filed Date:* 11/12/21.

*Accession Number:* 20211112–5297.

*Comment Date:* 5 p.m. ET 12/3/21.

Take notice that the Commission received the following qualifying facility filings:

*Docket Numbers:* QF22–121–000.

*Applicants:* Sonata Green Owner, LLC.

*Description:* Form 556 of Sonata Green Owner, LLC.

*Filed Date:* 11/12/21.

*Accession Number:* 20211112–5212.

*Comment Date:* 5 p.m. ET 12/3/21.

The filings are accessible in the Commission's eLibrary system by clicking on the links or 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.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2021–25174 Filed 11–17–21; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. CP20–48–000]**

### Iroquois Gas Transmission System, L.P.; Notice of Availability of The Final Environmental Impact Statement for The Proposed Enhancement by Compression Project

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared a final environmental impact statement (EIS) for the Enhancement by Compression Project (Project), proposed by Iroquois Gas Transmission System, L.P. (Iroquois) in the above-referenced docket. Iroquois requests authorization to construct and operate natural gas transmission facilities in New York and Connecticut. The Project is designed to provide a total of 125,000 dekatherms per day of incremental firm transportation service for two existing customers of Iroquois, Consolidated Edison Company of New York, Inc. and KeySpan Gas East Corporation doing business as National Grid.

The final EIS assesses the potential environmental effects of the construction and operation of the Project in accordance with the requirements of the National Environmental Policy Act. The final EIS is not a decision document. It presents Commission staff's independent analysis of the environmental issues for the Commission to consider when addressing the merits of all issues in this proceeding.

The final EIS responds to comments that were received on the Commission's September 30, 2020 Environmental Assessment (EA) and June 11, 2021 draft EIS [1] and discloses downstream greenhouse gas emissions for the Project. With the exception of climate change impacts, FERC staff concludes that approval of the proposed Project, with the mitigation measures recommended in this EIS, would not result in significant environmental impacts. FERC staff continues to be unable to determine significance with regards to climate change impacts.

The final EIS incorporates the above-referenced EA, which addressed the potential environmental effects of the construction and operation of the following Project facilities:

- Athens Compressor Station—installation of one new 12,000 horsepower (hp) natural gas-fired turbine (Unit A2) in a new building with associated cooling, filter separators, and other facilities connecting to Iroquois' existing 24-inch-diameter mainline within the existing fenced compressor station boundary (Greene County, New York).
- Dover Compressor Station—installation of one new 12,000 hp natural gas-fired turbine (Unit A2) in a new building with associated cooling, filter separators, and other facilities connecting to Iroquois' existing 24-inch-diameter mainline and expansion of the existing compressor station fenceline within the property boundary (Dutchess County, New York).
- Brookfield Compressor Station—construction of a control/office building, addition of two new 12,000 hp, natural gas-fired turbines (Unit B1 and Unit B2) in a new building with associated cooling, filter separators, and other typical facilities connecting to Iroquois' existing 24-inch-diameter mainline. Additionally, Iroquois would install incremental cooling at Plant 2–A to allow for compressed discharge gas to be cooled, prior to being compressed at the proposed downstream compressors (Units B1 and B2). Iroquois would also replace existing turbine stacks on the existing compressor units (Unit-A1 and Unit-A2) and add other noise reduction measures (*e.g.,* louvers, seals) to minimize existing noise at the site. Modifications at this site would require expansion of the existing compressor station fenceline within the property boundary (Fairfield County, Connecticut).
- Milford Compressor Station—addition of gas cooling to existing compressor units and associated piping to allow for compressed discharge gas to be cooled within the current fenced boundaries of the existing compressor station, where no gas cooling facilities currently exist (New Haven County, Connecticut).

The Commission mailed a copy of the *Notice of Availability of the Final Environmental Impact Statement for the Proposed Enhancement by Compression Project* to federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American Tribes; potentially affected landowners and other interested individuals and groups; and newspapers and libraries in the Project area. The final EIS is only available in electronic format. It may be viewed and downloaded from the FERC's website (*www.ferc.gov*), on the natural gas environmental documents page (*https://www.ferc.gov/industries-data/natural-gas/environment/environmental-documents*). In addition, the final EIS may be accessed by using the eLibrary link on the FERC's website. Click on the eLibrary link (*https://elibrary.ferc.gov/eLibrary/search*) select ''General Search'' and enter the docket number in the ''Docket Number'' field (*i.e.,* CP20–48–000). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

Additional information about the Project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website (*www.ferc.gov*) using the eLibrary link. The eLibrary link also

[1] The Project's Environmental Assessment is available on eLibrary under accession no. 20200930–3011 and the draft EIS is available under accession no. 20210611–3022.

provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription that allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *https://www.ferc.gov/ferc-online/overview* to register for eSubscription.

Dated: November 12, 2021.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2021–25179 Filed 11–17–21; 8:45 am]

**BILLING CODE 6717–01–P**

## FEDERAL DEPOSIT INSURANCE CORPORATION

### Notice to All Interested Parties of Intent To Terminate Receivership

*Notice is hereby given* that the Federal Deposit Insurance Corporation (FDIC or Receiver) as Receiver for the institution listed below intends to terminate its receivership for said institution.

NOTICE OF INTENT TO TERMINATE RECEIVERSHIP

| Fund | Receivership name | City | State | Date of appointment of receiver |
|---|---|---|---|---|
| 10444 | Waccamaw Bank | Whiteville | NC | 06/08/2012 |

The liquidation of the assets for the receivership has been completed. To the extent permitted by available funds and in accordance with law, the Receiver will be making a final dividend payment to proven creditors.

Based upon the foregoing, the Receiver has determined that the continued existence of the receivership will serve no useful purpose. Consequently, notice is given that the receivership shall be terminated, to be effective no sooner than thirty days after the date of this notice. If any person wishes to comment concerning the termination of the receivership, such comment must be made in writing, identify the receivership to which the comment pertains, and sent within thirty days of the date of this notice to: Federal Deposit Insurance Corporation, Division of Resolutions and Receiverships, Attention: Receivership Oversight Department 34.6, 1601 Bryan Street, Dallas, TX 75201.

No comments concerning the termination of this receivership will be considered which are not sent within this time frame.

(Authority: 12 U.S.C. 1819)

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on November 12, 2021.

**Mary Calkins,**

*Acting Assistant Executive Secretary.*

[FR Doc. 2021–25105 Filed 11–17–21; 8:45 am]

**BILLING CODE 6714–01–P**

## FEDERAL HOUSING FINANCE AGENCY

**[No. 2021–N–12]**

### Privacy Act of 1974; System of Records

**AGENCY:** Federal Housing Finance Agency.

**ACTION:** Notice of a new system of records.

**SUMMARY:** In accordance with the requirements of the Privacy Act of 1974, as amended, (Privacy Act), the Federal Housing Finance Agency (FHFA or Agency) is establishing FHFA–26, Public Health Emergency Records System, a system of records under the Privacy Act. This system of records maintains information collected in response to a public health emergency, such as a pandemic or epidemic, from FHFA staff (including political appointees, employees, former employees, detailees, applicants for employment, and interns), contractors, and visitors to FHFA facilities or FHFA-sponsored events, that is necessary to ensure a safe and healthy work environment. FHFA may collect these records in response to a health-related declaration of a national emergency by the President, a public health emergency declared by the Health and Human Service (HHS) Secretary or designated federal official, or a public health emergency declared by a state or local authority. Even in the absence of a declaration of a health-related national emergency or public health emergency, FHFA may collect these records if it determines that a significant risk of substantial harm exists to the health of FHFA staff (as defined above), contractors, and visitors to FHFA facilities or FHFA-sponsored events.

**DATES:** In accordance with 5 U.S.C. 552a(e)(4) and (11), this system of records will go into effect without further notice on November 18, 2021, unless otherwise revised pursuant to comments received. New routine uses will go into effect on December 20, 2021. Comments must be received on or before December 20, 2021. FHFA will publish a new notice if the effective date is delayed in order for the Agency to review the comments or if changes are made based on comments received.

**ADDRESSES:** Submit comments to FHFA, identified by ''2021–N–12,'' using any one of the following methods:

- *Agency Website: www.fhfa.gov/open-for-comment-or-input.*
- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. If you submit your comment to the Federal eRulemaking Portal, please also send it by email to FHFA at *RegComments@fhfa.gov* to ensure timely receipt by FHFA. Please include ''Comments/No. 2021–N–12'' in the subject line of the message.
- *Hand Delivered/Courier:* The hand delivery address is: Clinton Jones, General Counsel, Attention: Comments/No. 2021–N–12, Federal Housing Finance Agency, 400 Seventh Street SW, Washington, DC 20219. The package should be delivered to the Seventh Street entrance Guard Desk, First Floor, on business days between 9 a.m. and 5 p.m., EST.
- *U.S. Mail, United Parcel Service, Federal Express, or Other Mail Service:* The mailing address for comments is: Clinton Jones, General Counsel, Attention: Comments/No. 2021–N–12, Federal Housing Finance Agency, 400 Seventh Street SW, Washington, DC 20219. *Please note that all mail sent to FHFA via the U.S. Postal Service is routed through a national irradiation*

*facility, a process that may delay delivery by approximately two weeks. For any time-sensitive correspondence, please plan accordingly.* See **SUPPLEMENTARY INFORMATION** for additional information on submission and posting of comments.

**FOR FURTHER INFORMATION CONTACT:** Stephanie L. Beavers, Supervisory Security Specialist, *Stephanie.Beavers@fhfa.gov,* (202) 649–3940; Stacy Easter, Privacy Act Officer, *privacy@fhfa.gov* or (202) 649–3803; or Tasha Cooper, Senior Agency Official for Privacy, *privacy@fhfa.gov* or (202) 649–3091 (not toll-free numbers), Federal Housing Finance Agency, 400 Seventh Street SW, Washington, DC 20219. For TTY/TRS users with hearing and speech disabilities, dial 711 and ask to be connected to any of the contact numbers above.

**SUPPLEMENTARY INFORMATION:**

## I. Comments

FHFA seeks public comments on a new system of records and will take all comments into consideration. *See* 5 U.S.C. 552a(e)(4) and (11). In addition to referencing ''Comments/No. 2021–N–12,'' please reference FHFA–26, Public Health Emergency Records System. All comments received will be posted without change on the FHFA website at *https://www.fhfa.gov* and will include any personal information provided, such as name, address (mailing and email), telephone numbers.

## II. Introduction

This notice informs the public of FHFA's proposal to establish a new FHFA system of records. This notice satisfies the Privacy Act's requirement that an agency publish a system of records notice in the **Federal Register** when establishing a new or making a significant change to an agency's system of records. Congress has recognized that application of all requirements of the Privacy Act to certain categories of records may have an undesirable and often unacceptable effect upon agencies in the conduct of necessary public business. Consequently, Congress established general exemptions and specific exemptions that could be used to exempt records from provisions of the Privacy Act. Congress also required that exempting records from provisions of the Privacy Act would require the head of an agency to publish a determination to exempt a record from the Privacy Act as a rule in accordance with the Administrative Procedure Act. The General Counsel has determined that records and information in this system of records are not exempt from the requirements of the Privacy Act.

As required by the Privacy Act, 5 U.S.C. 552a(r), and pursuant to section 7 of OMB Circular No. A–108, *Federal Agency Responsibilities for Review, Reporting, and Publication under the Privacy Act,* (81 FR 94424 (Dec. 23, 2016)), prior to publication of this notice, FHFA submitted a report describing the system of records covered by this notice to the Office of Management and Budget, the Committee on Oversight and Government Reform of the House of Representatives and the Committee on Homeland Security and Governmental Affairs of the Senate.

## III. New System of Records

The purpose of the new ''Public Health Emergency Records System'' (FHFA–26) is to assist FHFA with maintaining a safe and healthy workplace and responding to a public health emergency. These measures may include instituting activities such as: Requiring FHFA staff (as defined above), contractors, and visitors to FHFA facilities or FHFA-sponsored events to provide information related to medical/health screening, contact tracing, and vaccination status before being allowed access to an FHFA facility or FHFA-sponsored event, a regulated entity's facility, or the facility of a third-party for official business purposes.

FHFA may collect these records in response to a health-related declaration of a national emergency by the President, a public health emergency declared by the HHS Secretary or a designated federal official, or a public health emergency declared by a state or local authority. In the absence of a declaration of a health-related national emergency or public health emergency, FHFA may collect these records if it determines that a significant risk of substantial harm exists to the health of FHFA staff (as defined above), contractors, and visitors to FHFA facilities or FHFA-sponsored events. FHFA will collect and maintain the records in accordance with the Americans with Disabilities Act of 1990 and guidance published by the U.S. Occupational Safety and Health Administration, the U.S. Equal Employment Opportunity Commission, and the U.S. Centers for Disease Control and Prevention.

The new system of records is described in detail below.

**SYSTEM NAME AND NUMBER:**

Public Health Emergency Records System, FHFA–26.

**SECURITY CLASSIFICATION:**

Controlled Unclassified Information.

**SYSTEM LOCATION:**

Federal Housing Finance Agency, 400 Seventh Street SW, Washington, DC 20219, and any alternate work site used by employees of FHFA, including contractors assisting agency employees, FHFA-authorized cloud service providers, and FHFA-authorized contractor networks located within the Continental United States.

**SYSTEM MANAGER(S):**

Office of Facilities and Operations Management, Security & Transportation Operations Branch, Supervisory Security Specialist, (202) 649–3940, Federal Housing Finance Agency, 400 Seventh Street SW, Washington, DC 20219.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Workforce safety federal requirements, including the Occupational Safety and Health Act of 1970 (29 U.S.C. 654); Occupational safety and health programs for Federal employees; 5 U.S.C. 7902; the Rehabilitation Act of 1973 (29 U.S.C. 791 *et seq.*); Title VII of the Civil Rights Act (42 U.S.C. 2000e(j)); 29 CFR 1605; the Americans with Disabilities Act (42 U.S.C. 12112(d)(3)(B)); Executive Order Nos. 12196, 12148, 12656, 13991, 13994, 14042 and 14043; the federal laws that authorize FHFA to create and maintain federal records of agency activities, 5 U.S.C. 301, 44 U.S.C. 3101; and the Federal Housing Enterprises Financial Safety and Soundness Act of 1992, as amended (12 U.S.C. 4501 *et seq.*).

**PURPOSE(S) OF THE SYSTEM:**

The Public Health Emergency Records System (FHFA–26) is being established by FHFA to assist the agency with maintaining a safe and healthy workplace and responding to a public health emergency. These measures may include instituting activities such as: Requiring FHFA staff, contractors, and visitors to FHFA facilities or FHFA-sponsored events to provide information related to medical/health screening, contact tracing, and vaccination status before being allowed access to an FHFA facility or FHFA-sponsored event, a regulated entity's facility, or the facility of a third-party for official business purposes, in response to a health-related declaration of a national emergency by the President, a public health emergency declared by the HHS Secretary or designated federal official, or a public health emergency declared by a state or local authority. In the

absence of a declaration of a health-related national emergency or public health emergency, FHFA may collect these records if it determines that a significant risk of substantial harm exists to the health of FHFA staff, contractors, and visitors to FHFA facilities, FHFA-sponsored events, a regulated entity's facility, or a third-party's facility. The system serves four main purposes: 1. Assist with medical/health screening for individuals requesting entry into FHFA facilities or FHFA-sponsored events; 2. Perform contact tracing to notify individuals who may have had exposure to someone who is known or is believed to be infected with a contagious or communicable disease that is the subject of a public health emergency; 3. Establish a record collection to ensure FHFA collects medical information if it determines that a significant risk of substantial harm exists to the health of FHFA Staff, in addition to collecting medical information pursuant to the implementing guidance of applicable federal laws, public health mandates, and executive orders; and 4. Evaluate, approve, deny, and implement requests for medical and religious exceptions.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Individuals covered by this system include FHFA staff (as defined above), contractors, and visitors to FHFA facilities and FHFA-sponsored events during a public health emergency, such as a pandemic or epidemic.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

*Records may include:* Name; contact information (*i.e.,* business and home addresses, business and personal electronic mail (email) addresses, business, home, cellular, personal telephone numbers); and any other information provided.

The system includes medical/health and relevant religious information collected about FHFA staff (as defined above), contractors, and visitors before being allowed to access an FHFA facility or FHFA-sponsored event, a regulated entity's facility, or a third-party's facility for official business purposes including, but not limited to: Temperature checks; expected or confirmed test results for an illness that is the subject of a public health emergency in accordance with federal, state, or local public health orders; symptoms; potential or actual exposure to a contagious or communicable disease; immunization and vaccination information for FHFA staff and contractors; attestation of vaccination and/or exposure to a communicable disease status from visitors; medical history related to the treatment of a contagious or communicable disease that is identified as part of a public health emergency; and the dates associated with any of the foregoing information.

The system also includes information collected from FHFA staff (as defined above), contractors, visitors to an FHFA facility or FHFA-sponsored event, a regulated entity's facility, or facility of a third-party for official business purposes that is necessary to conduct contact tracing that may include, but is not limited to, the above information.

This information may also include, but is not limited to, the dates and the relevant facilities visited or FHFA-sponsored event attended; the names or descriptions (*e.g.,* gender, race, approximate age, and other physical descriptors) of individuals they came into contact with; the specific locations (*e.g.* building floor, specific FHFA office) visited within the facility; the duration of time spent in the facility or in close proximity to other individuals; whether the individual may have potentially come into contact with a contagious person while visiting the facility; travel dates and locations; and contact information (phone, email address, and mailing address).

The system also includes medical, vaccination, and immunization records for FHFA staff and contractors pertaining to any illness that is the subject of a public health emergency including, but not limited to, the type and dose of vaccinations received, date(s) of vaccination(s), and vaccine provider, as well as the absence of vaccination information or other medical information.

The system also includes records documenting the evaluation, approval, and denial of requests for medical and religious exceptions.

**RECORD SOURCE CATEGORIES:**

Information is provided by FHFA staff (as defined above), contractors, and visitors before being allowed access to an FHFA facility, FHFA-sponsored event, a regulated entity's facility, or the facility of a third-party for official business purposes.

For FHFA contractors and visitors, information may also be provided by their employer or the organization the individual is affiliated with for purposes of accessing an FHFA facility or FHFA-sponsored event, a regulated entity's facility, or the facility of a third-party for official business purposes. For any of the individuals above who are minors, the information may be provided by the individual's parent or legal custodian.

Information may also be sourced from existing FHFA systems of records, including but not limited to, Benefits Records (FHFA–10), Emergency Notification System (FHFA–14), Reasonable Accommodations (FHFA–18), and also Government-wide systems of records, such as OPM/GOVT–10, Employee Medical File System Records.

Information is also provided by individuals who are responsible for processing requests for medical and/or religious exceptions.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records and the information contained therein may specifically be disclosed outside of FHFA as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows, to the extent such disclosures are compatible with the purposes for which the information was collected:

(1) To a federal, state, or local agency to the extent necessary to comply with laws governing reporting of infectious disease.

(2) To the emergency contact(s) of FHFA staff (as defined above), contractors, or visitors for purposes of locating such individuals during a public health emergency or communicate that an individual may have been exposed to a contagious or communicable disease as the result of a pandemic or epidemic while visiting an FHFA facility, FHFA-sponsored event, a regulated entity's facility, or a third-party's facility while the individual was there for official business.

(3) To appropriate agencies, entities, and persons when—(a) FHFA suspects or has confirmed that there has been a breach of the system of records; (b) FHFA has determined that as a result of a suspected or confirmed breach there is a risk of harm to individuals, FHFA (including its information systems, programs, and operations), the Federal Government, or national security; and (c) the disclosure made to such agencies, entities, and persons as are reasonably necessary to assist with FHFA's efforts to respond to a suspected or confirmed breach or to prevent, minimize, or remedy harm;

(4) To another federal agency or federal entity, when FHFA determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in: (a) Responding to a suspected or confirmed breach or (b) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or

entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

(5) When there is an indication of a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether federal, state, local, tribal, foreign or a financial regulatory organization charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing a statute, or rule, regulation or order issued pursuant thereto.

(6) To any individual during the course of any inquiry or investigation conducted by FHFA, or in connection with civil litigation, if FHFA has reason to believe that the individual to whom the record is disclosed may have further information about the matters related thereto, and those matters appeared to be relevant at the time to the subject matter of the inquiry.

(7) To any individual with whom FHFA contracts to collect, store, or maintain, or reproduce by typing, photocopy or other means, any record within this system for use by FHFA and its employees in connection with their official duties, or to any individual who is engaged by FHFA to perform clerical or stenographic functions relating to the official business of FHFA.

(8) To a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual.

(9) To a court, magistrate, or administrative tribunal in the course of presenting evidence, including disclosures to opposing counsel or witnesses in the course of civil discovery, litigation, or settlement negotiations or in connection with criminal law proceedings or in response to a subpoena from a court of competent jurisdiction.

(10) To the Office of Management and Budget, Department of Justice (DOJ), Department of Labor, Office of Personnel Management, Equal Employment Opportunity Commission, Office of Special Counsel, or other federal agencies to obtain advice regarding statutory, regulatory, policy, and other requirements related to the purpose for which FHFA collected the records.

(11) To outside counsel contracted by FHFA, DOJ (including United States Attorney Offices), or other federal agencies conducting litigation or in proceedings before any court, adjudicative or administrative body, when it is necessary to the litigation and one of the following is a party to the litigation or has an interest in such litigation—

(a) FHFA;

(b) Any employee of FHFA in his/her official capacity;

(c) Any employee of FHFA in his/her individual capacity where DOJ or FHFA has agreed to represent the employee; or

(d) The United States or any agency thereof, is a party to the litigation or has an interest in such litigation, and FHFA determines that the records are both relevant and necessary to the litigation and the use of such records is compatible with the purpose for which FHFA collected the records.

(12) To the National Archives and Records Administration or other federal agencies pursuant to records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

(13) To an agency, organization, or individual for the purpose of performing audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function.

(14) To a regulated entity or third-party for the purpose of providing FHFA staff or contractors access to a facility for official business purposes, limited to the least amount of information necessary for such purpose as determined or agreed to by FHFA.

**POLICIES AND PRACTICES FOR STORAGE OF RECORDS:**

Records are maintained in electronic or paper format. Electronic records are stored on FHFA's secured network, FHFA-authorized cloud service providers and FHFA-authorized contractor networks located within the Continental United States. Paper records are stored in locked offices, locked file rooms, and locked file cabinets or safes.

**POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:**

*Records may be retrieved by any of the following:* Name, contact information such as address (home, mailing and/or business); telephone numbers (personal and/or business); electronic mail addresses (personal and/or business); photographic identifiers; geospatial and/or geolocation data; date of entry into FHFA facilities; symptoms or other medical information reported; offices or floors visited within FHFA facilities; names of individuals reported as being in close proximity to another individual; the names of individuals contacted as part of contact tracing effort; vaccination status; vaccination date(s); vaccination type(s); and work status (full or part time FHFA employee, contractor, etc.).

**POLICIES AND PRACTICIES FOR RETENTION AND DISPOSAL OF RECORDS:**

Records are retained and disposed of in accordance with National Archives and Records Administration General Records Schedule 2.7, Item 060, Item 070, and General Records Schedule 2.3, Item 020.

**ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:**

Records are maintained in controlled access areas. Electronic records are protected by restricted access procedures, including user identifications and passwords. Only FHFA staff (and FHFA contractors assisting such staff) whose official duties require access are allowed to view, administer, and control these records.

**RECORD ACCESS PROCEDURES:**

See ''Notification Procedures'' Below.

**CONTESTING RECORD PROCEDURES:**

See ''Notification Procedures'' Below.

**NOTIFICATION PROCEDURES:**

Individuals seeking notification of any records about themselves contained in this system should address their inquiry to the Privacy Act Officer, via email to *privacy@fhfa.gov* or by mail to the Federal Housing Finance Agency, 400 Seventh Street SW, Washington, DC 20219, or in accordance with the procedures set forth in 12 CFR part 1204. *Please note that all mail sent to FHFA via the U.S. Postal Service is routed through a national irradiation facility, a process that may delay delivery by approximately two weeks. For any time-sensitive correspondence, please plan accordingly.*

**EXEMPTIONS PROMULGATED FOR THE SYSTEM:**

None.

**HISTORY:**

None.

**Clinton Jones,**

*General Counsel, Federal Housing Finance Agency.*

[FR Doc. 2021–25184 Filed 11–17–21; 8:45 am]

BILLING CODE 8070–01–P

## FEDERAL HOUSING FINANCE AGENCY

**[No. 2021–N–13]**

## Privacy Act of 1974; System of Records

**AGENCY:** Office of Inspector General, Federal Housing Finance Agency (FHFA–OIG).

**ACTION:** Notice of a new system of records.

**SUMMARY:** In accordance with the requirements of the Privacy Act of 1974, as amended, (Privacy Act), the Federal Housing Finance Agency Office of Inspector General (FHFA–OIG) is establishing FHFA–OIG–8, Public Health Emergency Records System, a system of records under the Privacy Act. This system of records maintains information collected in response to a public health emergency, such as a pandemic or epidemic, from contractors and visitors to FHFA–OIG facilities or FHFA–OIG-sponsored events, that is necessary to ensure a safe and healthy work environment. FHFA–OIG may collect these records in response to a health-related declaration of a national emergency by the President, a public health emergency declared by the Health and Human Services (HHS) Secretary or designated federal official, or state or local authority. Even in the absence of a declaration of a health-related national emergency or public health emergency, FHFA–OIG may collect these records if it determines that a significant risk of substantial harm exists to the health of FHFA–OIG staff, contractors, and visitors to FHFA–OIG facilities or FHFA–OIG-sponsored events.

**DATES:** In accordance with 5 U.S.C. 552a(e)(4) and (11), this system of records will go into effect without further notice on November 18, 2021, unless otherwise revised pursuant to comments received. New routine uses will go into effect on December 20, 2021. Comments must be received on or before December 20, 2021. FHFA–OIG will publish a new notice if the effective date is delayed in order for FHFA–OIG to review the comments or if changes are made based on comments received.

**ADDRESSES:** Submit comments to FHFA–OIG, identified by ''FHFA–OIG–SORN,'' using any one of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. If you submit your comment to the Federal eRulemaking Portal, please also send it by email to FHFA–OIG at *privacy@fhfaoig.gov* to ensure timely receipt by FHFA–OIG. Please include ''Comments/FHFA–OIG SORN'' in the subject line of the message.
- *U.S. Mail, United Parcel Service, Federal Express, or Other Mail Service:* The mailing address for comments is: Leonard DePasquale, Chief Counsel, Attention: Comments/FHFA–OIG SORN, Office of Inspector General, Federal Housing Finance Agency, 400 Seventh Street SW, Washington, DC 20219. *Please note that all mail sent to FHFA–OIG via the U.S. Postal Service is routed through a national irradiation facility, a process that may delay delivery by approximately two weeks. For any time-sensitive correspondence, please plan accordingly.* See **SUPPLEMENTARY INFORMATION** for additional information on submission and posting of comments.

**FOR FURTHER INFORMATION CONTACT:** Leonard DePasquale, Chief Counsel, *privacy@fhfaoig.gov,* (202) 730–0880 (not a toll-free number), Office of Inspector General, Federal Housing Finance Agency, 400 Seventh Street SW, Washington, DC 20219. For TTY/TRS users with hearing and speech disabilities, dial 711 and ask to be connected to the contact number above.

**SUPPLEMENTARY INFORMATION:**

### I. Comments

FHFA–OIG seeks public comments on a new system of records and will take all comments into consideration. *See* 5 U.S.C. 552a(e)(4) and (11). In addition to referencing ''Comments/FHFA–OIG SORN,'' please reference the ''Public Health Emergency Records System'' (FHFA–OIG–8). All comments received will be posted without change on the FHFA–OIG website at *https://www.fhfaoig.gov,* and will include any personal information provided, such as name, address (mailing and email), telephone numbers, and any other information you provide.

### II. Introduction

This notice informs the public of FHFA–OIG's proposal to establish a new FHFA–OIG system of records. This notice satisfies the Privacy Act's requirement that an agency publish a system of records notice in the **Federal Register** when establishing a new or making a significant change to an agency's system of records. Congress has recognized that application of all requirements of the Privacy Act to certain categories of records may have an undesirable and often unacceptable effect upon agencies in the conduct of necessary public business. Consequently, Congress established general exemptions and specific exemptions that could be used to exempt records from provisions of the Privacy Act. Congress also required that exempting records from provisions of the Privacy Act would require the head of an agency to publish a determination to exempt a record from the Privacy Act as a rule in accordance with the Administrative Procedure Act.

As required by the Privacy Act, 5 U.S.C. 552a(r), and pursuant to section 7 of OMB Circular No. A–108, *Federal Agency Responsibilities for Review, Reporting, and Publication under the Privacy Act* (81 FR 94424 (Dec. 23, 2016)), prior to publication of this notice, FHFA–OIG submitted a report describing the system of records covered by this notice to the Office of Management and Budget, the Committee on Oversight and Reform of the House of Representatives, and the Committee on Homeland Security and Governmental Affairs of the Senate.

### III. New System of Records

The purpose of the new Public Health Emergency Records System (FHFA–OIG–8) is to assist FHFA–OIG with maintaining a safe and healthy workplace and responding to a public health emergency. These measures may include instituting activities such as requiring contractors and visitors to FHFA–OIG facilities or FHFA–OIG-sponsored events to provide information related to medical/health screening, contact tracing, and vaccination status before being allowed access to an FHFA–OIG facility or FHFA–OIG-sponsored event.

FHFA–OIG may collect these records in response to a health-related declaration of a national emergency by the President, a public health emergency declared by the Health and Human Services (HHS) Secretary or a designated federal official, or state or local authority. Even in the absence of a declaration of a health-related national emergency or public health emergency, FHFA–OIG may collect these records if it determines that a significant risk of substantial harm exists to the health of FHFA–OIG staff, contractors, and visitors to FHFA–OIG facilities or FHFA–OIG-sponsored events. FHFA–OIG will collect and maintain the records in accordance with the Americans with Disabilities Act of 1990 and guidance published by the U.S. Occupational Safety and Health Administration, the U.S. Equal Employment Opportunity Commission, and the U.S. Centers for Disease Control and Prevention.

The new system of records is described in detail below.

**SYSTEM NAME AND NUMBER:**

Public Health Emergency Records System, FHFA–OIG–8.

**SECURITY CLASSIFICATION:**

Controlled Unclassified Information.

**SYSTEM LOCATION:**

Office of Inspector General, Federal Housing Finance Agency, 400 Seventh Street SW, Washington, DC 20219, and any alternate work site used by FHFA–OIG employees, including contractors assisting FHFA–OIG employees, FHFA–OIG-authorized cloud service providers, and FHFA–OIG-authorized contractor networks located within the Continental United States.

**SYSTEM MANAGER(S):**

Division of Human Resources, (202) 730–4014, Office of Inspector General, Federal Housing Finance Agency, 400 Seventh Street SW, Washington, DC 20219.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Workforce safety federal requirements, including the Occupational Safety and Health Act of 1970, Occupational safety and health programs for Federal employees, 5 U.S.C. 7902; the Rehabilitation Act of 1973 (29 U.S.C. 791 *et seq.*); Title VII of the Civil Rights Act (42 U.S.C. 2000e(j)); 29 CFR 1605; the Americans with Disabilities Act, including 42 U.S.C. 12112(d)(3)(B); Executive Order Nos. 12196, 12148, 12656, 13991, 13994, 14042 and 14043; and 12 U.S.C. 4517(d) and 5 U.S.C. App. 3.

**PURPOSES OF THE SYSTEM:**

The Public Health Emergency Records System (FHFA–OIG–8) is being established by FHFA–OIG to assist the office with maintaining a safe and healthy workplace and responding to a public health emergency. These measures may include instituting activities such as requiring contractors and visitors to FHFA–OIG facilities or FHFA–OIG-sponsored events to provide information related to medical/health screening, contact tracing, and vaccination status before being allowed access to an FHFA–OIG facility or FHFA–OIG-sponsored event, in response to a health-related declaration of a national emergency by the President, a public health emergency declared by the HHS Secretary or designated federal official, or a public health emergency declared by a state or local authority. In the absence of a declaration of a health-related national emergency or public health emergency, FHFA–OIG may collect these records if it determines that a significant risk of substantial harm exists to the health of FHFA–OIG staff, contractors, and visitors to FHFA–OIG facilities or FHFA–OIG-sponsored events. The system serves four main purposes: (1) Assist with medical/health screening for individuals requesting entry into FHFA–OIG facilities or FHFA–OIG-sponsored events; (2) Perform contact tracing to notify individuals who may have had exposure to someone who is known or is believed to be infected with a contagious or communicable disease that is the subject of a public health emergency; and (3) Establish a record collection to ensure FHFA–OIG collects medical information pursuant to the implementing guidance of applicable federal laws, public health mandates, and executive orders.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Individuals covered by this system include contractors and visitors to FHFA–OIG facilities and FHFA–OIG-sponsored events during a public health emergency, such as a pandemic or epidemic.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Records may include name; contact information (*i.e.,* business and home addresses; business and personal electronic mail (email) addresses; business, home, cellular, and personal telephone numbers); and any other information provided.

The system includes medical/health information collected about contractors and visitors who access or attempt to access an FHFA–OIG facility or FHFA–OIG-sponsored event, including, but not limited to: Temperature checks, expected or confirmed test results for an illness that is the subject of a public health emergency in accordance with federal, state or local public health orders; symptoms; potential or actual exposure to a contagious or communicable disease; immunization and vaccination information for contractors; attestation of vaccination and/or exposure to a communicable disease status from visitors; medical history related to the treatment of a contagious or communicable disease that is identified as part of a public health emergency; and the dates associated with any of the foregoing information.

The system also includes information collected from contractors and visitors to FHFA–OIG facilities and FHFA–OIG-sponsored events necessary to conduct contact tracing that may include the above information.

This information may include the dates and FHFA–OIG facility visited or FHFA–OIG-sponsored event that was attended; the names or descriptions (*e.g.,* gender, race, approximate age, and other physical descriptors) of individuals they came into contact with; the specific locations (*e.g.,* building floor, specific FHFA–OIG office) visited within the facility; the duration of time spent in the facility or in close proximity to other individuals; whether the individual may have potentially come into contact with a contagious person while visiting the facility; travel dates and locations; and contact information (phone, email address, and mailing address).

The system also includes medical, vaccination, and immunization records from contractors pertaining to any illness that is the subject of a public health emergency including, but not limited to, the type and dose of vaccinations received, date(s) of vaccination(s), and vaccine provider as well as the absence of vaccination information or other medical information.

**RECORD SOURCE CATEGORIES:**

Information is provided by contractors and visitors who access or attempt to access an FHFA–OIG facility or FHFA–OIG-sponsored events. For FHFA–OIG contractors or visitors, information may be also provided by their employer/or organization the individual is affiliated with for purposes of accessing or attempting to access an FHFA–OIG facility or FHFA–OIG-sponsored event. For any of the individuals above who are minors, the information may be provided by the individual's parent or legal custodian. Information may also be sourced from existing Government-wide systems of records.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records and the information contained in them may specifically be disclosed outside of FHFA–OIG as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows, to the extent such disclosures are compatible with the purposes for which the information was collected:

1. To a federal, state, or local agency to the extent necessary to comply with laws governing reporting of infectious disease.

2. To emergency contact(s) of FHFA–OIG staff members, contractors, or visitors for purposes of locating such individuals during a public health emergency or to communicate that an individual may have been exposed to a

contagious or communicable disease as the result of a pandemic or epidemic while visiting an FHFA–OIG facility or FHFA–OIG sponsored event.

3. To appropriate agencies, entities, and persons when—(a) FHFA–OIG suspects or has confirmed that there has been a breach of the system of records; (b) FHFA–OIG has determined that as a result of a suspected or confirmed breach there is a risk of harm to individuals, FHFA–OIG (including its information systems, programs, and operations), the Federal Government, or national security; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist with FHFA–OIG's efforts to respond to a suspected or confirmed breach or to prevent, minimize, or remedy harm.

4. To another federal agency or federal entity, when FHFA–OIG determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (a) responding to a suspected or confirmed breach; or (b) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

5. When there is an indication of a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule, or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether federal, state, local, tribal, foreign, or a financial regulatory organization charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing a statute, or rule, regulation, or order issued pursuant thereto.

6. To any individual during the course of any inquiry or investigation conducted by FHFA–OIG, or in connection with civil litigation, if FHFA–OIG has reason to believe that the individual to whom the record is disclosed may have further information about the matters related thereto, and those matters appeared to be relevant at the time to the subject matter of the inquiry.

7. To any individual with whom FHFA–OIG contracts to collect, store, or maintain, or reproduce by typing, photocopy or other means, any record within this system for use by FHFA–OIG and its employees in connection with their official duties, or to any individual who is engaged by FHFA–OIG to perform clerical or stenographic functions relating to the official business of FHFA–OIG.

8. To a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual.

9. To a court, magistrate, or administrative tribunal in the course of presenting evidence, including disclosures to opposing counsel or witnesses in the course of civil discovery, litigation, or settlement negotiations or in connection with criminal law proceedings or in response to a subpoena from a court of competent jurisdiction.

10. To the Office of Management and Budget, Department of Justice (DOJ), Department of Labor, Office of Personnel Management, Equal Employment Opportunity Commission, Office of Special Counsel, or other federal agencies to obtain advice regarding statutory, regulatory, policy, and other requirements related to the purpose for which FHFA–OIG collected the records.

11. To outside counsel contracted by FHFA–OIG, DOJ (including United States Attorney Offices), or other federal agencies conducting litigation or in proceedings before any court, adjudicative or administrative body, when it is necessary to the litigation and one of the following is a party to the litigation or has an interest in such litigation—

(a) FHFA–OIG;

(b) An employee of FHFA–OIG in his/her official capacity;

(c) An employee of FHFA–OIG in his/her individual capacity where DOJ or FHFA–OIG has agreed to represent the employee; or

(d) The United States, or an agency thereof, is a party to the litigation or has an interest in such litigation, and FHFA–OIG determines that the records are both relevant and necessary to the litigation and the use of such records is compatible with the purpose for which FHFA–OIG collected the records.

12. To the National Archives and Records Administration or other federal agencies pursuant to records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

13. To an agency, organization, or individual for the purpose of performing audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function.

14. To another federal Office of the Inspector General, law enforcement Task Force, or other federal, state, local, foreign, territorial, or tribal unit of government, other public authorities, or self-regulatory organizations for the purpose of preventing and/or identifying fraud, waste, or abuse related to FHFA's programs or operations.

15. To other federal Offices of Inspector General or other entities, during the conduct of internal and external peer reviews of FHFA–OIG.

16. To the public or to the media for release to the public when the matter under audit, review, evaluation, investigation, or inquiry has become public knowledge, or when the Inspector General determines that such disclosure is necessary either to preserve confidence in the integrity of FHFA–OIG's audit, review, evaluation, investigative, or inquiry processes or is necessary to demonstrate the accountability of FHFA–OIG employees, officers or individuals covered by the system, unless the Inspector General or his/her delegee determines, after consultation with counsel and the Senior Privacy Official, that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

17. To Congress, congressional committees, or the staffs thereof, once an FHFA–OIG report or management alert has become final and the Inspector General determines that its disclosure is necessary to fulfill the Inspector General's responsibilities under the Inspector General Act of 1978.

18. To a federal agency or other entity which requires information relevant to a decision concerning the hiring, appointment, or retention of an employee or contractor; the assignment, detail, or deployment of an employee or contractor; the issuance, renewal, suspension, or revocation of an employee's or contractor's security clearance; the execution of a security or suitability investigation; the adjudication of liability; or coverage under FHFA–OIG's liability insurance policy.

19. To the Council of the Inspectors General on Integrity and Efficiency and its committees, another federal Office of Inspector General, or other Federal law enforcement office in connection with an allegation of wrongdoing by the Inspector General or by designated FHFA–OIG staff members.

**POLICIES AND PRACTICES FOR STORAGE OF RECORDS:**

Records are maintained in electronic or paper format. Electronic records are stored on FHFA–OIG's secured network, FHFA–OIG-authorized cloud service

providers and FHFA–OIG-authorized contractor networks located within the Continental United States. Paper records are stored in locked offices, locked file rooms and locked file cabinets or safes.

**POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:**

Records may be retrieved by any of the following: name, contact information such as address (home, mailing, and/or business); telephone numbers (personal and/or business); electronic mail addresses (personal and/or business), photographic identifiers; geospatial and/or geolocation data, date of entry into FHFA–OIG facilities; symptoms or other medical information reported; offices or floors visited within FHFA–OIG facilities; names of individuals reported as being in close proximity to another individual; the names of individuals contacted as part of contact tracing effort; vaccination status; vaccination date(s); vaccination type(s); and work status (full or part time contractor, etc.).

**POLICIES AND PRACTICIES FOR RETENTION AND DISPOSAL OF RECORDS:**

Records are retained and disposed of in accordance with National Archives and Records Administration General Records Schedule 2.7, Item 060 and Item 070.

**ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:**

Records are maintained in controlled access areas. Electronic records are protected by restricted access procedures, including user identifications and passwords. Only FHFA–OIG staff (and FHFA–OIG contractors assisting such staff) whose official duties require access are allowed to view, administer, and control these records.

**RECORD ACCESS PROCEDURES:**

See ''Notification Procedures,'' below.

**CONTESTING RECORD PROCEDURES:**

See ''Notification Procedures,'' below.

**NOTIFICATION PROCEDURES:**

Individuals seeking notification of any records about themselves contained in this system should address their inquiry via email to *privacy@fhfaoig.gov,* or by mail to the Office of Inspector General, Federal Housing Finance Agency, 400 Seventh Street SW, 3rd Floor, Washington, DC 20219, or in accordance with the procedures set forth in 12 CFR part 1204. *Please note that all mail sent to FHFA–OIG via the U.S. Postal Service is routed through a national irradiation facility, a process that may delay delivery by approximately two weeks. For any time-sensitive correspondence, please plan accordingly.*

**EXEMPTIONS PROMULGATED FOR THE SYSTEM:**

None.

**HISTORY:**

None.

**Leonard DePasquale,**

*Chief Counsel, Federal Housing Finance Agency, Office of Inspector General.*

[FR Doc. 2021–25189 Filed 11–17–21; 8:45 am]

BILLING CODE 8070–01–P

## DEPARTMENT OF THE TREASURY

## Office of the Comptroller of the Currency

## FEDERAL RESERVE SYSTEM

## FEDERAL DEPOSIT INSURANCE CORPORATION

## Joint Report: Differences in Accounting and Capital Standards Among the Federal Banking Agencies as of September 30, 2021; Report to Congressional Committees

**AGENCY:** Office of the Comptroller of the Currency (OCC), Treasury; Board of Governors of the Federal Reserve System (Board); and Federal Deposit Insurance Corporation (FDIC).

**ACTION:** Report to Congressional committees.

**SUMMARY:** The Office of the Comptroller of the Currency (OCC), the Board of Governors of the Federal Reserve System (Board), and the Federal Deposit Insurance Corporation (FDIC) (collectively, the agencies) have prepared this report pursuant to section 37(c) of the Federal Deposit Insurance Act. Section 37(c) requires the agencies to jointly submit an annual report to the Committee on Financial Services of the U.S. House of Representatives and to the Committee on Banking, Housing, and Urban Affairs of the U.S. Senate describing differences among the accounting and capital standards used by the agencies for insured depository institutions (institutions).[1] Section 37(c) requires that this report be published in the **Federal Register**. The agencies have not identified any material differences among the agencies' accounting and capital standards applicable to the insured depository institutions they regulate and supervise.

**FOR FURTHER INFORMATION CONTACT:**

*OCC:* Andrew Tschirhart, Risk Expert, Capital and Regulatory Policy, (202) 649–6370, Rima Kundnani, Counsel, Chief Counsel's Office, (202) 649–5490, Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219.

*Board:* Andrew Willis, Manager, (202) 912–4323, Jennifer McClean, Senior Financial Institution Policy Analyst II, (202) 785–6033, Division of Supervision and Regulation, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

*FDIC:* Benedetto Bosco, Chief, Capital Policy Section, (703) 245–0778, Richard Smith, Capital Policy Analyst, Capital Policy Section, (703) 254–0782, Division of Risk Management Supervision, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

**SUPPLEMENTARY INFORMATION:** The text of the report follows:

### Report to the Committee on Financial Services of the U.S. House of Representatives and to the Committee on Banking, Housing, and Urban Affairs of the U.S. Senate Regarding Differences in Accounting and Capital Standards Among the Federal Banking Agencies

### Introduction

In accordance with section 37(c), the agencies are submitting this joint report, which covers differences among their accounting or capital standards existing as of September 30, 2021, applicable to institutions.[2] In recent years, the agencies have acted together to harmonize their accounting and capital standards and eliminate as many differences as possible. As of September 30, 2021, the agencies have not identified any material differences among the agencies' accounting standards applicable to institutions.

In 2013, the agencies revised the risk-based and leverage capital rule for institutions (capital rule),[3] which harmonized the agencies' capital rule in

[1] 12 U.S.C. 1831n(c)(1) and 12 U.S.C. 1831n(c)(3).

[2] Although not required under section 37(c), this report includes descriptions of certain of the Board's capital standards applicable to depository institution holding companies where such descriptions are relevant to the discussion of capital standards applicable to institutions.

[3] *See* 78 FR 62018 (October 11, 2013) (final rule issued by the OCC and the Board); 78 FR 55340 (September 10, 2013) (interim final rule issued by the FDIC). The FDIC later issued its final rule in 79 FR 20754 (April 14, 2014). The agencies' respective capital rule is at 12 CFR part 3 (OCC), 12 CFR part 217 (Board), and 12 CFR part 324 (FDIC). The capital rule applies to institutions, as well as to certain bank holding companies and savings and loan holding companies. *See* 12 CFR 217.1(c).

a comprehensive manner.[4] Since 2013, the agencies have revised the capital rule on several occasions, further reducing the number of differences in the agencies' capital rule.[5] Today, only a few differences remain, which are statutorily mandated for certain categories of institutions or which reflect certain technical, generally nonmaterial differences among the agencies' capital rule. No new material differences were identified in the capital standards applicable to institutions in this report compared to the previous report submitted by the agencies pursuant to section 37(c).

## Differences in the Standards Among the Federal Banking Agencies

### Differences in Accounting Standards

As of September 30, 2021, the agencies have not identified any material differences among themselves in the accounting standards applicable to institutions.

### Differences in Capital Standards

The following are the remaining technical differences among the capital standards of the agencies' capital rule.[6]

*Definitions*

The agencies' capital rule largely contains the same definitions.[7] The differences that exist generally serve to accommodate the different needs of the institutions that each agency charters, regulates, and/or supervises.

The agencies' capital rule has differing definitions of a pre-sold construction loan. The capital rule of all three agencies provides that a pre-sold construction loan means any ''one-to-four family residential construction loan to a builder that meets the requirements of section 618(a)(1) or (2) of the Resolution Trust Corporation Refinancing, Restructuring, and Improvement Act of 1991 (12 U.S.C. 1831n), and, in addition to other criteria, the purchaser has not terminated the contract.''[8] The Board's definition provides further clarification that, if a purchaser has terminated the contract, the institution must immediately apply a 100 percent risk weight to the loan and report the revised risk weight in the next quarterly Consolidated Reports of Condition and Income (Call Report).[9] Similarly, if the purchaser has terminated the contract, the OCC and FDIC capital rule would immediately disqualify the loan from receiving a 50 percent risk weight, and would apply a 100 percent risk weight to the loan. The change in risk weight would be reflected in the next quarterly Call Report. Thus, the minor wording difference between the agencies should have no practical consequence.

*Capital Components and Eligibility Criteria for Regulatory Capital Instruments*

While the capital rule generally provides uniform eligibility criteria for regulatory capital instruments, there are some textual differences among the agencies' capital rule. The capital rule of each of the three agencies requires that, for an instrument to qualify as common equity tier 1 or additional tier 1 capital, cash dividend payments be paid out of net income and retained earnings, but the Board's capital rule also allows cash dividend payments to be paid out of related surplus.[10] In addition, both the Board's capital rule and the FDIC's capital rule include an additional sentence noting that institutions regulated by each agency are subject to restrictions independent of the capital rule on paying dividends out of surplus and/or that would result in a reduction of capital stock.[11] These additional sentences do not create differences in substance between the agencies' capital standards, but rather note that restrictions apply under separate regulations.

The provision in the Board's capital rule that allows dividends to be paid out of related surplus is a difference in substance among the agencies' capital rule. However, due to the restrictions on institutions regulated by the Board in separate regulations, this additional language in the Board's rule has a practical impact only on bank holding companies and savings and loan holding companies and is not a difference as applied to institutions. The agencies apply the criteria for determining eligibility of regulatory capital instruments in a manner that ensures consistent outcomes for institutions.

In addition, the Board's capital rule includes a requirement that a Board-regulated institution[12] must obtain prior approval before redeeming regulatory capital instruments.[13] This requirement effectively applies only to a bank holding company or a savings and loan holding company and is, therefore, not included in the OCC and FDIC capital rule. All three agencies require institutions to obtain prior approval before redeeming regulatory capital instruments in other regulations.[14] The additional provision in the Board's capital rule, therefore, only has a practical impact on bank holding companies and savings and loan holding companies and is not a difference as applied to institutions.

*Capital Deductions*

There is a technical difference between the FDIC's capital rule and the OCC's and Board's capital rule with regards to an explicit requirement for deduction of examiner-identified losses. The agencies require their examiners to determine whether their respective supervised institutions have appropriately identified losses. The FDIC's capital rule, however, explicitly requires FDIC-supervised institutions to deduct identified losses from common equity tier 1 capital elements, to the extent that the institutions' common equity tier 1 capital would have been reduced if the appropriate accounting entries had been recorded.[15] Generally, identified losses are those items that an examiner determines to be chargeable against income, capital, or general valuation allowances.

For example, identified losses may include, among other items, assets classified as loss, off-balance-sheet items classified as loss, any expenses that are necessary for the institution to record in order to replenish its general

[4] The capital rule reflects the scope of each agency's regulatory jurisdiction. For example, the Board's capital rule includes requirements related to bank holding companies, savings and loan holding companies, and state member banks, while the FDIC's capital rule includes provisions for state nonmember banks and state savings associations, and the OCC's capital rule includes provisions for national banks and federal savings associations.

[5] *See e.g.,* 84 FR 35234 (July 22, 2019). The OCC and FDIC revised their capital rule to conform with language in the Board's capital rule related to the qualification criteria for additional tier 1 capital instruments and the definition of corporate exposures. As a result, these differences, which were included in previous reports submitted by the agencies pursuant to section 37(c), have been eliminated.

[6] Certain minor differences, such as terminology specific to each agency for the institutions that it supervises, are not included in this report.

[7] *See* 12 CFR 3.2 (OCC); 12 CFR 217.2 (Board); 12 CFR 324.2 (FDIC).

[8] 12 CFR 3.2 (OCC); 12 CFR 217.2 (Board); 12 CFR 324.2 (FDIC).

[9] 12 CFR 217.2.

[10] 12 CFR 217.20(b)(1)(v) and 217.20(c)(1)(viii) (Board).

[11] 12 CFR 217.20(b)(1)(v) and 217.20(c)(1)(viii) (Board); 12 CFR 324.20(b)(1)(v) and 324.20(c)(1)(viii) (FDIC). Although not referenced in the capital rule, the OCC has similar restrictions on dividends; 12 CFR 5.55 and 12 CFR 5.63. Certain restrictions on the payment of dividends that apply under separate regulations, and therefore not discussed in this report, are different among the agencies. Compare 12 CFR 208.5 (Board) and 12 CFR 5.64 (OCC) with 12 CFR 303.241 (FDIC).

[12] Board-regulated institution means a state member bank, bank holding company, or savings and loan holding company. *See* 12 CFR 217.2.

[13] 12 CFR 217.20(f); *see also* 12 CFR 217.20(b)(1)(iii).

[14] *See* 12 CFR 5.46, 5.47, 5.55, and 5.56 (OCC); 12 CFR 208.5 (Board); 12 CFR 303.241 (FDIC).

[15] 12 CFR 324.22(a)(9).

valuation allowances to an adequate level, and estimated losses on contingent liabilities. The Board and the OCC expect their supervised institutions to promptly recognize examiner-identified losses, but the requirement is not explicit under their capital rule. Instead, the Board and the OCC apply their supervisory authorities to ensure that their supervised institutions charge off any identified losses.

*Subsidiaries of Savings Associations*

There are special statutory requirements for the agencies' capital treatment of a savings association's investment in or credit to its subsidiaries as compared with the capital treatment of such transactions between other types of institutions and their subsidiaries. Specifically, the Home Owners' Loan Act (HOLA) distinguishes between subsidiaries of savings associations engaged in activities that are permissible for national banks and those engaged in activities that are not permissible for national banks.[16]

When subsidiaries of a savings association are engaged in activities that are not permissible for national banks,[17] the parent savings association generally must deduct the parent's investment in and extensions of credit to these subsidiaries from the capital of the parent savings association. If a subsidiary of a savings association engages solely in activities permissible for national banks, no deduction is required and investments in and loans to that organization may be assigned the risk weight appropriate for the activity.[18] As the appropriate federal banking agencies for federal and state savings associations, respectively, the OCC and the FDIC apply this capital treatment to those types of institutions. The Board's regulatory capital framework does not apply to savings associations and, therefore, does not include this requirement.

*Tangible Capital Requirement*

Federal statutory law subjects savings associations to a specific tangible capital requirement but does not similarly do so with respect to banks. Under section 5(t)(2)(B) of HOLA, savings associations are required to maintain tangible capital in an amount not less than 1.5 percent of total assets.[19] The capital rule of the OCC and the FDIC includes a requirement that savings associations maintain a tangible capital ratio of 1.5 percent.[20] This statutory requirement does not apply to banks and, thus, there is no comparable regulatory provision for banks. The distinction is of little practical consequence, however, because under the Prompt Corrective Action (PCA) framework, all institutions are considered critically undercapitalized if their tangible equity falls below 2 percent of total assets.[21] Generally speaking, the appropriate federal banking agency must appoint a receiver within 90 days after an institution becomes critically undercapitalized.[22]

*Enhanced Supplementary Leverage Ratio*

The agencies adopted enhanced supplementary leverage ratio standards that took effect beginning on January 1, 2018.[23] These standards require certain bank holding companies to exceed a 5 percent supplementary leverage ratio to avoid limitations on distributions and certain discretionary bonus payments and also require the subsidiary institutions of these bank holding companies to meet a 6 percent supplementary leverage ratio to be considered ''well capitalized'' under the PCA framework.[24] The rule text establishing the scope of application for the enhanced supplementary leverage ratio differs among the agencies. The Board and the FDIC apply the enhanced supplementary leverage ratio standards for institutions based on parent bank holding companies being identified as global systemically important bank holding companies as defined in 12 CFR 217.2.[25] The OCC applies enhanced supplementary leverage ratio standards to the institution subsidiaries under their supervisory jurisdiction of a top-tier bank holding company that has more than $700 billion in total assets or more than $10 trillion in assets under custody.[26]

**Michael J. Hsu,**

*Acting Comptroller of the Currency.*

Board of Governors of the Federal Reserve System.

**Ann E. Misback,**

*Secretary of the Board.*

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on November 8, 2021.

**James P. Sheesley,**

*Assistant Executive Secretary.*

[FR Doc. 2021–25159 Filed 11–17–21; 8:45 am]

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## 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 December 20, 2021.

*A. Federal Reserve Bank of Dallas* (Karen Smith, Director, Applications) 2200 North Pearl Street, Dallas, Texas 75201–2272:

[16] 12 U.S.C. 1464(t)(5).

[17] Subsidiaries engaged in activities not permissible for national banks are considered non-includable subsidiaries.

[18] A deduction from capital is only required to the extent that the savings association's investment exceeds the generally applicable thresholds for deduction of investments in the capital of an unconsolidated financial institution.

[19] 12 U.S.C. 1464(t)(1)(A)(ii) and (t)(2)(B).

[20] 12 CFR 3.10(a)(6) (OCC); 12 CFR 324.10(a)(6) (FDIC). The Board's regulatory capital framework does not apply to savings associations and, therefore, does not include this requirement.

[21] *See* 12 U.S.C. 1831o(c)(3); *see also* 12 CFR 6.4 (OCC); 12 CFR 208.45 (Board); 12 CFR 324.403 (FDIC).

[22] 12 U.S.C. 1831o(h)(3)(A).

[23] *See* 79 FR 24528 (May 1, 2014).

[24] 12 CFR 6.4(b)(1)(i)(D)(2) (OCC); 12 CFR 208.43(b)(1)(iv)(B) (Board); 12 CFR 324.403(b)(1)(v) (FDIC).

[25] 12 CFR 208.43(b)(1)(iv)(B) (Board); 12 CFR 324.403(b)(1)(ii) (FDIC).

[26] 12 CFR 6.4(b)(1)(i)(D)(2) (OCC).

1. *Animo Bancorp, Inc., Ganado, Texas;* to become a bank holding company by acquiring Ganado Bancshares, Inc, and thereby indirectly acquiring The Citizens State Bank of Ganado, both of Ganado, Texas.

*B. Federal Reserve Bank of Atlanta* (Erien O. Terry, Assistant Vice President) 1000 Peachtree Street NE, Atlanta, Georgia 30309. Comments can also be sent electronically to *Applications.Comments@atl.frb.org:*

1. *CB Investment Holdings, LLC, Nashville, Tennessee;* to become a bank holding company by acquiring CSB&T Bancorp, Inc., and thereby indirectly acquiring Citizens Savings Bank & Trust Company, both of Nashville, Tennessee.

Board of Governors of the Federal Reserve System, November 15, 2021.

**Michele Taylor Fennell,**

*Deputy Associate Secretary of the Board.*

[FR Doc. 2021–25195 Filed 11–17–21; 8:45 am]

**BILLING CODE P**

## FEDERAL RESERVE SYSTEM

### Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than December 3, 2021.

*A. Federal Reserve Bank of Dallas* (Karen Smith, Director, Applications) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *Lane Lowery and The Lane Lowery 2021 Trust, both of Huntington, Texas, and The Shana Lowery De Paoli 2021 Trust and Shana Lowery De Paoli, individually, and as trustee to both trusts, both of Dallas, Texas;* to join a group acting in concert to retain voting shares of UBank Holdings, Inc. (formerly, Huntington Bancshares, Inc.), and thereby indirectly retain voting shares of UBank, both of Huntington, Texas.

Board of Governors of the Federal Reserve System, November 15, 2021.

**Michele Taylor Fennell,**

*Deputy Associate Secretary of the Board.*

[FR Doc. 2021–25180 Filed 11–17–21; 8:45 am]

**BILLING CODE P**

## FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

### Privacy Act of 1974; System of Records

**AGENCY:** Federal Retirement Thrift Investment Board (FRTIB).

**ACTION:** Notice of a modified system of records.

**SUMMARY:** Pursuant to the Privacy Act of 1974, the Federal Retirement Thrift Investment Board (FRTIB) proposes to modify an existing system of records notice in order to collect information related to sincerely held religious beliefs, practices, or observances when necessary to evaluate requests for a religious accommodation.

**DATES:** The modifications to this system will become effective upon publication in today's **Federal Register**. FRTIB invites written comments on the routine uses and other aspects of this system of records. Submit any comments by December 20, 2021.

**ADDRESSES:** You may submit written comments to FRTIB by any one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the website instructions for submitting comments.
- *Fax:* 202–942–1676.
- *Mail or Hand Delivery:* Office of General Counsel, Federal Retirement Thrift Investment Board, 77 K Street NE, Suite 1000, Washington, DC 20002.

**FOR FURTHER INFORMATION CONTACT:** Peter Robbins, Chief Privacy Officer, Federal Retirement Thrift Investment Board, Office of General Counsel, 77 K Street NE, Suite 1000, Washington, DC 20002, (202) 942–1600. For access to any of the FRTIB's systems of records, contact Amanda Haas, FOIA Officer, Office of General Counsel, at the above address and phone number.

**SUPPLEMENTARY INFORMATION:** Records contained in this system are collected to: (1) Allow FRTIB to collect and maintain records on prospective, current, and former employees with disabilities who request or receive a reasonable accommodation by FRTIB; (2) allow FRTIB to collect and maintain records on prospective, current, and former employees with sincerely held religious beliefs, practices, or observances who request or receive an accommodation by FRTIB; (3) track and report the processing of requests for FRTIB-wide reasonable accommodations to comply with applicable laws and regulations; and (4) preserve and maintain the confidentiality of medical and religious information submitted by or on behalf of applicants or employees requesting a reasonable accommodation.

On September 9, 2021, the President issued Executive Order 14043, *Executive Order on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees,* requiring the COVID–19 vaccination for all Federal employees, subject to such exceptions as required by law. On October 4, 2021, the Safer Federal Workforce Task Force issued guidance to Federal agencies regarding collecting information for medical and religious accommodations. In order to meet the requirements of Executive Order 14043 and the Task Force recommendations, the FRTIB is modifying this system of records notice to include the collection of information related to religious accommodations.

Changes being made to this SORN are for that purpose and include changes to the Authority for Maintenance of the System, Purpose(s) of the System, Categories of Individuals Covered by the System, Categories of Records in the System, Routine Uses of Records Maintained in the System, Policies and Practices for Retention and Disposal of Records, and the Publication History of the System of Records Notice.

There are no new routine uses being published at this time; four previously published routine uses have been removed from this publication of SORN FRTIB–18.

In accordance with 5 U.S.C. 552a(r), the Agency has provided a report to

OMB and to Congress on this notice of modified systems of records.

**Dharmesh Vashee,**

*General Counsel and Senior Agency Official for Privacy.*

**SYSTEM NAME AND NUMBER:**

FRTIB–18, Reasonable Accommodation Records.

**SECURITY CLASSIFICATION:**

Unclassified.

**SYSTEM LOCATION:**

Records are maintained at the Federal Retirement Thrift Investment Board, 77 K Street NE, Suite 1000, Washington, DC 20002. Records may also be maintained at an additional location for Business Continuity Purposes.

**SYSTEM MANAGER(S):**

Human Resources Officer, Federal Retirement Thrift Investment Board, 77 K Street NE, Suite 1000, Washington, DC 20002, (202) 942–1600.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

5 U.S.C. 8474; 5 U.S.C. 301; 29 U.S.C. 791; 42 U.S.C. 12101 *et seq.;* 42 U.S.C. 2000e *et seq.;* 42 U.S.C. 2000bb *et seq.;* 44 U.S.C. 3101; Executive Order 13164 (July 28, 2000); and Executive Order 13548 (July 10, 2010).

**PURPOSE(S) OF THE SYSTEM:**

The purpose of this system is to: (1) Allow FRTIB to collect and maintain records on prospective, current, and former employees with disabilities who request or receive a reasonable accommodation by FRTIB; (2) allow FRTIB to collect and maintain records on prospective, current, and former employees with sincerely held religious beliefs, practices, or observances who request or receive an accommodation by FRTIB; (3) track and report the processing of requests for FRTIB-wide reasonable accommodations to comply with applicable laws and regulations; and (4) preserve and maintain the confidentiality of medical and religious information submitted by or on behalf of applicants or employees requesting a reasonable accommodation.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Prospective, current, and former FRTIB employees who request and/or receive a reasonable accommodation for a disability or a sincerely held religious belief, practice, or observance; and authorized individuals or representatives (*e.g.,* family members or attorneys) who file a request for a reasonable accommodation on behalf of a prospective, current, or former employee.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Name and employment information of employees needing an accommodation; requestor's name and contact information (if different than the employee who needs an accommodation); date request was initiated; information concerning the nature of the disability and the need for accommodation, including appropriate medical documentation; information concerning the nature of the sincerely held religious belief, practice, or observance and the need for accommodation, including any appropriate documentation; details of the accommodation request, such as: Type of accommodation requested, how the requested accommodation would assist in job performance, the sources of technical assistance consulted in trying to identify alternative reasonable accommodation, any additional information provided by the requestor related to the processing of the request, and whether the request was approved or denied, and whether the accommodation was approved for a trial period; and notification(s) to the employee and his/her supervisor(s) regarding the accommodation.

**RECORD SOURCE CATEGORIES:**

Subject individuals; subject individuals' supervisors.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:**

Information about covered individuals may be disclosed without consent as permitted by the Privacy Act of 1974, 5 U.S.C. 552a(b), and:

1. Routine Use—Audit: A record from this system of records may be disclosed to an agency, organization, or individual for the purpose of performing an audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function when necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to FRTIB officers and employees.

2. Routine Use—Clearance Processing: A record from this system of records may be disclosed to an appropriate federal, state, local, tribal, foreign, or international agency, if the information is relevant and necessary to a requesting agency's decision concerning the hiring or retention of an individual, or issuance of a security clearance, background investigation, license, contract, grant, or other benefit, or if the information is relevant and necessary to a FRTIB decision concerning the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant or other benefit and when disclosure is appropriate to the proper performance of the official duties of the person making the request.

3. Routine Use—Congressional Inquiries: A record from this system of records may be disclosed to a Congressional office from the record of an individual in response to an inquiry from that Congressional office made at the request of the individual to whom the record pertains.

4. Routine Use—Contractors, *et al.:* A record from this system of records may be disclosed to contractors, grantees, experts, consultants, the agents thereof, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for FRTIB, when necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to FRTIB officers and employees.

5. Routine Use—Former Employees: A record from this system of records may be disclosed to a former employee of the FRTIB, in accordance with applicable regulations, for purposes of responding to an official inquiry by a federal, state, or local government entity or professional licensing authority; or facilitating communications with a former employee that may be necessary for personnel-related or other official purposes where the FRTIB requires information or consultation assistance from the former employee regarding a matter within that person's former area of responsibility.

6. Routine Use—Law Enforcement Referrals: A record from this system of records may be disclosed to an appropriate federal, state, tribal, local, international, or foreign agency or other appropriate authority charged with investigating or prosecuting a violation or enforcing or implementing a law, rule, regulation, or order, where a record, either on its face or in conjunction with other information, indicates a violation or potential violation of law, which includes criminal, civil, or regulatory violations and such disclosure is proper and consistent with the official duties of the person making the disclosure.

7. Routine Use—Litigation, DOJ or Outside Counsel: A record from this

system of records may be disclosed to the Department of Justice, FRTIB's outside counsel, other federal agency conducting litigation or in proceedings before any court, adjudicative or administrative body, when: (1) FRTIB, or (b) any employee of FRTIB in his or her official capacity, or (c) any employee of FRTIB in his or her individual capacity where DOJ or FRTIB has agreed to represent the employee, or (d) the United States or any agency thereof, is a party to the litigation or has an interest in such litigation, and FRTIB determines that the records are both relevant and necessary to the litigation and the use of such records is compatible with the purpose for which FRTIB collected the records.

8. Routine Use—Litigation, Opposing Counsel: A record from this system of records may be disclosed to a court, magistrate, or administrative tribunal in the course of presenting evidence, including disclosures to opposing counsel or witnesses in the course of civil discovery, litigation, or settlement negotiations or in connection with criminal law proceedings or in response to a subpoena.

9. Routine Use—NARA/Records Management: A record from this system of records may be disclosed to the National Archives and Records Administration (NARA) or other federal government agencies pursuant to the Federal Records Act.

10. Routine Use—Redress: A record from this system of records may be disclosed to a federal, state, tribal, local, international, or foreign government agency or entity for the purpose of consulting with that agency or entity: (1) To assist in making a determination regarding redress for an individual in connection with the operations of a FRTIB program; (2) for the purpose of verifying the identity of an individual seeking redress in connection with the operations of a FRTIB program; or (3) for the purpose of verifying the accuracy of information submitted by an individual who has requested such redress on behalf of another individual.

11. Routine Use—Medical Professionals, Reasonable Accommodation Documentation: A record from this system of records may be disclosed to physicians or other medical professionals to provide them with or obtain from them the necessary medical documentation and/or certification for reasonable accommodations.

12. Routine Use—Federal Agencies, Equal Employment and Reasonable Accommodation Issues: A record from this system of records may be disclosed to another federal agency or commission with responsibility for labor or employment relations or other issues, including equal employment opportunity and reasonable accommodation issues, when that agency or commission has jurisdiction over reasonable accommodation issues.

13. Routine Use—Federal Agencies, Reasonable Accommodation Requirements: A record from this system of records may be disclosed to the Department of Labor (DOL), Office of Personnel Management (OPM), Equal Employment Opportunity Commission (EEOC), or Office of Special Counsel (OSC) to obtain advice regarding statutory, regulatory, policy, and other requirements related to reasonable accommodation.

14. Routine Use—Mediation/Alternative Dispute Resolution: A record from this system of records may be disclosed to appropriate third-parties contracted by the Agency to facilitate mediation or other alternative dispute resolution procedures or programs.

15. Routine Use—Department of Defense, Procurement of Assistive Technologies: A record from this system of records may be disclosed to the Department of Defense (DOD) for the purpose of procuring assistive technologies and services through the Computer/Electronic Accommodation Program in response to a request for reasonable accommodation.

16. Routine Use—Breach Mitigation and Notification: A record from this system may be disclosed to appropriate agencies, entities, and persons when (1) FRTIB suspects or has confirmed that there has been a breach of the system of records, (2) FRTIB has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, FRTIB (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 FRTIB's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

17. Routine Use—Response to Breach of Other Records: A record from this system may be disclosed to another Federal agency or Federal entity, when FRTIB 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:**

Records are maintained in paper and electronic form, including on computer databases, all of which are stored in a secure location.

**POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:**

Records are retrieved by any one or more of the following: Employee name or assigned case number.

**POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:**

Records are maintained in accordance with the General Records Retention Schedule 2.3, item 20, issued by the National Archives and Records Administration (NARA).

**ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:**

FRTIB has adopted appropriate administrative, technical, and physical controls in accordance with FRTIB's security program to protect the security, confidentiality, availability, and integrity of the information, and to ensure that records are not disclosed to or accessed by unauthorized individuals.

Paper records are stored in locked file cabinets in areas of restricted access that are locked after office hours. Electronic records are stored on computer networks and protected by assigning usernames to individuals needing access to the records and by passwords set by unauthorized users that must be changed periodically.

**RECORD ACCESS PROCEDURES:**

Individuals seeking to determine whether this system of records contains information about themselves should submit a written request to the FOIA Officer, FRTIB, 77 K Street NE, Suite 1000, Washington, DC 20002, and include the following information:

a. Full name;

b. Any available information regarding the type of record involved;

c. The address to which the record information should be sent; and

d. You must sign your request.

Attorneys or other persons acting on behalf of an individual must provide written authorization from that individual, such as a Power of Attorney, in order for the representative to act on their behalf. Individuals requesting access must also comply with FRTIB's Privacy Act regulations regarding verification of identity and access to such records, available at 5 CFR part 1630.

**CONTESTING RECORD PROCEDURES:**

See Record Access Procedures above.

**NOTIFICATION PROCEDURES:**

See Record Access Procedures above.

**EXEMPTIONS PROMULGATED FOR THE SYSTEM:**

None.

**HISTORY:**

81 FR 7106 (Feb. 10, 2016); 85 FR 43654, 43675 (July 21, 2020).

[FR Doc. 2021–24712 Filed 11–17–21; 8:45 am]

BILLING CODE 6760–01–P

## FEDERAL TRADE COMMISSION

**[File No. 191 0082; Docket No. C–4710]**

## Petition for Prior Approval of Sartorius Stedim Biotech S.A.'s Proposed Acquisition of Novasep Process SAS's Chromatography Equipment Business

**AGENCY:** Federal Trade Commission.

**ACTION:** Announcement of petition; request for comment.

**SUMMARY:** Sartorius Stedim Biotech S.A. (''Sartorius'') has petitioned the Federal Trade Commission (''FTC'' or ''Commission'') for approval of its acquisition of the chromatography equipment business of Novasep Process SAS. Sartorius was the FTC-approved divestiture buyer in 2020, when the FTC required Danaher Corporation to divest assets as a condition of acquiring General Electric's biopharmaceutical business, which included chromatography assets. Sartorius agreed to obtain the Commission's prior approval if it proposed to acquire Novasep's chromatography business.

**DATES:** Comments must be received on or before December 20, 2021.

**ADDRESSES:** Interested parties may file comments online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Please write: ''Sartorius Petition for Prior Approval; Docket No. C–4710'' on your comment, and file your comment online at *www.regulations.gov* by following the instructions on the web-based form. If you prefer to file your comment on paper, please mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580; or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

**FOR FURTHER INFORMATION CONTACT:** Lisa De Marchi Sleigh (202–326–2535), Bureau of Competition, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

**SUPPLEMENTARY INFORMATION:** Pursuant to FTC Rule 2.41(f), 16 CFR 2.41(f), notice is hereby given that the public [redacted] version of the above-captioned petition has been filed with the Secretary of the Commission and is being placed on the public record for a period of thirty (30) days. After the period for public comments has expired, the Commission shall determine whether to approve the petition. In making its determination, the Commission will consider, among other information, all timely and responsive comments submitted in connection with this document.

The text of the public [redacted] version of the petition is provided below. An electronic copy of the text of the public [redacted] version of the petition can be obtained from the FTC website at this web address: *https://www.ftc.gov/enforcement/cases-proceedings/191-0082/danaher-corporation-matter.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before December 20, 2021. Write ''Sartorius Petition for Prior Approval; Docket No. C–4710'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the *www.regulations.gov* website.

Due to protective actions in response to the COVID–19 pandemic and the agency's heightened security screening, postal mail addressed to the Commission will be subject to delay. We strongly encourage you to submit your comments online through the *www.regulations.gov* website.

If you prefer to file your comment on paper, write ''Sartorius Petition for Prior Approval; Docket No. C–4710'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580; or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the publicly accessible website at *www.regulations.gov,* you are solely responsible for making sure your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . is privileged or confidential''—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on *www.regulations.gov*—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from that website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC website at *http://www.ftc.gov* to read this document and the news release describing this matter. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before December 20, 2021. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see

*https://www.ftc.gov/site-information/privacy-policy.*

**Joel Christie,**

*Acting Secretary.*

## Petition for Prior Approval of Sartorius Stedim Biotech S.A.'s Proposed Acquisition of Novasep Process SAS's Chromatography Equipment Business

### I. Introduction

Pursuant to Section 2.41(f) of the Federal Trade Commission (the ''FTC'' or the ''Commission'') Rules of Practice and Procedure [1] and Section X(B) of the May 28, 2020 final decision and order in *In the Matter of Danaher Corporation and General Electric Company* (the ''Danaher Order'' or ''Order''),[2] Sartorius Stedim Biotech S.A. (''Sartorius'') hereby petitions the Commission to approve its proposed acquisition of the chromatography equipment business of Novasep Process SAS (''Novasep'' and, together with Sartorius, the ''Parties'') (the ''Proposed Transaction'').

The Commission's Order was entered to resolve competition concerns arising from Danaher Corporation's (''Danaher'') $21.4 billion acquisition of General Electric Company's (''GE'') biopharma business. Danaher and GE have been leading suppliers of manufacturing equipment and related products to the biopharma industry for many years. The FTC was concerned that combining Danaher's Pall Biotech and GE's Cytiva chromatography equipment product lines would create or reinforce dominant market positions in: (1) Conventional low pressure liquid chromatography (''LPLC'') columns; [3] (2) conventional LPLC skids; [4] (3) single-use (''SU'') LPLC chromatography skids; and (4) LPLC continuous chromatography systems.[5] By requiring Danaher to divest to Sartorius the overlapping Pall Biotech products in these segments (collectively, the ''Pall Assets''), the FTC facilitated a new entrant in this important area of downstream biopharmaceutical manufacturing.[6] In support of its determination that Sartorius would be a suitable purchaser of the Pall Assets and other Danaher divested assets, the Commission explained: ''Sartorius's existing biopharma business includes products that are highly complementary to the divestiture assets. Sartorius has the expertise, worldwide sales infrastructure, and resources to restore the competition that otherwise would have been lost due to the proposed Acquisition.'' [7] Sartorius completed the acquisition on April 30, 2020.[8]

As a new entrant in the chromatography equipment business, Sartorius is playing ''catch up'' with incumbent chromatography suppliers that have long dominated the industry, including Danaher/GE, Merck Millipore, and Thermo Fisher. To compete with these incumbent suppliers, which benefit from an extensive installed base of chromatography equipment, Sartorius must offer customers a range of innovative products and disruptive technologies that generate significant productivity gains and cost savings to justify customers replacing their existing legacy equipment.[9]

By bringing together the Parties' largely complementary chromatography equipment businesses and technologies, the Proposed Transaction will accelerate Sartorius's efforts to commercialize disruptive technologies needed to achieve a more efficient, more productive, and lower cost drug and vaccine production infrastructure that will improve healthcare outcomes and benefit consumers throughout the U.S. and around the world.

#### *a. Background to the Proposed Transaction*

Through the Proposed Transaction, the Parties will be able to achieve innovations in biopharma manufacturing that are necessary to bring new drugs and vaccines to market more quickly, cost-effectively, and equitably. The COVID–19 pandemic has underscored the critical importance of having a robust biopharma infrastructure to combat new viruses and diseases. There is a need for innovative manufacturing processes that are capable of developing and mass-producing new drugs and vaccines rapidly and cost-effectively. Although the biopharma industry quickly rose to the challenge of developing biologic therapies and vaccines to ameliorate the severity of COVID–19, those medical breakthroughs were not available on a large scale to populations in the U.S. and around the world in time to avoid significant loss of human life. New COVID–19 variants and novel diseases will remain an ongoing public health concern, and the biopharma industry needs to be able to respond quickly, equitably, and efficiently to address these threats to public health and economic security around the world.

To ensure that all members of the population have timely access to life saving drugs and vaccines at reasonable cost, disruptive technologies are needed to remove bottlenecks in biopharma drug and vaccine development and manufacturing. One of the primary roadblocks to achieving this goal with protein-based therapies is that ''downstream'' biopharma production—the purification of cell mass to eliminate contaminants and unwanted viruses that occurs after the ''upstream'' process of discovery, development, and growth of therapeutic cell mass—is still a relatively inefficient process. These inefficiencies inhibit the biopharma industry from being able to provide patients with rapid access to life saving therapies and provide new vaccines to entire populations on a large scale. For decades, downstream chromatography has been performed using conventional ''batch'' LPLC equipment packed with specialized, costly resins (such as Protein A resins) to purify the product. This process does not utilize resins efficiently, and significant volumes are

[1] 16 CFR 2.41(f).

[2] *In the Matter of Danaher Corp. and General Electric Co.,* Decision and Order, Docket No. C–4710, (F.T.C. May 28, 2020), *https://www.ftc.gov/system/files/documents/cases/191_0082_c4710_danaher_do_0.pdf* (hereinafter, the ''Danaher Order''), at § X(B).

[3] ''Conventional LPLC columns are containers that hold chromatography resins used as the adsorbent during the stationary phase. Columns are made of glass, stainless steel, acrylic glass, or plastic[.]'' *In the Matter of Danaher Corp. and General Electric Co.,* Complaint at ¶ III(5)(b), Docket No. C–4710 (F.T.C. Mar. 19, 2020), *https://www.ftc.gov/system/files/documents/cases/191_0082_c4710_danaher_ge_complaint.pdf* (hereinafter, the ''Danaher Complaint'').

[4] ''Conventional LPLC skids control the flow of liquid in the chromatography process. Conventional LPLC skids contain a system of pumps, valves, sensors, tubing, electronic components, software, and flow paths composed of multi-use components[.]'' Danaher Complaint, at ¶ III(5)(c).

[5] ''LPLC continuous chromatography systems allow for the simultaneous processing of multiple columns in LPLC. LPLC continuous chromatography systems consist of pumps, valves, sensors, tubing, electronic components, software, and flow paths composed of either multi-use or single-use components[.]'' Danaher Complaint, at ¶ III(5)(f). ''While continuous chromatography has for some time been an accepted practice by small-molecule manufacturers, it is not yet [as] widely used in larger bio-manufacturing processes.'' European Commission: DG Competition, *Danaher/GE Healthcare Life Sciences Biopharma,* Case M.9331, Commission Decision, at ¶ 367, *https://ec.europa.eu/competition/mergers/cases/decisions/m9331_3668_3.pdf* (last visited Oct. 22, 2021) (hereinafter, ''European Commission Decision'').

[6] *See* Danaher Order at § I(N); Danaher Complaint, at ¶ 5.

[7] *In the Matter of Danaher Corp. and General Electric Co.,* Analysis of Agreement Containing Consent Orders to Aid Public Comment. at 5, Docket No. C–4710, File No. 191–0082 (F.T.C.), *https://www.ftc.gov/system/files/documents/cases/191_0082_danaher-ge_aapc.pdf* (last visited Oct. 22, 2021).

[8] *Sartorius closes acquisition of selected assets of Danaher Life Sciences,* Sartorius (Apr. 30, 2020), *https://www.sartorius.com/en/company/newsroom/corporate-news/483898-483898.*

[9] *See* SART_0002159—SART_0002187, at SART_0002173 (comparing projected customer cost savings of the Parties' jointly developed BioSC–RCC system to GE/Cytiva's conventional LPLC batch equipment).

wasted in the process.[10] Furthermore, each of the up to four downstream chromatography steps are performed using separate equipment, which results in additional inefficiencies and bottlenecks.[11]

The leading incumbent suppliers of conventional LPLC systems—including Danaher/GE, Merck Millipore, and Thermo Fisher—also have resin supply businesses (including the costly Protein A resin) that are highly profitable and generate very significant recurring revenues. These incumbent suppliers are incentivized to maintain the status quo to protect their installed base of conventional LPLC equipment and the significant recurring resin revenues they generate. As a result, they have not aggressively pursued innovations in downstream chromatography that are necessary to address the bottlenecks that inhibit the rapid and cost-effective development and production of biologic drugs and vaccines. New disruptive technologies are required to replace this installed base of resin-dependent legacy chromatography equipment with innovative equipment and technologies that reduce (and ultimately will eliminate) bottlenecks.

The acquisition will allow Sartorius to accelerate the development and commercialization of ''intensified'' LPLC chromatography systems as platforms for innovation to support the biopharma industry's need to develop and commercialize lifesaving vaccines and biologic drugs faster and at lower cost.

*b. The Sartorius-Novasep Collaboration*

Sartorius is a disruptor to the resin industry and a new entrant in the chromatography equipment business that must continue to innovate to successfully compete with larger incumbent suppliers. For the past several years, Sartorius has been pursuing a strategic collaboration with Novasep that utilizes Sartorius's disruptive membrane technology, Sartobind (which eliminates the need for costly resins), with Novasep's innovative LPLC continuous chromatography system, BioSC (which combines several downstream processing steps in one platform). The innovative product development that Sartorius and Novasep have been pursuing through their collaboration offers the potential for significant productivity gains and cost savings in the development and production of biopharma drugs and vaccines. Notably, the Parties have developed a unique new product, BioSC–RCC, an intensified chromatography system that eliminates the need for resin, which is currently in customer trials.

After the collaboration was already well advanced, Novasep made a strategic decision to exit the chromatography equipment business for reasons that are further explained in Section II below.[12] Novasep viewed Sartorius as the natural acquirer of the business because Sartorius was already utilizing Novasep's LPLC continuous chromatography system (BioSC) as a platform for its innovative membrane technology.[13] Since Novasep had decided to exit and sell the business, both Parties concluded that acquiring the business was the only way to preserve the fruits of the collaboration, and achieve further innovations utilizing a combination of Novasep and Sartorius technologies, know-how, and equipment.

Due to the accelerated timing of the Pall Asset divestitures, Sartorius acquired the Pall Assets before finalizing its agreement to acquire Novasep's chromatography equipment business. The Pall Assets include BioSMB, a LPLC continuous chromatography system that offers some of the same process intensification capabilities as BioSC. Because the Novasep acquisition was not reportable under the Hart-Scott-Rodino Act, Sartorius agreed to provide the FTC an opportunity to review the transaction and not to close without the Commission's prior approval.[14]

*c. The Proposed Transaction*

On March 2, 2021, following approval by Novasep's French Works Council, the Parties executed a share and asset purchase agreement (''SAPA'') to sell Novasep's chromatography equipment business to Sartorius.[15] To effectuate the Proposed Transaction, Novasep has contributed the assets that comprise its chromatography business in France to a NewCo that Sartorius will acquire in a stock purchase transaction, in addition to assets that comprise Novasep's U.S. and Chinese chromatography businesses. Both Parties have received uniformly positive feedback from customers who view Sartorius as an innovative supplier that will be able to overcome the challenges that Novasep has experienced with its LPLC business.[16]

*d. The PharmaZell-Novasep Transaction*

On September 16, 2021, Novasep announced it had entered into exclusive negotiations to create a common platform in the contract development and manufacturing organization (''CDMO'') space through a proposed merger with PharmaZell.[17] The transaction excludes Novasep's chromatography equipment business, which is not a strategic fit with PharmaZell's or Novasep's CDMO businesses.[18] PharmaZell has no interest in acquiring Novasep's chromatography equipment business if the sale to Sartorius does not proceed. In that event, the chromatography equipment business (the French portion of which has already been transferred to a NewCo in preparation for the sale to Sartorius) would be transferred to NVHL S.A., a non-operating holding company owned by Novasep's private investors, which include funds focused on credit and special situations investments.

*e. Procompetitive Effects of the Proposed Transaction*

As described further in Section III below, as a result of the Proposed Transaction:

- Novasep's high pressure liquid chromatography (''HPLC'') equipment, which is used for the production of small molecules, and LPLC equipment will be supported by a manufacturer with a reputation for producing high quality innovative products and a global marketing, sales and service infrastructure. As part of Sartorius's broader product portfolio and global sales and service infrastructure, Novasep's chromatography business will have a stronger platform for commercial success.

[10] *See* SART_0016472, at 19 (indicating customers' most significant chromatography challenges include the high cost associated with the inefficient use of resins, the relatively slow speed of conventional batch chromatography, and the large spaces within manufacturing facilities required to house conventional batch chromatography equipment).

[11] *See infra* Section III(c)(i).

[12] *See* Rebecca H. Farrington Letter to Lisa DeMarchi Sleigh, dated August 9, 2021 (regarding Novasep's decision to exit the chromatography equipment business).

[13] *Id.* at 6–7; *see also* NOVA–002147, at NOVA–002147 (containing Novasep Holding Meeting Minutes from November 20, 2020).

[14] Danaher Order at §§ II(A), X(B).

[15] SART_0001673—SART_0002117.

[16] *See, e.g.,* SART_0171028 (customer letter in support of transaction); NOVA–002483—NOVA–002484; NOVA–002485; NOVA–002486 (customer declarations in support of transaction).

[17] *See PharmaZell and Novasep enter into exclusive negotiations in new drive to create a technology-driven leader for complex small molecules and ADCs of global scale,* PharmaZell (Sept. 16, 2021), *https://pharmazell-group.com/blog/2021/09/16/pharmazell-and-novasep-enter-into-exclusive-negotiations-in-new-drive-to-create-a-technology-driven-leader-for-complex-small-molecules-and-adcs-of-global-scale/.*

[18] *See* Rebecca H. Farrington Letter to Lisa DeMarchi Sleigh, dated October 7, 2021 (regarding proposed PharmaZell-Novasep transaction).

○ The benefits will be particularly pronounced in the U.S. where Sartorius has a robust sales and service infrastructure and Novasep has very limited presence.

• All of Novasep's chromatography equipment product lines will benefit from Sartorius's more efficient manufacturing and distribution, greater security of supply, and accelerated delivery times, which will increase their competitiveness and penetration with new customers and in new applications.

• The Parties' LPLC continuous chromatography systems are differentiated products that virtually never compete directly.

○ Sartorius's BioSMB system and Novasep's BioSC system are based on different technologies that provide process intensification in different ways and meet distinct customer needs and manufacturing strategies.

• As a disruptor and new entrant in a space with strong incumbents and increasing competition, Sartorius has a strong incentive to continue to invest in and innovate with both of the differentiated process intensification platforms it will be offering to biopharma customers: BioSC and BioSMB.

○ Sartorius's product roadmap and research and development plans demonstrate that Sartorius will continue to support, enhance, and innovate with both of these platforms.

○ Sartorius also has made specific commitments to the French government to maintain and invest in Novasep's chromatography equipment business and retain its employees.[19]

• The transaction poses no risk to competition in HPLC columns or skids as Sartorius has no HPLC product offering.

• The transaction similarly poses no risk to competition in conventional LPLC columns or skids because Novasep has *de minimis* sales and market shares in these products.

## II. The Parties and the Transaction Rationale

### *a. The Parties*

#### i. Sartorius

Sartorius is a supplier of innovative, cost-effective technologies and products that accelerate biopharma development and increase the speed, efficiency, and safety of biopharma production. Sartorius's Bioprocessing Solutions Division (''BPS'') supports all phases of biopharmaceutical product development, from early phase development to commercial manufacturing, from cell line development to process development, including upstream and downstream processing. Sartorius's innovative membrane technology (Sartobind) eliminates the use of resins in certain downstream chromatography processing steps—a significant advance that holds the promise of improving the efficiency and reducing the cost of developing and manufacturing biologic drugs and vaccines, compared to traditional batch chromatography systems.[20]

Sartorius has a worldwide presence with manufacturing, sales, and research and development (''R&D'') sites in more than 20 countries in Europe, North America, and Asia. Sartorius also has expertise in SU bioprocessing technologies, including LPLC equipment, as well as in value-added automation technology and software, which it uses to meet the evolving technology needs of its large molecule biopharma customers.

#### ii. Novasep

Novasep is a provider of services, equipment, and ingredients to the pharmaceutical, chemical, and food industries. Novasep's core focus and competency is its CDMO business, which accounts for over [REDACTED] of its overall revenues. Novasep's much smaller chromatography equipment business is focused on supporting the development and production of smaller molecule drugs and applications.

From its historic roots in food production, Novasep has developed expertise in multi-use (''MU'') HPLC equipment, which is used in the production of small molecule drugs. Novasep derives a high proportion (75–85%) of its chromatography equipment revenue and profits from the sale of HPLC equipment.[21] Novasep's LPLC equipment business, by contrast, is very small, as Novasep has struggled to penetrate biopharma customers. Novasep's equipment utilizes MU technology, which is cleaned and then re-used in different bioprocessing production runs. Many biopharma customers increasingly require equipment that uses SU flow-paths for manufacturing at commercial scale. Novasep has no expertise in the plastics technologies required to produce SU (*i.e.,* disposable) flow-paths and has been unable to develop a SU flow-path for BioSC or its other LPLC equipment.[22] Novasep's LPLC business is not profitable on a standalone basis, and has declined over the last several years.[23]

### *b. The Transaction Rationale*

In 2019, Novasep made a strategic decision to exit the chromatography equipment business. Novasep has had significant financial and operational challenges with the business,[24] which is highly capital intensive and lacks synergies with its core CDMO business. As mentioned above, Novasep's chromatography equipment business generates 75–85% of its revenues from sales of HPLC equipment used in small molecule drug production.[25] To address the increasing importance of biopharmaceutical medicine, Novasep also has developed LPLC equipment for larger molecule biopharma drug and vaccine production. However, Novasep has been unable to gain traction with larger biomolecule customers and applications. Thus, its LPLC business remains very small. Novasep's lack of SU technology, which many biopharma customers (particularly in North America) prefer for drug and vaccine manufacturing at clinical and commercial scales, also has hampered

[19] *See* Andrew S. Wellin Letter to Lisa DeMarchi Sleigh, dated July 1, 2021 (regarding Sartorius's commitments in connection with French foreign investment approval of the Proposed Transaction).

[20] SART_0006206, at 5, 12 (indicating that Sartobind Rapid A membranes have significantly higher productivity than Protein A resins and can be easily scaled up for commercial production). Sartorius's membrane innovations have the potential to be a significant disrupter to traditional resin suppliers, led by Danaher (Cytiva), which has an estimated 75% market share in Protein A resin.

[21] *See* NOVA–Appendix 13–00000095, at NOVA–Appendix 13–00000098; NOVA–Appendix 13–00000143, at NOVA–Appendix 13–00000147.

[22] *See* Rebecca H. Farrington Letter to Lisa DeMarchi Sleigh, dated August 9, 2021, at 5–6 (regarding Novasep's decision to exit the chromatography equipment business); Rebecca H. Farrington Letter to Lisa DeMarchi Sleigh, dated October 4, 2021 (regarding Novasep's inability to develop a SU flow-path); NOVA–000872, at NOVA–000875, NOVA–000881 (Budget 2020 BU Process Solutions, October 30, 2019); NOVA–000691, at NOVA–000703 (Budget 2021 Equipment Solutions, December 22, 2020); NOVA–000783, at NOVA–000796 (Novasep Business Review, April 2020); SART_0000526—SART_0000538, at SART_0000533 (stating Novasep's ''[i]nability to develop SU flowpath has challenged business growth especially in North America.''); NOVA–001091—NOVA–001097, at NOVA–001095.

[23] *See* NOVA–Appendix 13–00000001, at NOVA–Appendix 13–00000004; NOVA–Appendix 13–00000048, at NOVA–Appendix 13–00000051; NOVA–Appendix 13–00000095, at NOVA–Appendix 13–00000098; NOVA–Appendix 13–00000143, at NOVA–Appendix 13–00000147; *see also* Rebecca H. Farrington Letter to Lisa DeMarchi Sleigh, dated October 8, 2021 (regarding Novasep's financial condition).

[24] *See e.g.,* NOVA–VAL–0028970 at 2; NOVA–VAL–0028981, at 2; NOVA–VAL–0039971, at 3; *see generally* Rebecca H. Farrington Letter to Lisa DeMarchi Sleigh, dated August 9, 2021 (regarding Novasep's decision to exit the chromatography equipment business).

[25] *See* NOVA–Appendix 13–00000095, at NOVA–Appendix 13–00000098; NOVA–Appendix 13–00000143, at NOVA–Appendix 13–00000147.

its efforts to develop the LPLC business.[26]

In sum, Novasep concluded that it did not have the infrastructure,[27] reputation, or SU technology to grow its LPLC business successfully on its own. Furthermore, because Novasep is dependent on equipment sales, which are lumpy and unpredictable, and Novasep lacks a consumables business that would generate regular recurring revenues, Novasep has been unable to make the necessary investments to update its LPLC product line or develop next generation chromatography technologies, despite customer needs and requests for SU technology.[28] Given these challenging financial dynamics and the significant ongoing capital needs of its chromatography equipment business, Novasep realized that it would continue to lose competitive ground in an increasingly competitive space if it held on to this business.[29] In contrast, selling the equipment business to Sartorius would allow Novasep to focus resources on its core CDMO business.

i. The Proposed Transaction is Necessary To Protect the Fruits of the Parties' Collaboration

Sartorius's acquisition of Novasep's chromatography equipment business was a natural evolution of the Parties' multi-year collaboration to develop innovative alternatives to the legacy batch chromatography equipment that is dependent on the use of resin, which is often supplied by incumbent chromatography equipment suppliers. These incumbent suppliers, including Danaher/GE, Merck Millipore, and Thermo Fisher, generate significant revenues and profits from the sale of costly resins, such as Protein A, required for the batch chromatography process. Protein A, which is required for the production of monoclonal antibody (''mAb'') drug therapies (*e.g.,* COVID antibody ''cocktails''), can cost anywhere from $5,000 to $16,000 per liter.

Sartorius's collaboration with Novasep already has produced a new product—BioSC–RCC—that utilizes Novasep's BioSC LPLC continuous chromatography system as a platform for Sartorius's innovative membrane technology. BioSC–RCC provides an alternative to resin-based chromatography, and promises to accelerate the speed and efficiency of large molecule discovery and production, while greatly reducing process risk and cost.

To accelerate access to this disruptive new product, the Parties initially developed and launched BioSC–RCC MU, which utilizes BioSC's existing BioSC platform and MU technology. BioSC–RCC MU is currently being tested by potential customers, who have shown strong interest in this unique new product that eliminates the need for costly resin and offers productivity gains, and cost and process risk reductions. However, to convert customer interest to actual sales, many of these potential customers will need to be assured that Sartorius will develop a BioSC–RCC version with a SU flow-path that they can use at larger scales. Once the transaction closes, Sartorius will be able to move forward with the development of a SU flow-path for the BioSC–RCC system and launch a SU version (BioSC–RCC SU) in 2022.[30]

Although Sartorius was willing to make the investments to develop a prototype of BioSC–RCC MU pursuant to the collaboration, transforming the BioSC–RCC prototype into a commercially viable product has been (and will continue to be) challenging absent the Proposed Transaction due, in part, to Novasep's high cost of manufacturing BioSC, which limits the return on investment required to launch and maintain a new product long term.[31]

Furthermore, the BioSC platform needs substantial upgrades and enhancements before any BioSC system (BioSC or BioSC–RCC) can be successfully commercialized. While BioSC utilizes an innovative continuous chromatography process and its integrated architecture works well with Sartorius's rapid cycling chromatography (''RCC'') process and membrane technology, it has suffered from years of underinvestment. In addition to its lack of a SU flow-path, there have been ongoing challenges with its software (which is supplied by GE/Cytiva), the lab scale version of the system does not easily ''scale up'' to clinical and commercial scale versions of the system, and its engineered-to-order design and manufacturing process does not meet biopharma customer preferences for off-the-shelf systems with accelerated delivery times. The investments required to address these problems with the BioSC platform are beyond Sartorius's ability to address in the context of the Parties' collaboration because Sartorius does not own the platform, and in the case of BioSC–RCC MU has limited, short-term marketing rights and, for a potential BioSC–RCC SU version, no rights at all.[32]

While Sartorius believes that the development of a SU flow-path, redesign of BioSC lab to easily scale up, standardization of the platform and manufacturing process, and software improvements will allow BioSC and BioSC–RCC to be commercially successful,[33] these investments only make sense if Sartorius has the ability to achieve the necessary innovations and recoup its investment. Sartorius cannot achieve these innovations or recoup its investment in a system it does not own and, therefore, has no ability to redesign, manufacture, market or sell.

The acquisition of Novasep's chromatography equipment business is critical to successfully commercializing those innovations. Unless the acquisition is approved, the innovations the Parties have already developed (and plan to pursue after the acquisition) very likely will be lost. The ''winners'' will be incumbent suppliers, who will remain immune from disruptive technologies that would erode their installed base of outdated and inefficient equipment. The biggest ''losers'' will be biopharma producers and consumers who need new and improved biopharma manufacturing infrastructure to provide timely, efficient, and cost-effective access to new drugs and vaccines to address

[26] *See* Rebecca H. Farrington Letter to Lisa DeMarchi Sleigh, dated August 9, 2021, at 5–6 (regarding Novasep's decision to exit the chromatography equipment business); *see also* Rebecca H. Farrington Letter to Lisa DeMarchi Sleigh, dated October 4, 2021 (regarding Novasep's inability to develop a SU flow-path); NOVA–000691—NOVA–000748, at NOVA–000708 (Budget 2021 Equipment Solutions).

[27] For example, Novasep has limited customer service and support. *See, e.g.,* NOVA–VAL–0000079; NOVA–VAL–0014556; NOVA–VAL–0018504; NOVA–VAL–0025513; NOVA–VAL–0027911; NOVA–VAL–0063924; NOVA–VAL–0063984; NOVA–VAL–0073282; NOVA–VAL–0073557; NOVA–VAL–0075029 (documents discussing software challenges, December 22, 2020).

[28] *See* NOVA–000001, at NOVA–000039 (Novasep Strategy Discussions and Options, July 2019). *See also, e.g.,* NOVA–001208, at NOVA–001208, NOVA–001209; NOVA–VAL–0027941; NOVA–VAL–0038766; NOVA–VAL–0040141.

[29] *See* Rebecca H. Farrington Letter to Lisa DeMarchi Sleigh, dated August 9, 2021, at 2–3 (regarding Novasep's decision to exit the chromatography equipment business).

[30] *See* SART_0000487—SART_0000498, at SART_0000498; SART_0001130—SART_1177, at SART_0001151 (Sartorius's acquisition business case assumes a multiyear investment in the development of a SU flow-path for BioSC RCC); *id.* at SART_0001171 (Sartorius's acquisition business plan assumptions include sales projections for SU BioSC–RCC systems).

[31] *See* SART_0063502 (Sartorius BioSC–RCC margin calculations).

[32] *See generally* SART_0002268—SART_0002303 (Collaboration Interim Manufacturing and Marketing Agreement).

[33] *See* SART_0000539, at ''EUR Summary'' tab (Sartorius discounted cash flow analysis prepared for transaction valuation purposes indicating accelerating BioSC/BioSC–RCC growth due to investments).

public health risks and keep economies functioning well.

ii. The Proposed Transaction Will Enhance Sartorius's Competitiveness as a New Entrant That Competes Through Innovation

Sartorius's acquisition of Novasep's chromatography equipment business will provide complementary technologies and expertise to ''fill in the gaps'' in Sartorius's newly acquired downstream LPLC bioprocessing equipment portfolio.[34]

The acquisition of Novasep's HPLC equipment will enable Sartorius to offer customers a complete range of technologies for the purification of smaller molecules, complementing Sartorius's LPLC equipment that serves larger molecule biopharma manufacturing. Historically, Novasep's HPLC equipment was predominantly used to purify smaller molecule active ingredients and insulin. Recently, Novasep's HPLC equipment has played a critical role in the purification of key components of mRNA and recombinant protein COVID vaccines. Through its extensive sales and service network, Sartorius will be able to expand the reach and availability of Novasep's HPLC equipment across the globe, offer a full line of LPLC and HPLC equipment for customers who prefer to purchase from one source, and provide more choices in equipment and services for producers of life-saving drug therapies and vaccines.

In addition to supporting and enhancing Novasep's HPLC business, the acquisition will enable Sartorius to successfully commercialize BioSC, Novasep's LPLC ''multistep'' intensified chromatography system, an innovative technology that Novasep has struggled to commercialize, particularly in North America, for reasons that include its limited sales presence, lack of SU technology, and inability to invest in necessary improvements and innovations (see further Section III(c)(ii) below). BioSC has achieved very few sales at the clinical or commercial scale, and sales have stagnated. Biopharma customers are making decisions today about investments in their manufacturing infrastructure for decades to come. Absent the Proposed Transaction and the investment and innovation Sartorius is uniquely placed to make to transform BioSC into a commercially attractive option, customers will miss a critical window to realize BioSC's potential to improve the downstream biopharma manufacturing process.

*c. FTC Procedural History*

The FTC has conducted an extensive investigation of Sartorius's proposed acquisition of Novasep's chromatography equipment business. Sartorius provided an initial briefing on the Proposed Transaction in July 2020 and formally notified the transaction on January 21, 2021. The Parties have voluntarily produced numerous documents, data and submissions to the FTC, and regularly addressed staff questions as they arose in their investigation of the Proposed Transaction. In addition, Sartorius and Novasep management presented to, and were interviewed by, FTC staff. Both before and in response to the FTC's Voluntary Access Letters (''VALs'') issued in June 2021, Sartorius and Novasep each produced thousands of ordinary course business documents and data, and, at the FTC's request, both parties certified substantial compliance with the VALs.

Now that the FTC staff have completed their investigation, the Parties submit this petition requesting the Commission's approval to permit the transaction to close before year end. In addition to enabling the Parties to meet their contractual obligations and transaction timetable, permitting closing before year end will eliminate the state of uncertainty that has hung over the Novasep chromatography equipment business for the past year, further business deterioration, and the ongoing challenge of retaining critical employees while the business is in limbo. Furthermore, essential innovation, including the completion of the development of the SU flow-path for BioSC–RCC and BioSC, along with necessary software improvements[35] and innovative product development for the BioSC system and other projects cannot be achieved until the transaction has closed. In the event that approval is not obtained by mid-December, Novasep likely will be forced to transfer the business back to its private investor shareholders, in which case the business will operate with even fewer financial and organizational resources than it has today.

Permitting the transaction to close before year end will enable the Novasep and Sartorius product development engineers to integrate and work together as a single team to move forward with product development and other innovations that cannot be achieved in the Parties' collaboration. Most importantly, approving the transaction before year end will ensure that customers and consumers benefit from the innovation resulting from new product launches and necessary improvements to existing products, which will be further delayed if the deal does not close by year end (and very likely will be lost altogether if the transaction is not approved).

## III. The Transaction Is Procompetitive and Will Not Lessen Competition in Any Relevant Chromatography Market

As the Commission alleged in the Danaher Complaint, ''[t]he relevant geographic area in which to assess the competitive effects of the Acquisition [of chromatography equipment] is no narrower than the United States and may be as broad as the entire world.''[36]

As described further below, the acquisition of Novasep's HPLC column and skid assets will not lessen competition because Sartorius does not manufacture or sell HPLC equipment. Similarly, although Sartorius and Novasep each manufacture and sell conventional LPLC columns and skids, Novasep's sales and market share in each of these products is very small. Finally, the addition of Novasep's LPLC intensified chromatography system (BioSC) to Sartorius's product portfolio will be procompetitive because BioSC and Sartorius's BioSMB systems are complementary, highly differentiated products that meet distinct customer needs.[37]

*a. HPLC Columns and Skids*

Sartorius's acquisition of Novasep's HPLC equipment fills a gap in its chromatography equipment portfolio and enhances Sartorius's ability to compete with incumbent chromatography equipment suppliers

[34] *See* SART_0160423, at 2 (explaining how Sartorius is positioning itself to provide customers with more options in intensified downstream processing in a highly competitive environment of large, established players, where technology progress is already pointing towards continuous manufacturing); SART_0115519, at 12 (July 2021 BioSMB Business Plan projecting distinct growth rates for BioSC, BioSMB, and BioSC RCC).

[35] *See* NOVA–VAL–0000079; NOVA–VAL–0014556; NOVA–VAL–0018504; NOVA–VAL–0025513; NOVA–VAL–0027911; NOVA–VAL–0063924; NOVA–VAL–0063984; NOVA–VAL–0073282; NOVA–VAL–0073557; NOVA–VAL–0075029 (documents discussing software challenges). *See also* Rebecca H. Farrington Letters to Lisa DeMarchi Sleigh, dated September 15, 2021 and October 5, 2021.

[36] Danaher Complaint at ¶ III(6).

[37] The segmentation of approaches to intensified/continuous LPLC chromatography between single-step and multistep solutions, demonstrates that customer demand exists for both intensification approaches, which will incentivize Sartorius to continue innovating with both BioSC and BioSMB platforms following the transaction. [REDACTED]. *See* SART_0000601—SART_0000605 (regarding Sartorius's plans to continue to support both systems).

that offer a full range of HPLC and LPLC equipment. By expanding its product portfolio, Sartorius will be able to serve customers who prefer to source their HPLC and LPLC equipment needs from a single supplier and give them more competitive choices.

Novasep's HPLC equipment will allow Sartorius to offer a complete range of technologies for both the needs of the biopharma industry and adjacent pharmaceutical segments. The availability of Novasep's HPLC offerings alongside LPLC solutions from a single source also will allow Sartorius to achieve economies of scale and conform control systems across platforms.

Following the acquisition, Sartorius will have every incentive to support and enhance Novasep's HPLC equipment. In addition to purification of small molecule active ingredients and insulin, Novasep's HPLC equipment is increasingly being used in COVID–19 vaccine development. For example, Novasep's Hipersep Pilot skid is being used to purify COVID–19 vaccine components, including the mRNA strands and lipid nanoparticles that are critical to the vaccines' efficacy. With its robust global marketing, sales and service infrastructure, Sartorius will be able to increase sales and penetration of Novasep's HPLC product lines with new customers and in new applications, including supporting vaccine producers' efforts to combat the COVID–19 pandemic.

*b. Conventional LPLC Columns and Skids*

As alleged in the FTC's Danaher Complaint, conventional LPLC column and skid markets have ''only three significant suppliers'': Danaher, GE and Merck Millipore.[38]

In the case of columns, the FTC ''estimate[d] the combined firm [*i.e.,* Danaher/GE] would have a market share of greater than 45 percent'' with ''[s]everal fringe firms.'' [39] In the case of skids, the FTC estimated that GE was ''the leading supplier of conventional LPLC skids with over 30 percent market share [and that combined] Danaher and GE would have an even larger share of the market.'' [40]

Novasep is one of the ''fringe'' firms that the FTC concluded in its GE/Danaher investigation had an insufficient market presence to competitively constrain GE/Danaher in these product areas. Novasep estimates that its global market share in conventional LPLC columns and conventional LPLC skids is de minimis (less than [REDACTED] globally and in the U.S.).[41] Accordingly, the acquisition by Sartorius would not risk substantially lessening competition in those products in any relevant geographic market.

*c. LPLC Intensified/Continuous Chromatography Systems*

Different technologies have been developed to address biopharma customers' needs for faster, more efficient downstream bioprocessing at lower cost and bioprocess risk. Sartorius's BioSMB and Novasep's BioSC systems each provide a form of ''intensified'' chromatography using distinct technologies that addresses different customer needs.[42] Customers have different manufacturing strategies and equipment preferences that, in turn, depend on a number of factors, including the configuration of their facilities, available and desired footprint, type of products (*e.g.,* innovator or biosimilar), stage of production (development, clinical or commercial scale), volumes and mix of products, efficiencies desired from affinity capture step intensification versus other chromatography steps, and labor costs.[43]

i. BioSMB and BioSC Product Differentiation

BioSMB and BioSC exemplify two distinct approaches to bioprocessing intensification that have evolved over the past decade:

- ''Single-step'' intensification of the affinity capture chromatography step alone.
  - Other steps in the chromatography process (the virus inactivation step and two polishing steps) are achieved using separate LPLC batch chromatography equipment.
  - Commercially available systems using ''single step'' intensification include BioSMB, Cytiva's PCC (now owned by Danaher), YMC/ChromaCon Contichrom Twin, and Tosoh/Semba ProGMP).
- ''Multistep'' intensification of all chromatography steps by integrating each chromatography step in a single system and continuous process.
  - Commercially available systems include BioSC, PAK BioSolutions, and Sepragen QuantaSep).[44]

BioSMB (and other single step systems) are designed to maximize the productivity of resin at the affinity capture step using a sequential multi-column chromatography (''S–MCC'') process. BioSMB offers the greatest efficiencies for customers that make biologic drugs such as mAbs, which require expensive Protein A resin for purification. Because BioSMB only performs the affinity capture step, it may be more attractive to customers who are looking to reduce costs and improve productivity without replacing their entire downstream bioprocessing production line. Customers can still generate significant resin savings and increase productivity by replacing their existing batch LPLC equipment with BioSMB to perform the affinity capture step without having to invest in an entirely new production line (and securing the extensive regulatory approvals that are required to do so).

With its SU flow path technology, BioSMB also is attractive to customers who prefer not to undertake intensive cleaning and sterilization of MU equipment between process runs. In particular, innovator biopharma customers in North America and Europe increasingly prefer to use disposable SU flow-kits so that they can quickly switch between process runs for different biologic products without time-consuming cleaning and sterilization, or risk cross-contamination between process runs for different drugs.[45] Some customers explicitly make SU technology a requirement in their ''request for proposal'' specifications.[46]

[38] *See* Danaher Complaint at ¶ IV(9); European Commission Decision at ¶¶ 388, 401.

[39] Danaher Complaint at ¶ IV(9).

[40] *Id.* ¶ IV(10).

[41] Rebecca H. Farrington Letter to Lisa DeMarchi Sleigh, dated July 15, 2021 (regarding MU LPLC columns); *see also* NOVA–000296—NOVA–000303, at NOVA–000300.

[42] SART_0016281, at 2 (illustrating the different customer applications for BioSMB and the Parties' recently launched BioSC–RCC system based on customer consumable usage strategy, product development stage, and risk tolerance); SART_0145766 (indicating that BioSC–RCC is for customers with different preferences or needs than multi-column chromatography (''MCC'') systems like BioSMB).

[43] *See* SART_0000606—SART_0000607, at SART_0000606; SART_0170114 (illustrating the distinct applications for resin-based MCC and membrane-based RCC systems based on customer consumable usage strategies, product development status, and customer risk tolerance); SART_0115519, at 12 (projecting distinct growth rates for BioSC, BioSMB, and BioSC–RCC in Sartorius's July 2021 BioSMB Business Plan).

[44] Suppliers of multistep systems also include various in-house systems developed by biopharma companies such as Fujifilm, Bayer, Boehringer Ingelheim, and Novartis.

[45] *See* NOVA–001242—NOVA–001755, at NOVA0001572 (''With single-use equipment now in routine common use, [biopharma survey] respondents may be viewing disposable options from more of an economic vs. technological perspective, particularly eliminating weeks of manual labor-intensive cleaning and sterilizing stainless steel equipment.'').

[46] When intensified chromatography systems were first introduced to customers as a nascent technology, customers purchased benchtop/lab scale models for equipment testing and

Continued

Because BioSC lacks a SU option,[47] it cannot compete with BioSMB for these opportunities.

In contrast, BioSC's greatest value to customers is its ability to continuously perform multi-step, multi-column chromatography (''MS–MCC'').[48] Although it is technically capable of performing S–MCC alone, most customers have placed orders without the S–MCC configuration because this would eliminate the system's ability to continuously perform multiple chromatography steps in an MS–MCC process.[49] To perform the affinity capture step, MS–MCC typically uses a simplified, less efficient form of multi-column intensification or a conventional batch process, which is not as efficient as BioSMB. BioSC's productivity benefits are largely achieved through the integration of the entire downstream chromatography process in a single system using an onboard software suite to coordinate each chromatography step.[50] BioSC's integrated system also eliminates time consuming (and productivity reducing) intermediate steps such as product storage in holding tanks between chromatography processes that are required for single-step, standalone systems such as BioSMB.[51]

BioSC is an attractive option for customers who have the flexibility to implement a new downstream production line or are building a new manufacturing facility. BioSC's integrated system reduces manufacturing footprint by reducing the size (and associated operational costs) of the sterile ''clean rooms'' required to produce biologics.[52] In addition, certain customers may prefer BioSC's MU technology if, for example, they are producing larger product runs (*e.g.,* biosimilars), switching between products infrequently, and/or are located in regions where labor costs for cleaning and sterilization of MU equipment are lower (*e.g.,* Southeast Asia).[53]

Because BioSMB and Novasep BioSC are highly differentiated products that provide process intensification in different ways, customers generally do not view them as close substitutes, particularly at clinical and manufacturing scales.

ii. BioSC Has Failed To Penetrate the U.S. and Its Global Sales Are Declining

Since BioSC's launch in 2015, Novasep has sold only a few lab scale units in the U.S.[54] To the extent that BioSC Lab sales are viewed as an indication of potential future BioSC sales at commercial scale, Novasep lacks an installed base of lab scale equipment to generate future sales. Novasep has faced challenges convincing customers to scale up to BioSC's larger (clinical or manufacturing scale systems), in part because Novasep's product family does not have a simple scale-up pathway.[55]

BioSC's lack of sales in the U.S. is attributable to several challenges that Sartorius is uniquely placed to overcome and to do so quickly, given its extensive experience working with the BioSC platform.[56] First, Novasep does not have an established reputation as an LPLC supplier and is relatively unknown to the North American biopharma industry for LPLC. Second, unlike BioSMB, Novasep's BioSC product family does not provide customers an easily achievable scale-up pathway because the system architecture of the BioSC lab scale model, which biopharma customers can use to test the BioSC proof of concept, differs significantly from that of BioSC Pilot and BioSC M, which are used for drug development and manufacture.[57] Third, innovator biotechnology companies in North America prefer to purchase from longstanding suppliers that have significant local sales and support infrastructure. Novasep has only [REDACTED] salespeople and [REDACTED] service technicians in the U.S. to support all of its HPLC and LPLC product lines.[58] In contrast, Sartorius's specialized chromatography sales and service ''task force'' already includes 11 individuals in the U.S. supporting its LPLC chromatography products alone, and Sartorius is planning to expand the team. Fourth, there is an increasing customer preference in the U.S., particularly at commercial scale, to use SU flow-path technology (which Novasep does not have).[59] Fifth, BioSC's software, which controls and coordinates the MS–MCC process, has experienced challenges and the system will benefit from Sartorius's expertise in software and process automation.[60]

Despite the potential benefits of the system, the trajectory of Novasep's BioSC sales over the past several years has been declining and its sales prospects are unlikely to improve without necessary investment and improvements that Sartorius is uniquely placed to provide.[61] In order to achieve commercial adoption and deliver its potential benefits to customers, BioSC requires the investment and innovations that Sartorius is planning to provide once it owns the platform including, *inter alia,* updating and redesigning the systems to a more ''off the shelf'' design and streamlined manufacturing process at a lower cost, the development of a SU flow-path and software improvements, as well as the support of Sartorius's U.S. and global sales and service infrastructure.

experimentation. Given the small scale of production and the corresponding relative ease of changing tubing for SU systems or cleaning the tubing for MU systems, customers did not necessarily have a strong preference for SU versus MU flow path technology because there is not necessarily a significant difference in cost or contamination risks at this scale. This was the competitive environment the Commission analyzed in its review of the Danaher-GE transaction. Now that large molecule innovators are advancing to pilot/process development stage production, their preference for SU technology has become more pronounced.

[47] NOVA–000691—NOVA–000748, at NOVA–000703, NOVA–000707, NOVA–000730 (''No Single Use skills'').

[48] *See* Rebecca H. Farrington Letter to Lisa DeMarchi Sleigh, dated April 26, 2021, at 3–4 (regarding BioSC chromatography processes).

[49] *Id.* at 3. A BioSC system configured for MS–MCC in Novasep's factory cannot be ''switched'' to the S–MCC process that BioSMB uses by a customer. Customers must ship the equipment back to the Novasep factory for modification and, in practice, they have not done so. *Id.*

[50] *See* SART_0002159—SART_0002187, at SART_0002171.

[51] *See* Sartorius BioSMB Technical Discussion Presentation: Meeting with FTC (Apr. 22, 2021), at 9.

[52] *See* Rebecca H. Farrington Letter to Lisa DeMarchi Sleigh, dated April 26, 2021, at 2 (regarding BioSC chromatography processes).

[53] *See, e.g.,* NOVA–001210—NOVA–001241; NOVA–001759—NOVA–001800; NOVA–001756—NOVA001758; NOVA–001191—NOVA–001207.

[54] Novasep manufactures the BioSC system at three different scales: Lab, pilot/clinical, and manufacturing. Bioprocesses that are investigated on BioSC Lab are ''scaled up'' (*i.e.,* increased in size/volume) to the larger BioSC Pilot system for clinical development (although BioSC faces challenges when scaling up that Sartorius plans to address in its redesign of the three scales of the system), and ultimately to BioSC Manufacturing system for commercial production.

[55] *See* Bates White's CRM Data Analysis Presentation and exhibits, dated May 26, 2021, at 8.

[56] *See* NOVA–000691—NOVA–000748, at NOVA–000738 (Novasep's customer sales, service, and support infrastructure is underdeveloped.).

[57] *See* NOVA–001208—NOVA–001209 (explaining that BioSC Lab does not scale up to BioSC Pilot).

[58] *See* Novasep's Voluntary Access Letter Response dated September 17, 2021, at 25.

[59] *See* SART_0001180—SART_0001181, at SART_0001180; SART_0003306 (providing Sartorius' projections of customer preference for the SU version of BioSC RCC); SART_0168117, at 17 (June 2021 Business Review indicating ''Growth to achieve 2025 driven by steady-increased Multi-Use System and explosive-increased Single-Use System''); *see also* NOVA–000872, NOVA–000881 (Budget 2020 BU Process Solutions).

[60] *See, e.g.,* NOVA–VAL–0000079; NOVA–VAL–0014556; NOVA–VAL–0018504; NOVA–VAL–0025513; NOVA–VAL–0027911; NOVA–VAL–0063924; NOVA–VAL–0063984; NOVA–VAL–0073282; NOVA–VAL–0073557; NOVA–VAL–0075029.

[61] *See* F. Schaeffer Letter to Lisa DeMarchi Sleigh, dated July 9, 2021, at 3 (regarding BioSC scale up and sales).

iii. BioSMB and BioSC Virtually Never Compete Head-to-Head

Because BioSMB and BioSC utilize different technologies and approaches that meet different customer needs, there has been very little head-to-head competition between them since their lab scale systems were launched. Indeed, the Parties have identified only one instance of BioSMB and BioSC pursuing the same opportunity at commercial (*i.e.,* clinical or manufacturing) scale. This was an opportunity to sell to a potential customer located outside of the U.S., which neither company won.

Because BioSMB and BioSC are highly differentiated products that are very rarely in direct competition in new sales opportunities,[62] there is no practical risk of unilateral price effects from the acquisition.[63] The Parties' win/loss data confirms that BioSMB and BioSC virtually never compete directly[64] and that any attempted unilateral price increase for either product post-merger would be unprofitable.[65]

iv. Sartorius Must Continue To Offer Multiple Platforms and Innovate To Displace Incumbent Batch LPLC Suppliers and Meet Increasing Process Intensification Competition

Sartorius views the acquisition of the multistep BioSC system as filling a gap in its chromatography portfolio to meet customer demand for an integrated continuous chromatography system that BioSMB's single-step system does not provide. Sartorius has forecast distinct customer demand (and growth rates) for both BioSMB and BioSC platforms.[66]

Sartorius has already made investments in the BioSC–RCC and BioSMB platforms.[67] Once the transaction is approved, Sartorius will be able to make necessary investments in BioSC to make it a commercially attractive option for customers. As a new entrant in the chromatography equipment business, Sartorius needs to overcome the incumbency advantages of the dominant batch LPLC chromatography equipment suppliers by convincing customers that it is worth replacing their legacy batch systems with superior Sartorius equipment. Sartorius has a better prospect of convincing customers across the board to make the switch if it can offer multiple options for intensification in a range of systems and approaches that meet different customer priorities and needs.

The Proposed Transaction also will combine Sartorius's and Novasep's complementary technologies, know-how, and engineering expertise that will accelerate the development of next generation systems and innovations, and meet escalating competition in intensified chromatography processing.[68] Intensification of downstream processing is a strategic focus of biopharma companies, which have an increasing number of competitive options through their own product development efforts, as well as strategic combinations and investments by their supplier base:

*Tosoh/Semba:* In January 2019, Tosoh Corporation increased its investment in U.S.-based Semba Biosciences, Inc. in pursuit of its goal to become a full range solutions provider for biopharma purification.[69] The investment enhanced Semba's ability to market and innovate with its SU lab and process development scale LPLC continuous chromatography systems, and Tosoh's scale and resources, which include a significant resins business, allowed it to commercialize its first commercial scale SU LPLC continuous chromatography system this year.[70]

*YMC/ChromaCon:* In April 2019, YMC Co., Ltd. acquired ChromaCon AG, a manufacturer of LPLC continuous chromatography systems.[71] As a result, ChromaCon has been able to leverage YMC's expertise in resin and packed columns to enhance its lab, pilot, and commercial scale LPLC continuous chromatography systems.[72] In July 2020, the U.S. Food and Drug Administration purchased a ChromaCon LPLC continuous chromatography system for evaluation, signaling its interest and confidence in ChromaCon's equipment.[73]

*Sepragen:* Sepragen, a U.S.-based firm, offers a complete product portfolio including resins, columns, and MU and SU chromatography systems at lab, pilot, and commercial scales.[74] Sepragen has developed and sold MU LPLC continuous chromatography systems and recently added a lab scale chromatography system with a SU flow path to its product portfolio.[75]

*Repligen/ARTeSYN:* In October 2020, Repligen Corporation announced its acquisition of ARTeSYN Biosolutions.[76] ARTeSYN produces engineered-to-order (''ETO'') SU continuous chromatography systems at different

[62] ''In differentiated product industries, some products can be very close substitutes and compete strongly with each other, while other products are more distant substitutes and compete less strongly. . . . The extent of direct competition between the products sold by the merging parties is central to the evaluation of unilateral price effects.'' Dep't of Just. & Fed. Trade Comm'n, Horizontal Merger Guidelines § 6.1 (2010) [hereinafter Horizontal Merger Guidelines].

[63] ''Unilateral price effects are greater, the more the buyers of products sold by one merging firm consider products sold by the other merging firm to be their next choice. The Agencies consider any reasonably available and reliable information to evaluate the extent of direct competition between the products sold by the merging firms. This includes documentary and testimonial evidence, win/loss reports and evidence from discount approval processes, customer switching patterns, and customer surveys.'' *Id.*

[64] *See* Bates White's CRM Data Analysis Presentation and exhibits, dated May 26, 2021, at 8.

[65] ''A merger between firms selling differentiated products may diminish competition by enabling the merged firm to profit by unilaterally raising the price of one or both products above the pre-merger level. Some of the sales lost due to the price rise will merely be diverted to the product of the merger partner and, depending on relative margins, capturing such sales loss through merger may make the price increase profitable even though it would not have been profitable prior to the merger.'' Horizontal Merger Guidelines at § 6.1.

[66] *See* SART_0115519, at 12 (projecting distinct growth rates for BioSC, BioSMB, and BioSC–RCC in Sartorius's July 2021 BioSMB Business Plan); SART_0000601—SART_0000605 (regarding Sartorius's plans to continue to support both platforms).

[67] Sartorius also completed an extensive, in-house sales training program and launched a marketing campaign in March 2021 to promote the BioSMB system to prospective customers whom it had identified might be interested in moving from conventional batch processing to a continuous chromatography system. *See generally* SART_0016472.

[68] *See* Horizontal Merger Guidelines § 6.4 (''The Agencies also consider whether the merger is likely to enable innovation that would not otherwise take place, by bringing together complementary capabilities that cannot be otherwise combined or for some other merger-specific reason.'').

[69] *Tosoh Corporation Invests in Semba Biosciences, Inc.,* Tosoh (Jan. 10, 2019), *https://www.tosoh.com/news-press/news-releases/2019/tosoh-corporation-invests-in-semba-biosciences-inc.*

[70] *New ProGMP 150 System,* Semba Biosciences, *https://sembabio.com/progmp-150-system/#1617729557380-f5d67fe8-6d6a* (last visited Oct. 22, 2021).

[71] *YMC Acquires Chromacon,* ChromaCon (Apr. 9, 2019), *https://www.chromacon.com/en/news/ymc-acquires-chromacon.*

[72] *Contichrom TWIN—GMP Scale-up equipment,* ChromaCon, *https://www.chromacon.com/en/products/gmp-scale-up-equipment* (last visited Oct. 22, 2021).

[73] *FDA selects twin-column chromatography system by YMC ChromaCon for evaluation,* ChromaCon (July 2020), *https://www.chromacon.com/resources/public/lava3/media/kcfinder/files/FDA%20orders%20Twin%20Column%20Chromatography%20of%20YMC%20Press%20Release%2007F2020.pdf.*

[74] *Products Overview,* Sepragen, *https://www.sepragen.com/Products.html* (last visited Oct. 22, 2021).

[75] *QuantaSep Single Use,* Sepragen, *https://www.sepragen.com/Products-Chromatography-Systems-Single-Use.html* (last visited Oct. 22, 2021).

[76] *Repligen Corporation Announces Agreement to Acquire Bioprocess Systems Innovator ARTeSYN Biosolutions and Completes Acquisition of Non-Metallic Solutions,* Repligen (Oct. 27, 2020), *https://repligen.q4ir.com/news/news-details/2020/Repligen-Corporation-Announces-Agreement-to-Acquire-Bioprocess-Systems-Innovator-ARTeSYN-Biosolutions-and-Completes-Acquisition-of-Non-Metallic-Solutions/default.aspx.*

scales, which Repligen is now actively marketing.[77] As a leading resin supplier to biopharma companies in the U.S. and globally, Repligen has the financial resources and customer relationships to commercialize and improve ARTeSYN's continuous chromatography technology. For example, Repligen produces pre-packed columns, which are well suited to ARTeSYN systems. Repligen plans to continue developing ARTeSYN's single-use solutions as part of its portfolio.

*Merck Millipore:* Merck Millipore is leveraging a platform called BioContinuum to provide a form of intensified processing using chromatography equipment based on the company's ''Mobius'' concept. Merck Millipore has announced a collaboration in intensified downstream processing with Transcenta (formerly Just Bio).[78]

*PAK BioSolutions:* PAK BioSolutions is a new, U.S.-based, chromatography equipment entrant that was founded in 2018. In 2021, PAK introduced a SU pilot scale multistep intensified chromatography system that can perform MS–MCC in a manner similar to BioSC.[79]

In sum, competition in LPLC continuous chromatography systems and intensified processing approaches has significantly increased since the Danaher-GE transaction.[80] Larger players are investing in smaller competitors and developing their own products, and customers continue to develop their own in-house solutions.[81]

Following the transaction, Sartorius will continue to face competition from a range of intensified LPLC system suppliers including:

- At least six, well-capitalized suppliers that are actively marketing products in the chromatography intensification space: Danaher (Cytiva), Tosoh/Semba, YMC/ChromaCon, Sepragen, Repligen/ARTeSYN, and PAK BioSolutions;
- incumbent batch LPLC equipment suppliers, such as Merck Millipore, which are entering the space;
- emerging Chinese suppliers, such as Lisure Science; and
- customers who are continuing to develop their own intensification technologies in-house.

Intensified/continuous chromatography is an emerging area with a range of technologies. No single approach has achieved broad adoption at this time. To achieve commercial success, Sartorius will need to continue to innovate and demonstrate greater efficiencies to convince a critical mass of customers to adopt its products in place of incumbent conventional LPLC batch systems and other competing intensification solutions. The proposed acquisition will enhance Sartorius's ability to continue to successfully innovate in this growing and increasingly competitive field and to develop next generation solutions to meet industry needs for cost-effective, biologic drug development and large-scale production.

## IV. If the Proposed Acquisition Is Not Approved, the Parties' Existing and Future Innovations Will Be Lost and Customers and Consumers Will Be Harmed

In developing BioSC–RCC, the Parties have created a unique new product—a membrane-based intensified chromatography system that employs RCC as an alternative to resin-based systems.[82] The product is still in the testing phase and no sales have been made as yet. Sartorius has concluded that it needs to develop and launch a BioSC–RCC system with a SU flow-path option for the BioSC–RCC concept to achieve commercial success. A SU option would be preferred by many customers who are concerned about maintaining purity and low bioburden risk, while achieving quick turnaround times between batches.[83] However, Sartorius has no incentive to invest in this innovation without any right to manufacture or market the system. Developing and launching BioSC–RCC with a SU option will not be feasible unless Sartorius is able to acquire the Novasep equipment business.

If Sartorius were unable to acquire Novasep's chromatography equipment business, the innovations achieved by the collaboration are unlikely to be successfully commercialized and planned innovations, such as the BioSC–RCC SU version, will not be achieved. If the sale of the business to Sartorius is not approved, it would be transferred to Novasep's private investor shareholder until it could be divested. Uncertainty over the future ownership of the business would stall further investment and development by both Sartorius and the Novasep chromatography equipment team (which already is operating with significant resource constraints). The fruits of the Parties' collaboration would be lost and ultimately the collaboration would end.

Furthermore, if the Proposed Transaction does not close before year end, the business would be transferred to NVHL S.A., which would risk business deterioration and attrition of critical employees. The further uncertainty that would result from a transfer of the business to NVHL S.A. would risk employee attrition with further adverse business impacts. It would also undermine customers' confidence in the Novasep equipment business and its ability to support long-term investments in its equipment. In particular, biopharma customers, who prioritize security of supply and long-term business continuity when making equipment purchasing decisions, understandably would be reluctant to invest in Novasep equipment while the business' ownership and future remains uncertain. Thus, in addition to depriving the business of the resources needed to invest in, market, and sell its products that its acquisition by Sartorius would provide, this standalone scenario would likely lead to a reduction of revenue further undermining the competitiveness and prospects for the business.

Once the transaction is approved, Sartorius will be able to progress its planned investments in BioSC, including development of a SU flow-path, redesign of the BioSC family so that it scales up easily and without extensive and costly revalidation studies, redesign of the current ETO BioSC M system as an off-the-shelf system to improve customer delivery

[77] *ARTeSYN Chromatography Systems,* Repligen, *https://www.repligen.com/technologies/engineered-systems/chromatography-systems#collapse1-2* (last visited Oct. 22, 2021).

[78] *MilliporeSigma and Transcenta Collaborate to Advance Continuous Biomanufacturing, Make the 'Facility of the Future' a Reality,* MilliporeSigma (Nov. 7, 2020), *https://www.emdmillipore.com/US/en/20201106_153338?bd=1.*

[79] *The PAK System,* PAK BioSolutions, *https://www.pakbiosolutions.com/the-pak-system/* (last visited Oct. 22, 2021).

[80] SART_0009787—SART_0009826, at pp. 11–12 (comparing BioSC to PAK BioSolutions, a ''[n]ew entrant . . . offering SU equivalent to BioSC,'' and identifying biopharma companies developing systems in-house and noting that more biopharma companies are utilizing multistep processes).

[81] *MilliporeSigma and Transcenta Collaborate to Advance Continuous Biomanufacturing, Make the 'Facility of the Future' a Reality,* (Nov. 7, 2020), MilliporeSigma, *https://www.emdmillipore.com/US/en/20201106_153338?bd=1.*

[82] Membrane capsules and cassettes are an emerging technology that offer the potential for greater production efficiencies than conventional resin-based chromatography systems. *See* SART_0002159—SART_0002187, at SART_0002173 (comparing projected customer cost savings of BioSC–RCC to GE/Cytiva's conventional LPLC batch equipment).

[83] *See* SART_0000487—SART_0000498, at SART_000498; SART_0003206 (indicating Sartorius's expectation that BioSC–RCC would displace less-efficient, traditional batch equipment, notably GE/Cytiva's dominant conventional LPLC batch equipment and providing Sartorius' projections, showing sales of the SU version of BioSC–RCC exceeding the MU version over time); *see also* SART_0003306; SART_0168117, at 17.

times,[84] and redesign of BioSC's software, which has been unreliable and rendered some systems inoperable.[85] The Proposed Transaction will allow these innovations to be achieved and will accelerate product development by enabling each company's engineering personnel to work together under one roof[86] with a unified and stronger strategic focus on developing these products more quickly and cost-effectively.[87]

Combining Sartorius and Novasep technologies, IP, engineering personnel, and know-how also will accelerate innovation in the BioSMB product line. Planned innovations include value-engineering BioSMB's SU flow-kits to reduce their cost, developing BioSMB-specific applications data for additional types of therapies, and line extensions, such as the planned, [REDACTED].[88]

The Proposed Transaction will ensure that Novasep's products are effectively manufactured, marketed, and supported by an innovative supplier with the infrastructure that biopharma customers rely on to make long-term capital investments in these products. With the support of Sartorius's global manufacturing, supply chain, sales, and service infrastructure,[89] customers will have the confidence to purchase Novasep equipment as a long-term capital investment. All of these benefits will be particularly pronounced in the U.S., where Novasep has been unable to successfully commercialize BioSC or its other LPLC product lines.

## V. Request for Confidential Treatment

This petition, including its related documents, contains certain confidential and competitively sensitive business information relating to Sartorius, Novasep, and the Proposed Transaction. Disclosure of such confidential information may prejudice Sartorius and Novasep, and cause harm to the ongoing competitiveness of both companies. Pursuant to Sections 2.41(f)(4) and 4.9(c) of the FTC's Rules of Practice and Procedure,[90] Sartorius has redacted such information from the public version of this application, and requests confidential treatment for such redacted information under Section 4.10(a)(2) of the FTC's Rules of Practice and Procedure[91] and Sections 552(b)(4) and (b)(7) of the Freedom of Information Act.[92] In the event that a determination is made that any material marked as confidential is not subject to confidential treatment, Sartorius requests that the FTC provide prompt notice of that determination and adequate opportunity to appeal such a decision.

Respectfully submitted,

*/s/Fiona A. Schaeffer*

Fiona A. Schaeffer,
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*Counsel for Sartorius Stedim Biotech, S.A.*

Dated: October 28, 2021.

[FR Doc. 2021–25150 Filed 11–17–21; 8:45 am]

BILLING CODE 6750–01–P

[84] The average time from order to delivery for a BioSC system is significantly longer than for a BioSMB system, in part because Sartorius has a superior manufacturing process and efficiencies, and many of Novasep's products are manufactured on an ETO basis, which is more costly and time-consuming. SART_0000464—SART0000471, at SART0000468; *see also* SART_0001130—SART_1177, at SART_0001142 (regarding Sartorius's plans for significant additional investment in product development); *id.* at SART_0001151 (regarding Sartorius's acquisition business case, which includes a multiyear investment in the development of BioSC M).

[85] *See Why Novasep is Not a Competitive Constraint—White Paper Prepared for the U.S. Federal Trade Commission,* dated June 4, 2021, at 17, n.25 (regarding BioSC software challenges).

[86] *See* SART_0001130—SART_0001177, at SART_0001136; SART_0002571—SART_0002591, at SART_0002576 (outlining Sartorius' integration plans, including highlighting the creation of a centralized research and development site as ''priority #1'' as it will benefit from ''automation expertise for [the] full chromatography portfolio,'' the ''use of existing supplier network/cooperation partner—short distances (250km radius) to established suppliers/sub-contractors of BioSMB/Allegro systems,'' ''[c]lose collaboration with French [Sartorius] colleagues in Aubagne for single-use systems,'' and the ''[o]pportunity to hire former Pall people because of close proximity to Dreieich'').

[87] Although Sartorius's research and development plans confirm that it intends to do much more than maintain the status quo for Novasep's products, Sartorius also made specific guarantees to maintain and invest in Novasep at least at current levels for a three-year period in connection with French foreign investment approval, which demonstrates its commitment to Novasep's technologies and employees. *See* Andrew S. Wellin Letter to Lisa DeMarchi Sleigh, dated July 1, 2021 (regarding Sartorius's commitments in connection with French foreign investment approval of the Proposed Transaction).

[88] *See* SART_0000487—SART_0000498, at SART_0000496; SART_0009752, at SART_0009754–55 (illustrating Sartorius' development plans for BioSMB); SART_0153310, at 14 (listing ongoing BioSMB PD improvement projects).

[89] Currently, Sartorius has 306 sales and service employees in the BPS organization. Following the closing of the Danaher/Pall divestiture, Sartorius created a 20-person chromatography ''task force'' dedicated solely to chromatography sales with a special focus on intensified/continuous chromatography equipment. Over half of Sartorius's chromatography task force is located in the U.S.

[90] 16 CFR 2.41(f)(4) and 4.9(c).

[91] 16 CFR 4.10(a)(2).

[92] 5 U.S.C. 552(b)(4), 552(b)(7).

# FEDERAL TRADE COMMISSION

## Agency Information Collection Activities; Submission for OMB Review; Comment Request

**AGENCY:** Federal Trade Commission (FTC).

**ACTION:** Notice and request for comment.

**SUMMARY:** The FTC requests that the Office of Management and Budget (OMB) extend for three years the current Paperwork Reduction Act (PRA) clearance for information collection requirements contained in the rules and regulations under the Pay-Per-Call Rule (Rule). That clearance expires on November 30, 2021.

**DATES:** Comments must be received by December 20, 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. The *reginfo.gov* web link is a United States Government website produced by OMB and the General Services Administration (GSA). Under PRA requirements, OMB's Office of Information and Regulatory Affairs (OIRA) reviews Federal information collections.

**FOR FURTHER INFORMATION CONTACT:** P. Connell McNulty, Attorney, Division of Marketing Practices, Bureau of Consumer Protection, Federal Trade Commission, Mail Code CC–5201, 600 Pennsylvania Ave. NW, Washington, DC 20580, (202) 326–2061.

**SUPPLEMENTARY INFORMATION:**

*Title:* Trade Regulation Rule Pursuant to the Telephone Disclosure and Dispute Resolution Act of 1992 (''Pay-Per-Call Rule''), 16 CFR part 308.

*OMB Control Number:* 3084–0102.

*Type of Review:* Extension of a currently approved collection.

*Abstract:* The existing reporting and disclosure requirements of the Pay-Per-Call Rule are mandated by the Telephone Disclosure and Dispute Resolution Act of 1992 (TDDRA) to help prevent unfair and deceptive acts and practices in the advertising and operation of pay-per-call services and in the collection of charges for telephone-billed purchases. The information obtained by the Commission pursuant to the reporting requirement is used for law enforcement purposes. The disclosure requirements ensure that consumers are told about the costs of

using a pay-per-call service, that they will not be liable for unauthorized non-toll charges on their telephone bills, and how to deal with disputes about telephone-billed purchases.

*Likely Respondents:* telecommunications common carriers (subject to the reporting requirement only, unless acting as a billing entity), information providers (vendors) offering one or more pay-per-call services or programs, and billing entities.

*Estimated Annual Hours Burden:* 1,029,570 hours (18 + 1,029,552).

*Reporting:* 18 hours for reporting by common carriers.

Disclosure: 1,029,552 [(21,240 hours for advertising by vendors + 21,732 hours for preamble disclosure which applies to every pay-per-call service + 7,080 burden hours for telephone-billed charges in billing statements (applies to vendors; applies to common carriers if acting as billing entity) + 11,500 burden hours for dispute resolution procedures in billing statements (applies to billing entities) + 968,000 hours for disclosures related to consumers reporting a billing error (applies to billing entities)].

*Estimated annual cost burden:* $50,456,136 (solely relating to labor costs).[1]

**Request for Comment**

On August 18, 2021, the FTC sought public comment on the information collection requirements associated with the Rule. 86 FR 46254. The Commission received no germane comments. Pursuant to the OMB regulations, 5 CFR part 1320, that implement the PRA, 44 U.S.C. 3501 *et seq.,* the FTC is providing this second opportunity for public comment while seeking OMB approval to renew the pre-existing clearance for the Rules.

Your comment—including your name and your state—will be placed on the public record of this proceeding. Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, such as anyone's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . is privileged or confidential''—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

**Josephine Liu,**

*Assistant General Counsel for Legal Counsel.*

[FR Doc. 2021–25104 Filed 11–17–21; 8:45 am]

BILLING CODE 6750–01–P

[1] Non-labor (*e.g.,* capital/other start-up) costs are generally subsumed in activities otherwise undertaken in the ordinary course of business (*e.g.,* business records from which only existing information must be reported to the Commission, pay-per-call advertisements or audiotext to which cost or other disclosures are added, etc.). To the extent that entities incur operating or maintenance expenses, or purchase outside services to satisfy the Rule's requirements, staff believe those expenses are also included in (or, if contracted out, would be comparable to) the annual burden hour and cost estimates provided below (where such costs are labor-related), or are otherwise included in the ordinary cost of doing business (regarding non-labor costs).

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[CMS–9132–N]**

### Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—July Through September 2021

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Notice

**SUMMARY:** This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from July through September 2021, relating to the Medicare and Medicaid programs and other programs administered by CMS.

**FOR FURTHER INFORMATION CONTACT:** It is possible that an interested party may need specific information and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing contact persons to answer general questions concerning each of the addenda published in this notice.

| Addenda | Contact | Phone number |
|---|---|---|
| I CMS Manual Instructions | Ismael Torres | (410) 786–1864 |
| II Regulation Documents Published in the FEDERAL REGISTER | Terri Plumb | (410) 786–4481 |
| III CMS Rulings | Tiffany Lafferty | (410) 786–7548 |
| IV Medicare National Coverage Determinations | Wanda Belle, MPA | (410) 786–7491 |
| V FDA-Approved Category B IDEs | John Manlove | (410) 786–6877 |
| VI Collections of Information | William Parham | (410) 786–4669 |
| VII Medicare-Approved Carotid Stent Facilities | Sarah Fulton, MHS | (410) 786–2749 |
| VIII American College of Cardiology-National Cardiovascular Data Registry Sites. | Sarah Fulton, MHS | (410) 786–2749 |
| IX Medicare's Active Coverage-Related Guidance Documents | JoAnna Baldwin, MS | (410) 786–7205 |
| X One-time Notices Regarding National Coverage Provisions | JoAnna Baldwin, MS | (410) 786–7205 |
| XI National Oncologic Positron Emission Tomography Registry Sites | David Dolan, MBA | (410) 786–3365 |
| XII Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities. | David Dolan, MBA | (410) 786–3365 |
| XIII Medicare-Approved Lung Volume Reduction Surgery Facilities | Sarah Fulton, MHS | (410) 786–2749 |
| XIV Medicare-Approved Bariatric Surgery Facilities | Sarah Fulton, MHS | (410) 786–2749 |
| XV Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials | David Dolan, MBA | (410) 786–3365 |
| All Other Information | Annette Brewer | (410) 786–6580 |

**SUPPLEMENTARY INFORMATION**

## I. Background

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs and coordination and oversight of private health insurance. Administration and oversight of these programs involves the following: (1) Furnishing information to Medicare and Medicaid beneficiaries, health care providers, and the public; and (2) maintaining effective communications with CMS regional offices, state governments, state Medicaid agencies, state survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, National Association of Insurance Commissioners (NAIC), health insurers, and other stakeholders. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act) and Public Health Service Act. We also issue various manuals, memoranda, and statements necessary to administer and oversee the programs efficiently.

Section 1871(c) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**.

## II. Format for the Quarterly Issuance Notices

This quarterly notice provides only the specific updates that have occurred in the 3-month period along with a hyperlink to the full listing that is available on the CMS website or the appropriate data registries that are used as our resources. This is the most current up-to-date information and will be available earlier than we publish our quarterly notice. We believe the website list provides more timely access for beneficiaries, providers, and suppliers. We also believe the website offers a more convenient tool for the public to find the full list of qualified providers for these specific services and offers more flexibility and ''real time'' accessibility. In addition, many of the websites have listservs; that is, the public can subscribe and receive immediate notification of any updates to the website. These listservs avoid the need to check the website, as notification of updates is automatic and sent to the subscriber as they occur. If assessing a website proves to be difficult, the contact person listed can provide information.

## III. How To Use the Notice

This notice is organized into 15 addenda so that a reader may access the subjects published during the quarter covered by the notice to determine whether any are of particular interest. We expect this notice to be used in concert with previously published notices. Those unfamiliar with a description of our Medicare manuals should view the manuals at *http://www.cms.gov/manuals.*

The Director of the Office of Strategic Operations and Regulatory Affairs of the Centers for Medicare & Medicaid Services (CMS), Kathleen Cantwell, having reviewed and approved this document, authorizes Trenesha Fultz-Mimms, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: November 12, 2021.

**Trenesha Fultz-Mimms,**

*Federal Register Liaison, Department of Health and Human Services.*

**BILLING CODE 4120–01–P**

**Publication Dates for the Previous Four Quarterly Notices**

We publish this notice at the end of each quarter reflecting information released by CMS during the previous quarter. The publication dates of the previous four Quarterly Listing of Program Issuances notices are: November 4, 2020 (85 FR 70168), March 17, 2021 (86 FR 14629), May 3, 2021 (86 FR 23373) and August 17, 2021 (86 FR 45986. We are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the website to access this information and a contact person for questions or additional information.

**Addendum I: Medicare and Medicaid Manual Instructions (July through September 2021)**

The CMS Manual System is used by CMS program components, partners, providers, contractors, Medicare Advantage organizations, and State Survey Agencies to administer CMS programs. It offers day-to-day operating instructions, policies, and procedures based on statutes and regulations, guidelines, models, and directives. In 2003, we transformed the CMS Program Manuals into a web user-friendly presentation and renamed it the CMS Online Manual System.

How to Obtain Manuals

The Internet-only Manuals (IOMs) are a replica of the Agency's official record copy. Paper-based manuals are CMS manuals that were officially released in hardcopy. The majority of these manuals were transferred into the Internet-only manual (IOM) or retired. Pub 15-1, Pub 15-2 and Pub 45 are exceptions to this rule and are still active paper-based manuals. The remaining paper-based manuals are for reference purposes only. If you notice policy contained in the paper-based manuals that was not transferred to the IOM, send a message via the CMS Feedback tool.

Those wishing to subscribe to old versions of CMS manuals should contact the National Technical Information Service, Department of Commerce, 5301 Shawnee Road, Alexandria, VA 22312 Telephone (703-605-6050). You can download copies of the listed material free of charge at: http://cms.gov/manuals.

How to Review Transmittals or Program Memoranda

Those wishing to review transmittals and program memoranda can access this information at a local Federal Depository Library (FDL). Under the FDL program, government publications are sent to approximately 1,400 designated libraries throughout the United States. Some FDLs may have arrangements to transfer material to a local library not designated as an FDL. Contact any library to locate the nearest FDL. This information is available at http://www.gpo.gov/libraries/

In addition, individuals may contact regional depository libraries that receive and retain at least one copy of most federal government publications, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library. CMS publication and transmittal numbers are shown in the listing entitled Medicare and Medicaid Manual Instructions. To help FDLs locate the materials, use the CMS publication and transmittal numbers. For example, to find the manual for Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment, use (CMS-Pub. 100-04) Transmittal No. 10988.

Addendum I lists a unique CMS transmittal number for each instruction in our manuals or program memoranda and its subject number. A transmittal may consist of a single or multiple instruction(s). Often, it is necessary to use information in a transmittal in conjunction with information currently in the manual.

Fee-For Service Transmittal Numbers

Please Note: Beginning Friday, March 20, 2020, there will be the following change regarding the Advance Notice of Instructions due to a CMS internal process change. Fee-For Service Transmittal Numbers will no longer be determined by Publication. The Transmittal numbers will be issued by a single numerical sequence beginning with Transmittal Number 10000.

For the purposes of this quarterly notice, we list only the specific updates to the list of manual instructions that have occurred in the 3-month period. This information is available on our website at www.cms.gov/Manuals.

| Transmittal Number | Manual/Subject/Publication Number |
|---|---|
| | **Medicare General Information (CMS-Pub. 100-01)** |
| 10880 | Internet Only Manual Updates to Pub. 100-01, 100-02, and 100-04 to Implement Consolidated Appropriations Act Changes and Correct Errors and Omissions (SNF) |
| | **Medicare Benefit Policy (CMS-Pub. 100-02)** |
| 10880 | Internet Only Manual Updates to Pub. 100-01, 100-02, and 100-04 to Implement Consolidated Appropriations Act Changes and Correct Errors and Omissions (SNF) |
| | **Medicare National Coverage Determination (CMS-Pub. 100-03)** |
| 10888 | National Coverage Determination (NCD) Removal<br>Extracorporeal Immunoadsorption (ECI) Using Protein A Columns<br>Electrosleep Therapy<br>Implantation of Gastrointestinal Reflux Devices<br>Abarelix for the Treatment of Prostate Cancer<br>Magnetic Resonance Spectroscopy<br>Positron Emission Tomography (PET) Scans<br>FDG PET for Inflammation and Infection |
| 10891 | National Coverage Determination (NCD 110.24): Chimeric Antigen Receptor (CAR) T-cell Therapy - This CR Rescinds and Fully Replaces CR 11783. |

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| | Chimeric Antigen Receptor (CAR) T-cell therapy. |
| 10927 | National Coverage Determination (NCD) Removal<br>Extracorporeal Immunoadsorption (ECI) Using Protein A Columns<br>Electrosleep Therapy<br>Implantation of Gastrointestinal Reflux Devices<br>Abarelix for the Treatment of Prostate Cancer<br>Magnetic Resonance Spectroscopy<br>Positron Emission Tomography (PET) Scans<br>FDG PET for Inflammation and Infection |
| 10981 | National Coverage Determination (NCD) 270.3 Blood-Derived Products for Chronic, Non-Healing Wounds<br>Blood-Derived Products for Chronic, Non-Healing Wounds |
| 10985 | Claims Processing Instructions for National Coverage Determination 20.33 – Transcatheter Edge-to-Edge Repair [TEER] for Mitral Valve Regurgitation |
| **Medicare Claims Processing (CMS-Pub. 100-04)** | |
| 10862 | Section 50 in Chapter 30 of Publication (Pub.) 100-04 Manual Updates<br>Section 50 in Chapter 30 of Publication (Pub.) 100-04 Manual Updates<br>Advance Beneficiary Notice of Non-coverage (ABN<br>ABN Scope<br>ABN Uses<br>Optional ABN Uses<br>Issuance of the ABN<br>Triggering Events<br>ABN Standards<br>Completing the ABN<br>Retention Requirements<br>ABN Delivery Requirements<br>Options for Delivery Other than In-Person<br>Effects of Lack of Notification, Medicare Review and Claim Adjudication<br>Using ABNs for Medical Equipment and Supplies Claims When Denials Under §1834(a)(17)(B) of the Act (Prohibition Against Unsolicited Telephone Contacts) Are Expected<br>ABNs for Medical Equipment and Supplies Claims Denied Under §1834(j)(1) of the Act (Because the Supplier Did Not Meet Supplier Number Requirements)<br>ABNs for Claims Denied in Advance Under §1834(a)(15) of the Act<br>ABN Standards for Upgraded Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)<br>ABNs for items listed in a DMEPOS Competitive Bidding Program (CBP) /Collection of Funds and Refunds<br>Physicians' Services<br>DMEPOS RR Provision for Claims for Medical Equipment and Supplies<br>Time Limits and Penalties for Healthcare Providers and Suppliers in Making Refunds<br>Supplier's Right to Recover Resalable Items for Which Refund Has Been Made<br>CMS Regional Office (RO) Referral Procedures<br>ABN Special Considerations<br>Glossary |
| 10865 | July Quarterly Update for 2021 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule |
| 10872 | Annual Updates to the Prior Authorization/Pre-Claim Review Federal Holiday Schedule Tables for Generating Reports |
| 10875 | Instructions for Downloading the Medicare ZIP Code Files for October 2021 |
| 10876 | Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction |
| 10877 | Changes to the Laboratory National Coverage Determination [NCD] Edit Software for October 2021 |
| 10878 | Update to the Internet-only Manual (IOM) Publication (Pub.) 100-04, Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, Section 20.9 - Fee Schedule Administration and Coding Requirements<br>National Correct Coding Initiative (NCCI)<br>Correct Coding Modifier Indicators (CCMI) and HCPCS Codes Modifiers<br>Instructions for Codes With Modifiers (A/B MACs (B) Only<br>Appeals<br>Procedure-to-Procedure (PTP) Edits<br>Medically Unlikely Edits (MUEs)<br>National Correct Coding Initiative (NCCI) Edits Quarterly Updates |
| 10891 | National Coverage Determination (NCD 110.24): Chimeric Antigen Receptor (CAR) T-cell Therapy - This CR Rescinds and Fully Replaces CR 11783.<br>Chimeric Antigen Receptor (CAR) T-cell therapy<br>Coverage Requirements<br>Billing Requirements<br>A/B Medicare Administrative Contractor (MAC) (A) Bill Types<br>A/B MAC (A) Revenue Codes<br>A/B MAC Billing Healthcare Common Procedural Coding System (HCPCS) Codes<br>A/B MAC Diagnosis Requirements<br>Payment Requirements<br>Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages<br>Claims Editing |
| 10898 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 10918 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 10919 | Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction |
| 10920 | Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction |
| 10929 | Update to Hospice Payment Rates, Hospice Cap, Hospice Wage Index and Hospice Pricer for FY 2022 |
| 10931 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 10932 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 10934 | Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction |
| 10935 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 10937 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 10940 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 10941 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 10942 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 10943 | Inpatient Rehabilitation Facility (IRF) Annual Update: Prospective Payment System (PPS) Pricer Changes for FY 2022 |

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| 10944 | Inpatient Psychiatric Facilities Prospective Payment System (IPF PPS) Updates for Fiscal Year (FY) 2022<br>Annual Update<br>Cost-of-Living Adjustment (COLA) for Alaska and Hawaii |
| 10947 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 10950 | File Conversions Related to the Spanish Translation of the Healthcare Common Procedure Coding System (HCPCS) Descriptions |
| 10959 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 10961 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 10962 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 10964 | Combined Common Edits/Enhancements Modules (CCEM) Code Set Update |
| 10965 | Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction |
| 10966 | Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction |
| 10967 | Implement Operating Rules - Phase III Electronic Remittance Advice (ERA) Electronic Funds Transfer (EFT): Committee on Operating Rules for Information Exchange (CORE) 360 Uniform Use of Claim Adjustment Reason Codes (CARC), Remittance Advice Remark Codes (RARC) and Claim Adjustment Group Code (CAGC) Rule - Update from Council for Affordable Quality Healthcare (CAQH) CORE |
| 10968 | Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction |
| 10969 | Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - October 2021 Update |
| 10970 | Shared System Support Hours for Application Programming Interfaces (APIs) |
| 10971 | 2022 Annual Update for the Health Professional Shortage Area (HPSA) Bonus Payments |
| 10972 | January 2022 Healthcare Common Procedure Coding System (HCPCS) Quarterly Update Reminder Clotting Factor Furnishing Fee |
| 10979 | Instructions for Retrieving the January 2022 Opioid Treatment Program (OTP) Payment Rates Through the CMS Mainframe Telecommunications System |
| 10981 | National Coverage Determination (NCD) 270.3 Blood-Derived Products for Chronic, Non-Healing Wounds<br>Autologous Platelet-Rich Plasma (PRP) for Chronic Non-Healing Wounds Policy<br>Healthcare Common Procedure Coding System (HCPCS) Codes, Diagnosis Coding and Frequency Requirements<br>Types of Bill (TOB)<br>Payment Method<br>Place of Service (POS) for Professional Claims<br>Medicare Summary Notices (MSNs), Remittance Advice Remark Codes (RCs), Claim Adjustment Reason Codes (CARCs) and Group Codes |
| 10983 | Influenza Vaccine Payment Allowances - Annual Update for 2021-2022 Season |
| 10985 | Claims Processing Instructions for National Coverage Determination 20.33 - Transcatheter Edge-to-Edge Repair [TEER] for Mitral Valve Regurgitation<br>Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation Coding Requirements for Mitral Valve TEER Claims Furnished on or After August 7, 2014<br>Claims Processing Requirements for Mitral Valve TEER Services on Professional Claims |
| 10987 | Home Health Notices of Admission -- Additional Manual Instructions Submission of the Notice of Admission (NOA) HH PPS Claims |
| 10988 | Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment |
| 10991 | Instructions for Retrieving the January 2022 Medicare Physician Fee Schedule Database (MPFSDB) Files Through the CMS Mainframe Telecommunications System |
| 10992 | Quarterly Update to Home Health (HH) Grouper |
| 10996 | October 2021 Integrated Outpatient Code Editor (I/OCE) Specifications Version 22.3 |
| 10997 | October 2021 Update of the Hospital Outpatient Prospective Payment System (OPPS) |
| 11000 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| **Medicare Secondary Payer (CMS-Pub. 100-05)** | |
| 10873 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 10921 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 10939 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| **Medicare Financial Management (CMS-Pub. 100-06)** | |
| 10887 | Notice of New Interest Rate for Medicare Overpayments and Underpayments – 4th Qtr Notification for FY 2021 |
| 10982 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| **Medicare State Operations Manual (CMS-Pub. 100-07)** | |
| | None |
| **Medicare Program Integrity (CMS-Pub. 100-08)** | |
| 10849 | Revising Subsection 3.5.4, Tracking Medicare Contractors' Prepayment and Postpayment Reviews, in Chapter 3 of Publication (Pub.) 100-08 Tracking Medicare Contractors' Prepayment and Postpayment Reviews |
| 10867 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 10868 | Third General Update to Chapter 10 of Publication (Pub.) 100-08 Third General Update to Chapter 10 of Publication (Pub.) 100-08 Certified Providers and Certified Suppliers That Enroll Via the Form CMS- 855A<br>Community Mental Health Centers (CMHCs<br>Comprehensive Outpatient Rehabilitation Facilities (CORFs)<br>End-Stage Renal Disease Facilities (ESRDs)<br>Federally Qualified Health Centers (FQHCs)<br>Histocompatibility Laboratories<br>Home Health Agencies (HHAs<br>Hospices<br>Hospitals and Hospital Units<br>Indian Health Services (IHS) Facilities<br>Organ Procurement Organizations (OPOs)<br>Outpatient Physical Therapy/Outpatient Speech Pathology Services (OPT/OSP) |

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| | Religious Non-Medical Health Care Institutions (RNHCIs)<br>Rural Health Clinics (RHCs)<br>Skilled Nursing Facilities (SNFs)<br>Miscellaneous Policies<br>Other Enrollment Forms: Information and Processing<br>Form CMS-588 – Electronic Funds Transfer (EFT) Authorization Agreement<br>Form CMS-460 – Medicare Participating Physician or Supplier Agreement<br>Provider and Supplier Business Structures<br>Owning and Managing Information<br>Organizational Owning and Managing Information<br>Individual Owning and Managing Information<br>Owning and Managing Information – Tax Identification Numbers (TINs)<br>Billing Agencies |
| 10879 | Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions |
| 10882 | Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions |
| 10893 | Revision to Medicare Administrative Contractor (MAC) Complaint Screening Process - Checking the Recovery Audit Contractor (RAC) Data Warehouse (RACDW) Prior to Claim Adjustment Complaint Screening Process |
| 10909 | Fourth General Update to Chapter 10 of Publication (Pub.) 100-08<br>Opioid Treatment Programs<br>Opting-Out of Medicare<br>Application Fees<br>Screening: On-Site Inspections and Site Verifications<br>Miscellaneous Enrollment Topics |
| 10910 | Updates to Exhibit 16 in Exhibits Chapter of Publication (Pub.) 100-08<br>Model Payment Suspension Letters<br>Opioid Treatment Programs<br>Opting-Out of Medicare<br>Application Fees<br>Screening: On-Site Inspections and Site Verifications<br>Miscellaneous Enrollment Topic |
| 10911 | Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions |
| 10913 | Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions |
| 10926 | Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions |
| 10945 | Removal of Provider Enrollment Policy from Chapter 15 in Publication (Pub.) 100-08 |
| 10958 | Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions |
| 10975 | Changes of Information Involving Certified Providers and Certified Suppliers |
| 10976 | Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions |
| 10984 | Updates to Chapters 1, 3, 4, 5, 8 and 9 of Publication (Pub.) 100-08<br>Quality of Care Issues and Potential Fraud Issues<br>Provider Self Audits<br>Signature Requirements<br>Introduction<br>Program Integrity<br>Program Integrity Contractors<br>Unified Program Integrity Contractor<br>Investigations Medicare Drug Integrity Contractor |

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| | Organizational Requirements<br>Liability of Program Integrity Contractor Employees<br>Anti-Fraud Training<br>Procedural Requirements<br>MAC Complaint Screening<br>Referrals to the UPIC<br>Home Health Agency Misuse of Requests for Anticipated Payments<br>RAP Monitoring<br>Education and Additional Monitoring<br>Corrective Action Plans<br>Notification to the HHA<br>CAP Submission<br>CAP Acceptance and Monitoring<br>CAP Closeout<br>Suppression<br>Notice of RAP Suppression<br>Monitoring During RAP Suppression<br>Result of Initial RAP Suppression Monitoring Period |
| 10994 | Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions |
| **Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)** | |
| 1900 | Updates to Pub. 100-09, Chapter 6 Beneficiary and Provider Communications Manual, Chapter 6, Provider Customer Service Program<br>Note<br>Introduction to Provider Customer Service Program<br>PCSP Electronic Mailing Lists<br>PCUG Call<br>Integration of POE, PCC, and PSS Activities in the PCSP<br>Partners in Progress Meeting<br>Provider Outreach and Education<br>Partnering with External Entities and with Other MACs<br>Analysis of Claims Submission Errors<br>Provider Bulletins/Newsletters<br>Direct Mailings for the PCSP<br>Training Tailored for Small Medicare Providers<br>Remittance Advice (RA)<br>POE Advisory Groups (POE AGs<br>Ask-the-Contractor Teleconferences<br>POE Reporting<br>Provider Service Plan (PSP)<br>Provider Customer Service Program Activity Report (PAR)<br>Discretionary Reporting<br>Charging Fees to Providers for Medicare Education and Training<br>Reimbursement from Providers for POE Staff Attendance at Provider Meetings<br>Refunds/Credits for Cancellation of Education and Training Activities<br>Provider Contact Center (PCC)<br>Pre-Approved PCC Closures<br>Emergency and Similar PCC Closures<br>Inquiry Triage Process<br>Responding to Coding Questions<br>Provider Telephone Inquiries<br>Provider Inquiries Line<br>Troubleshooting PCC Service Interruptions<br>Requesting Changes to Telephone Configurations<br>Hours of Operation<br>Providing Busy Signals |

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| | Provider Telephone Line Staffing<br>Quality Call Monitoring<br>Quality Assurance Monitoring (QAM<br>Remote Monitoring<br>Telephone Responses to Provider Inquiries – QWCM Program Minimum Requirements<br>Recording Calls<br>QCM Calibration<br>Provider Written Inquiries<br>Telephone Responses to Provider Written Inquiries<br>Electronic Responses to Provider Written Inquiries<br>Guidelines for High Quality Responses to Provider Written Inquiries<br>Stock Language/Form Letters<br>QWCM Calibration<br>PRRS Operations<br>Complex Provider Inquiries<br>Complex Beneficiary Inquiries<br>Provider Inquiry Tracking<br>Updates to the CMS Standardized Provider Inquiry Chart<br>MAC Inquiry Tracking Self-Data Review and Self-Validation Process<br>Fraud and Abuse<br>PCSP Staff Development and Education<br>PCC Staff Development and Training<br>Required Training for PCC Staff<br>PCC Training Program<br>PCC Training Documentation<br>Provider Self-Service (PSS) Technology<br>Interactive Voice Response(IVR) System<br>Provider Education Website<br>General Requirements<br>Webmaster and Attestation Requirements<br>Website Governance<br>CMS Feedback<br>Contents<br>Dissemination of Information from CMS to Providers<br>Web-based Provider Educational Offerings<br>Provider Claims Payment Alerts<br>Electronic Mailing List<br>Targeted Electronic Mailing Lists<br>Electronic Mailing List Promotion<br>Social Media<br>Internet-based Provider Portal Service Interruptions<br>Surveys<br>Provider Satisfaction Survey<br>MAC Survey Participation Requirements<br>Closed-Loop Ticketing<br>MAC Satisfaction Score<br>Performance Management<br>Electronic Mailing List Subscribership<br>Call Completion<br>Average Speed of Answer (ASA)<br>Callbacks<br>PCSP Data Reporting<br>PIES<br>Due Date for Data Submission to PIES<br>MAC Contract and PCSP Data to be Reported in PCID<br>Additional Data to be Reported Monthly in PCID and Reporting Due Dates |

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| | Inquiry Tracking Data to be Reported in PCID<br>PCC Training Closure Information to be Reported in PCID<br>Provider Electronic Mailing List Subscriber Data to be Reported in PCID<br>Special Initiatives to be Reported in PCID<br>Emergency and Similar PCC Closure Data to be Reported in PCID<br>Telecommunications Service Interruptions to be Reported in PCID<br>QCM<br>QWCM<br>Disclosure of Information |
| 10930 | Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions |
| **Medicare Quality Improvement Organization (CMS- Pub. 100-10)** | |
| | None |
| **Medicare End Stage Renal Disease Network Organizations (CMS Pub 100-14)** | |
| | None |
| **Medicaid Program Integrity Disease Network Organizations (CMS Pub 100-15)** | |
| | None |
| **Medicare Managed Care (CMS-Pub. 100-16)** | |
| | None |
| **Medicare Business Partners Systems Security (CMS-Pub. 100-17)** | |
| | None |
| **Medicare Prescription Drug Benefit (CMS-Pub. 100-18)** | |
| | None |
| **Demonstrations (CMS-Pub. 100-19)** | |
| 10889 | Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions |
| 10894 | Modifications/Improvements to Value-Based Insurance Design (VBID) Model Implementation |
| 10924 | Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions |
| 10936 | Federally Qualified Health Center (FQHC) Participation in and Payment Under the Maryland Primary Care Program (MDPCP) – Implementation |
| 10938 | Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions |
| 10949 | Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions |
| 10956 | Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions |
| 10960 | Managing Clinician PPA and KCF PBA Implementation |
| 10974 | Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions |
| 10978 | Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions |
| 10993 | Kidney Care Choices (KCC) Kidney Care First (KCF) - Payment Mechanism (PM) and Benefit Enhancements (BEs) - Implementation |
| **One Time Notification (CMS-Pub. 100-20)** | |
| 10848 | Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions |
| 10852 | Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions |
| 10856 | Implementation of the Award for the Jurisdiction E (J-E) Part A and Part B Medicare Administrative Contractor (JE A/B MAC) |
| 10861 | Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Prior Authorization Coversheet Requirements |
| 10863 | User CR: MCS - Beneficiary Do Not Forward DLV Flag Changes Needed |

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| 10890 | Replacing Home Health Requests for Anticipated Payment (RAPs) with a Notice of Admission (NOA) – Implementation |
| 10895 | Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions |
| 10896 | Additional Payment Edits for DMEPOS Suppliers of Custom Fabricated and Prefabricated (Custom Fitted) Orthotics. Update to Change Request (CR) 3959, CR 8390, and CR 8730 |
| 10899 | Viable Information Processing Systems (ViPS) Medicare Systems (VMS) Changes to Accommodate National Provider Identifier Associations |
| 10928 | Medicare Fee-for-Service (FFS) Coverage of Costs for Kidney Acquisitions in Maryland Waiver (MW) Hospitals for Medicare Advantage (MA) Beneficiaries |
| 10933 | Implementation of the Capital Related Assets Adjustment (CRA) for the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) Under the End Stage Renal Disease Prospective Payment System (ESRD PPS) |
| 10948 | Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions |
| 10951 | Phase One Changes Needed to Implement the Revised Process for Handling Undeliverable Beneficiary Addresses in VMS |
| 10953 | Update to Nursing and Allied Health (N&AH) Education Medicare Advantage (MA) Payment Rates - Calendar Year (CY) 2019 |
| 10954 | User CR: MCS - Mass Load "PJ" Segments |
| 10955 | User CR: Multi-Carrier-System (MCS) - Expand Number of Details on Provider Profiles Inquiry (PI) Screen |
| 10957 | Send Electronic Funds Transfer [EFT] Information from Provider Enrollment Chain and Ownership System [PECOS] to Fiscal Intermediary Shared System [FISS] - Implementation CR, Consolidation of January 2022 and April 2022 Releases |
| 10963 | International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs)--January 2022 |
| 10977 | Replacing Home Health Requests for Anticipated Payment (RAPs) with a Notice of Admission (NOA) – Implementation |
| 10986 | Send Electronic Funds Transfer [EFT] Information from Provider Enrollment Chain and Ownership System [PECOS] to ViPS Medicare System [VMS]: Implementation CR |
| 10989 | User CR: MCS - Enhancement to Automate the XHIC Error Process |
| 10990 | User CR: MCS - Enhance Health Professional Shortage Area (HPSA) Reports |
| **Medicare Quality Reporting Incentive Programs (CMS- Pub. 100-22)** | |
| 10340 | Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions |
| 10980 | Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions |
| **State Payment of Medicare Premiums (CMS-Pub.100-24)** | |
| | None |
| **Information Security Acceptable Risk Safeguards (CMS-Pub. 100-25)** | |
| | None |

## Addendum II: Regulation Documents Published in the Federal Register (July through September 2021)

Regulations and Notices

Regulations and notices are published in the daily **Federal Register**. To purchase individual copies or subscribe to the **Federal Register,** contact GPO at www.gpo.gov/fdsys. When ordering individual copies, it is necessary to cite either the date of publication or the volume number and page number.

The **Federal Register** is available as an online database through GPO Access. The online database is updated by 6 a.m. each day the **Federal Register** is published. The database includes both text and graphics from Volume 59, Number 1 (January 2, 1994) through the present date and can be accessed at http://www.gpoaccess.gov/fr/index.html. The following website http://www.archives.gov/federal-register/ provides information on how to access electronic editions, printed editions, and reference copies.

This information is available on our website at: https://www.cms.gov/files/document/regs3q21qpu.pdf

For questions or additional information, contact Terri Plumb (410-786-4481).

## Addendum III: CMS Rulings (July through September 2021)

CMS Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, private health insurance, and related matters.

The rulings can be accessed at http://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings. For questions or additional information, contact Tiffany Lafferty (410-786-7548).

## Addendum IV: Medicare National Coverage Determinations (July through September 2021)

Addendum IV includes completed national coverage determinations (NCDs), or reconsiderations of completed NCDs, from the quarter covered by this notice. Completed decisions are identified by the section of the NCD Manual (NCDM) in which the decision appears, the title, the date the publication was issued, and the effective date of the decision. An NCD is a determination by the Secretary for whether or not a particular item or service is covered nationally under the Medicare Program (title XVIII of the Act), but does not include a determination of the code, if any, that is assigned to a particular covered item or service, or payment determination for a particular covered item or service. The entries below include information concerning completed decisions, as well as sections on program and decision memoranda, which also announce decisions or, in some cases, explain why it was not appropriate to issue an NCD. Information on completed decisions as well as pending decisions has also

been posted on the CMS website. For the purposes of this quarterly notice, we are providing only the specific updates to national coverage determinations (NCDs), or reconsiderations of completed NCDs published in the 3-month period. This information is available at: www.cms.gov/medicare-coverage-database/. For questions or additional information, contact Wanda Belle, MPA (410-786-7491).

| Title | NCDM Section | Transmittal Number | Issue Date | Effective Date |
|---|---|---|---|---|
| National Coverage Determination (NCD) 270.3 Blood-Derived Products for Chronic, Non-Healing Wounds | NCD 270.3 | 10981 | 09/15/2021 | 04/13/2021 |
| National Coverage Determination 20.33 - Transcatheter Edge-To-Edge Repair [Teer] For Mitral Valve | NCD 20.33 | 10985 | 09/08/2021 | 01/19/2021 |
| National Coverage Determination (NCD) Removal | "NCD 20.5 NCD 30.4 NCD 100.9 NCD 110.19 NCD 220.2.1 NCD 220.6.16".3 | 10927 | 08/02/2021 | 01/01/2021 |

**Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (July through September 2021)**

(Inclusion of this addenda is under discussion internally.)

**Addendum VI: Approval Numbers for Collections of Information (July through September 2021)**

All approval numbers are available to the public at Reginfo.gov. Under the review process, approved information collection requests are assigned OMB control numbers. A single control number may apply to several related information collections. This information is available at www.reginfo.gov/public/do/PRAMain. For questions or additional information, contact William Parham (410-786-4669).

**Addendum VII: Medicare-Approved Carotid Stent Facilities (July through September 2021)**

Addendum VII includes listings of Medicare-approved carotid stent facilities. All facilities listed meet CMS standards for performing carotid artery stenting for high risk patients. On March 17, 2005, we issued our decision memorandum on carotid artery stenting. We determined that carotid artery stenting with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. We have created a list of minimum standards for facilities modeled in part on professional society statements on competency. All facilities must at least meet our standards in order to receive coverage for carotid artery stenting for high risk patients. For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available at: http://www.cms.gov/MedicareApprovedFacilitie/CASF/list.asp#TopOfPage For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

| Facility | Provider Number | Effective Date | State |
|---|---|---|---|
| **The following facilities are new listings for this quarter.** | | | |
| Banner Del Webb Medical Center<br>14502 W. Meeker Boulevard<br>Sun City West, AZ 85375 | 030093 | 06/29/2021 | AZ |
| Orlando Health – Health Central Hospital<br>1222 S. Orange Avenue MP 856.<br>Orlando, FL 32806 | 1184709057 | 06/29/2021 | FL |
| WakeMed Cary Hospital<br>1900 Kildaire Farm Road<br>Cary, NC 27518 | 340173 | 04/05/2021 | NC |
| Community Hospital South<br>1402 East County Line<br>Indianapolis, IN 46227 | 150128 | 09/07/2021 | IN |
| Huntsville Health System – Marshall,<br>431 Highway<br>North Boaz, AL 35957 | 010005 | 09/21/2021 | AL |
| Sutter Roseville Medical Center<br>One Medical Plaza<br>Roseville, CA 95661 | 050309 | 09/28/2021 | CA |
| **The following facilities have editorial changes (in bold).** | | | |
| **FROM: Portsmouth Regional Hospital**<br>**TO: HCA Healthcare Services of New Hampshire, Inc.**<br>333 Borthwick Avenue<br>Portsmouth, NH 03801 | 300029 | 06/01/2005 | NH |
| **FROM: Clarian Arnett Health**<br>**TO: Indiana University Health Arnett**<br>5165 McCarty Lane<br>Lafayette, IN 47905 | 150173 | 07/02/2009 | IN |
| **FROM: Mills Peninsula Health Services**<br>**TO: Mills Peninsula Medical Center**<br>**FROM: 1783 El Camino Real**<br>**TO: 1501 Trousdale Drive**<br>Burlingame, CA 94010 | 050007 | 10/11/2005 | CA |

| Facility | Provider Number | Effective Date | State |
|---|---|---|---|
| **FROM: Utah Valley Regional Medical Center**<br>**TO: IHC Health Services, Inc. dba Utah Valley Hospital**<br>1034 N 500 West<br>Provo, UT 84604 | 460001 | 05/26/2005 | UT |
| **FROM: Mainland Medical Center**<br>**TO: HCA Houston Healthcare Mainland Campus**<br>6801 Emmett F. Lowry Expressway<br>Texas City, TX 77591 | 450530 | 10/20/2006 | TX |
| **The following facility has been removed.** | | | |
| St. Lucie Medical Center<br>1800 SE Tiffany Avenue<br>Port St. Lucie, FL 34952 | 10-0260 | 08/19/2021 | FL |

## Addendum VIII: American College of Cardiology's National Cardiovascular Data Registry Sites (July through September 2021)

The initial data collection requirement through the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) has served to develop and improve the evidence base for the use of ICDs in certain Medicare beneficiaries. The data collection requirement ended with the posting of the final decision memo for Implantable Cardioverter Defibrillators on February 15, 2018.

For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

## Addendum IX: Active CMS Coverage-Related Guidance Documents (July through September 2021)

CMS issued a guidance document on November 20, 2014 titled "Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development Document". Although CMS has several policy vehicles relating to evidence development activities including the investigational device exemption (IDE), the clinical trial policy, national coverage determinations and local coverage determinations, this guidance document is principally intended to help the public understand CMS's implementation of coverage with evidence development (CED) through the national coverage determination process. The document is available at http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27. There are no additional Active CMS Coverage-Related Guidance Documents for the 3-month period. For questions or additional information, contact JoAnna Baldwin, MS (410-786-7205).

## Addendum X: List of Special One-Time Notices Regarding National Coverage Provisions (July through September 2021)

There were no special one-time notices regarding national coverage provisions published in the 3-month period. This information is available at http://www.cms.gov . For questions or additional information, contact JoAnna Baldwin, MS (410-786 7205).

## Addendum XI: National Oncologic PET Registry (NOPR) (July through September 2021)

Addendum XI includes a listing of National Oncologic Positron Emission Tomography Registry (NOPR) sites. We cover positron emission tomography (PET) scans for particular oncologic indications when they are performed in a facility that participates in the NOPR.

In January 2005, we issued our decision memorandum on **positron emission tomography** (PET) scans, which stated that CMS would cover PET scans for particular oncologic indications, as long as they were performed in the context of a clinical study. We have since recognized the National Oncologic PET Registry as one of these clinical studies. Therefore, in order for a beneficiary to receive a Medicare-covered PET scan, the beneficiary must receive the scan in a facility that participates in the registry. There were no additions, deletions, or editorial changes to the listing of National Oncologic Positron Emission Tomography Registry (NOPR) in the 3-month period. This information is available at http://www.cms.gov/MedicareApprovedFacilitie/NOPR/list.asp#TopOfPage. For questions or additional information, contact David Dolan, MBA (410-786-3365).

## Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (July through September 2021)

Addendum XII includes a listing of Medicare-approved facilities that receive coverage for ventricular assist devices (VADs) used as destination therapy. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy. On October 1, 2003, we issued our decision memorandum on VADs for the clinical indication of destination therapy. We determined that VADs used as destination therapy are reasonable and necessary only if performed in facilities that have been determined to have the experience and infrastructure to ensure optimal patient outcomes. We established facility standards and an application process. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy.

For the purposes of this quarterly notice, we are providing only the specific updates to the list of Medicare-approved facilities that meet our standards that have occurred in the 3-month period. This information is available at

http://www.cms.gov/MedicareApprovedFacilitie/VAD/list.asp#TopOfPage. For questions or additional information, contact David Dolan, MBA, (410-786-3365).

| Facility | Provider Number | Date of Initial Certification | Date of Re-certification | State |
|---|---|---|---|---|
| **The following are new facilities.** | | | | |
| Baylor Scott & White All Saints Medical Center - Fort Worth<br>1400 8th Avenue<br>Fort Worth, TX 76104<br><br>Other information:<br>DNV GL# 10000469761-Assessment Services-DNV GL-USA<br><br>Previous Re-certification Dates: n/a | 450137 | 05/26/2021 | | TX |
| AU Medical Center<br>1120 15th Street<br>Augusta, GA 30912<br><br>Other information<br>DNV ID # 10000483076-MSC-DNV-USA<br><br>Previous Re-certification Dates: n/a | 110034 | 08/06/2021 | | GA |
| **The following facilities have editorial changes (in bold).** | | | | |
| **TO: Adventist Health System/Sunbelt Inc. dba Florida Hospital**<br>**FROM Adventist Health System/Sunbelt Inc. dba Advent Health**<br>601 East Rollins Street<br>Orlando, FL 32803<br><br>Other information:<br>Joint Commission ID # 6873<br><br>Previous Re-certification Dates:<br>10/24/2012; 10/07/2014; 11/15/2016; 01/30/2019 | 100007 | 10/24/2012 | **06/12/2021** | FL |
| Medical University of South Carolina Medical Center<br>169 Ashley Avenue<br>Charleston, SC 29425<br><br>**Joint Commission ID # 6584**<br><br>**Previous Re-certification Dates:**<br>**09/23/2010; 09/07/2012; 08/05/2014; 09/13/2016; 09/26/2018** | 420004 | 09/23/2010 | **03/24/2021** | WI |
| University of Utah, Hospitals and Clinics<br>50 N. Medical Drive<br>Salt Lake City, UT 84132<br><br>Other information:<br><br>Certificate #: 10000435189-MSC-DNV GL-USA<br>Previous Re-certification Dates:<br>01/13/2009; 07/13/2011; 06/18/2013; 06/23/2015; 08/08/2017; 05/25/2018 | 460009 | 01/13/2009 | **05/21/2021** | UT |
| Medical City Dallas<br>7777 Forest Lane<br>Dallas, TX 75230<br><br>Other information:<br>Joint Commission ID # 9008<br>Previous Re-certification Dates:<br>09/09/2008; 08/10/2010; 07/17/2012; 06/27/2014; 07/12/2016 | 450647 | 09/09/2008 | **04/03/2021** | TX |
| Vanderbilt University Medical Center<br>1211 Medical Center Drive<br>Nashville, TN 37232-2101<br><br>Joint Commission ID # 7892<br><br>Previous Re-certification Dates:<br>04/20/2012; 03/11/2014; 04/05/2016; 05/08/2018 | 440039 | 04/20/2012 | **04/28/2021** | TN |
| Memorial Regional Hospital<br>3501 Johnson Street<br>Hollywood, FL 33021<br><br>Joint Commission ID # 6811<br><br>Previous Re-certification Dates: 2016-08-11; 2014-08-20 | 100038 | 08/20/2014 | **03/27/2021** | FL |
| Moses H. Cone Memorial Hospital<br>1200 North Elm Street<br>Greensboro, NC 27401-1020<br>Other information:<br>Joint Commission ID # 6504 | 340091 | 01/07/2014 | **04/17/2021** | NC |

| Facility | Provider Number | Date of Initial Certification | Date of Re-certification | State |
|---|---|---|---|---|
| Previous Re-certification Dates: 01/07/2014; 02/09/2016; 02/13/2018 | | | | |
| Hospital of the University of Pennsylvania<br>3400 Spruce Street<br>Philadelphia, PA 19104<br><br>Other information:<br>Joint Commission ID # 6129<br><br>Previous Re-certification Dates: 2010-06-08; 2012-05-25; 2014-04-15; 2016-06-15; 2018-07-18 | 390111 | 06/08/2010 | **05/06/2021** | PA |
| University of Iowa Hospitals and Clinics<br>200 Hawkins Drive<br>Iowa City, IA 52242<br><br>Joint Commission ID # 8266<br><br>Previous Re-certification Dates: 06/22/2010; 07/26/2012; 07/29/2014; 08/02/2016; 7/11/2018 | 160058 | 06/22/2010 | **04/08/2021** | IA |
| Lutheran Hospital of Indiana<br>7950 West Jefferson Boulevard<br>Fort Wayne, IN 46804<br><br>Other information:<br>Joint Commission ID # 7157<br><br>Previous Re-certification Dates: 09/14/2010; 10/24/2012; 10/21/2014; 11/01/2016 | 150017 | 09/14/2010 | **05/05/2021** | IN |
| Emory Saint Joseph's Hospital of Atlanta, Inc.<br>5665 Peachtree Dunwoody Road<br>Atlanta, GA 30342<br><br>Other information:<br>Joint Commission ID # 6652<br><br>Previous Re-certification Dates: 07/13/2010; 07/11/2012; 06/03/2014; 07/12/2016; 06/05/2018 | 110082 | 07/13/2010 | **05/08/2021** | GA |
| Mercy General Hospital<br>4001 J Street<br>Sacramento, CA 95819<br><br>Other information:<br>Joint Commission ID # 10053<br><br>Previous Re-certification Dates: 02/11/2014; 03/08/2016; 03/13/2018 | 050017 | 02/11/2014 | **04/14//2021** | CA |
| Providence St. Vincent Medical Center<br>9205 SW Barnes Road<br>Portland, OR 97225<br><br>Other information:<br>Joint Commission ID # 9705<br><br>Previous Re-certification Dates: 12/06/2011; 12/10/2013; 01/26/2016; 02/13/2018 | 380004 | 12/06/2011 | **07/24/2021** | OR |
| University of Mississippi Medical Center<br>2500 North State Street<br>Jackson, MS 39216<br><br>Other information:<br>Joint Commission ID # 8064<br><br>Previous Re-certification Dates: 08/16/2016; 08/08/2018 | 250001 | 08/16/2016 | **05/20/2021** | MS |
| CHI St. Luke's Health Baylor College of Medicine Medical Ctr<br>6720 Bertner Avenue<br>Houston, TX 77030<br><br>Other information:<br>Joint Commission ID # 9098<br><br>Previous Re-certification Dates: 10/07/2008; 11/17/2010; 11/06/2012; | 450193 | 10/28/2003 | **06/05/2021** | TX |
| University of Cincinnati Medical Center, LLC<br>234 Goodman Street<br>Cincinnati, OH 45219<br><br>Other information:<br>Joint Commission ID # 6988 | 360003 | 12/13/2011 | **05/19/2021** | OH |

| Facility | Provider Number | Date of Initial Certification | Date of Re-certification | State |
|---|---|---|---|---|
| Previous Re-certification Dates:<br>12/13/2011; 01/07/2014; 02/23/2016; 03/13/2018 | | | | |
| **FROM: Old: Indiana University Health Methodist Hospital**<br>**TO: Indiana University Health, Inc.**<br>1701 North Senate Boulevard<br>Indianapolis, IN 46202<br><br>Other information:<br>Joint Commission ID # 188549<br><br>Previous Re-certification Dates:<br>08/12/2008; 08/17/2010; 08/17/2012; 08/19/2014; 10/04/2016 | 150056 | 08/12/2008 | **05/29/2021** | IN |
| University of Wisconsin Hospitals and Clinics Authority<br>600 Highland Avenue<br>Madison, WI 53792<br><br>Other information:<br>Joint Commission ID # 7656<br><br>Previous Re-certification Dates:<br>08/05/2008; 08/24/2010; 08/07/2012; 07/17/2014; 08/09/2016 | 520098 | 08/05/2008 | **06/04/2021** | WI |
| Loma Linda University Medical Center<br>11234 Anderson Street<br>Loma Linda, CA 92354<br><br>Other information:<br>Joint Commission ID # 9898<br><br>Previous Re-certification Dates:<br>02/07/2012; 01/23/2014; 02/23/2016; 04/10/2018 | 050327 | 02/07/2012 | **05/15/2021** | CA |
| INTEGRIS Baptist Medical Center<br>3300 Northwest Expressway<br>Oklahoma City, OK 73112<br><br>Other information:<br>Joint Commission ID # 8872 | 370028 | 08/12/2008 | **06/19/2021** | OK |

| Facility | Provider Number | Date of Initial Certification | Date of Re-certification | State |
|---|---|---|---|---|
| Previous Re-certification Dates:<br>08/12/2008; 07/20/2010; 07/24/2012; 07/08/2014; 08/23/2016 | | | | |
| Catholic Health Initiatives - Iowa, Corp.<br>1111 6th Avenue<br>Des Moines, IA 50314<br><br>Other information:<br>Joint Commission ID # 5518<br><br>Previous Re-certification Dates:<br>10/23/2008; 10/01/2010; 10/03/2012; 09/23/2014; 11/08/2016; 12/5/2018 | 160083 | 01/06/2015 | **07/01/2021** | IA |
| Tufts Medical Center<br>800 Washington Street<br>Boston, MA 02111<br><br>Other information:<br>Joint Commission ID # 5518<br>Previous Re-certification Dates:<br>10/23/2008; 10/01/2010; 10/03/2012; 09/23/2014; 11/08/2016; 12/5/2018 | 220116 | 10/23/2008 | **06/23/2021** | MA |
| Brigham and Women's Hospital<br>75 Francis Street<br>Boston, MA 02115<br><br>Other information:<br>Joint Commission ID # 5503<br><br>Previous Re-certification Dates:<br>11/04/2008; 12/09/2010; 12/07/2012; 11/07/2014; 12/13/2016; 2/27/2019 | 220110 | 11/04/2008 | **07/10/2021** | MA |
| **FROM: Maine Medical Center**<br>**TO: MaineHealth**<br>22 Bramhall Street<br>Portland, ME 04102<br><br>Other information:<br>Joint Commission ID # 5445<br><br>Previous Re-certification Dates:<br>11/05/2008; 09/27/2016; 10/3/2018 | 200009 | 11/05/2008 | **07/08/2021** | ME |

| Facility | Provider Number | Date of Initial Certification | Date of Re-certification | State |
|---|---|---|---|---|
| Sharp Memorial Hospital<br>7901 Frost Street<br>San Diego, CA 92123<br><br>Other information:<br>Joint Commission ID # 3910<br><br>Previous Re-certification Dates:<br>07/17/2008; 06/29/2010; 08/14/2012; 09/09/2014; 08/09/2016; 8/15/2018 | 050100 | 07/17/2008 | **06/05/2021** | CA |
| North Shore University Hospital<br>300 Community Drive<br>Manhasset, NY 11030<br><br>Other information:<br>Joint commission ID # 2091<br><br>Previous Re-certification Dates:<br>09/27/2016; 9/19/2018 | 330106 | 09/27/2016 | **06/26/2021** | NY |

## Addendum XIII: Lung Volume Reduction Surgery (LVRS) (July through September 2021)

Addendum XIII includes a listing of Medicare-approved facilities that are eligible to receive coverage for lung volume reduction surgery. Until May 17, 2007, facilities that participated in the National Emphysema Treatment Trial were also eligible to receive coverage. The following three types of facilities are eligible for reimbursement for Lung Volume Reduction Surgery (LVRS):

- National Emphysema Treatment Trial (NETT) approved (Beginning 05/07/2007, these will no longer automatically qualify and can qualify only with the other programs);
- Credentialed by the Joint Commission (formerly, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)) under their Disease Specific Certification Program for LVRS; and
- Medicare approved for lung transplants.

Only the first two types are in the list. There was an update to the listing of facilities for lung volume reduction surgery published in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilitie/LVRS/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

| The following facility has editorial changes in bold. | | | |
|---|---|---|---|
| **Facility Name** | **Provider #** | **Certification Date** | **State** |
| Ohio State University Hospitals<br>410 West Tenth Avenue, DN 168 Columbus, OH 43210<br><br>Other information:<br>Joint Commission ID # 7029<br><br>Previous Re-certification Dates:<br>12/15/2018<br><br>Tammie Hayes, Director, LVRS, 614-293-3629 | 360085 | **08/28/2021** | OH |

## Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (July through September 2021)

Addendum XIV includes a listing of Medicare-approved facilities that meet minimum standards for facilities modeled in part on professional society statements on competency. All facilities must meet our standards in order to receive coverage for bariatric surgery procedures. On February 21, 2006, we issued our decision memorandum on bariatric surgery procedures. We determined that bariatric surgical procedures are reasonable and necessary for Medicare beneficiaries who have a body-mass index (BMI) greater than or equal to 35, have at least one co-morbidity related to obesity and have been previously unsuccessful with medical treatment for obesity. This decision also stipulated that covered bariatric surgery procedures are reasonable and necessary only when performed at facilities that are: (1) certified by the American College of Surgeons (ACS) as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery (ASBS) as a Bariatric Surgery Center of Excellence (BSCOE) (program standards and requirements in effect on February 15, 2006).

There were no additions, deletions, or editorial changes to Medicare-approved facilities that meet CMS' minimum facility standards for bariatric surgery that have been certified by ACS and/or ASMBS in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilitie/BSF/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

## Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (July through September 2021)

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the 3-month period.

This information is available on our website at www.cms.gov/MedicareApprovedFacilitie/PETDT/list.asp#TopOfPage. For questions or additional information, contact David Dolan, MBA (410-786-3365).

[FR Doc. 2021–25103 Filed 11–17–21; 8:45 am]
BILLING CODE 4120–01–C

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2021–N–1195]**

### Discovery Therapeutics, LLC, et al.; Withdrawal of Approval of 18 Abbreviated New Drug Applications

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is withdrawing approval of 18 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

**DATES:** Approval is withdrawn as of December 20, 2021.

**FOR FURTHER INFORMATION CONTACT:** Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, *Martha.Nguyen@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

| Application No. | Drug | Applicant |
|---|---|---|
| ANDA 040619 | Methimazole Tablets, 15 milligrams (mg) | Discovery Therapeutics, LLC, 2831 Deer Hound Way, Palm Harbor, FL 34683. |
| ANDA 070254 | Naloxone Hydrochloride (HCl) Injection, 0.4 mg/milliliters (mL). | Hospira, Inc., 275 North Field Dr., Building H1, Lake Forest, IL 60045. |
| ANDA 070586 | Bupivacaine HCl Injection, 0.25% | Do. |
| ANDA 071850 | Morphine Sulfate Injection, 1 mg/mL | Do. |
| ANDA 075220 | Desmopressin Acetate Injection, 0.004 mg/mL | Do. |
| ANDA 076498 | Tretinoin Cream, 0.05% | ZO Skin Health, Inc., 9685 Research Dr., Irvine, CA 92618. |
| ANDA 077245 | Ciprofloxacin Injection, 200 mg/20 mL (10 mg/mL) and 400 mg/40 mL (10 mg/mL). | Hospira, Inc. |
| ANDA 080409 | Lidocaine HCl Solution, 4% | Do. |
| ANDA 087446 | Chloroprocaine HCl Injection, 3% | Do. |
| ANDA 087447 | Chloroprocaine HCl Injection, 2% | Do. |
| ANDA 201653 | Levocetirizine Dihydrochloride Tablets, 5 mg | Sun Pharmaceutical Industries, Inc., U.S. Agent for Sun Pharmaceutical Industries Ltd., 270 Prospect Plains Rd., Cranbury, NJ 08512. |
| ANDA 202524 | Levetiracetam Extended Release Tablets, 500 mg and 750 mg. | Rouses Point Pharmaceuticals, LLC, 11 Commerce Dr., Cranford, NJ 07016. |
| ANDA 202857 | Daptomycin Powder for Injection, 500 mg/vial | Hospira, Inc. |
| ANDA 203885 | Amiodarone HCl Injection, 50 mg/mL | Do. |
| ANDA 207864 | Eptifibatide Injection, 2 mg/mL and 75 mg/100 mL | The WhiteOak Group, LLC, U.S. Agent for Hybio Pharmaceutical Co., Ltd., 1629 K St. NW, Suite 300, Washington, DC 20006. |
| ANDA 209489 | Caspofungin Acetate Powder for Injection, 50 mg/vial and 70 mg/vial. | Cipla USA, Inc., U.S. Agent for Cipla Limited, 10 Independence Blvd., Suite 300, Warren, NJ 07059. |
| ANDA 210283 | Clofarabine Injection, 20 mg/20 mL (1 mg/mL) | Hospira, Inc. |
| ANDA 210855 | Sodium Nitroprusside Injection, 25 mg/mL | Cipla USA, Inc. |

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of December 20, 2021. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on December 20, 2021 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: November 12, 2021.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2021–25111 Filed 11–17–21; 8:45 am]
BILLING CODE 4164–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Eunice Kennedy Shriver National Institute of Child Health and Human Development; 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 Board of Scientific Counselors, NICHD.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the Eunice Kennedy Shriver National Institute of Child Health and Human Development, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Board of Scientific Counselors, NICHD.

*Date:* December 3, 2021.

*Time:* 10:00 a.m. to 5:00 p.m.

*Agenda:* A report by the Acting Scientific Director, NICHD, on the status of the NICHD

Division of Intramural Research; current organizational structure; to review and evaluate personnel qualifications and performance, and competence of individual investigators.

*Place:* National Institutes of Health, 31 Center Drive, Bethesda, MD 20892, (Video-Assisted Meeting).

*Contact Person:* Chris J. McBain, Ph.D., Acting Scientific Director, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 10 Center Drive, Room 10D39, Bethesda, MD 20892, (301) 594–5984, *mcbainc@mail.nih.gov.*

Information is also available on the Institute's/Center's home page: *https://www.nichd.nih.gov/about/advisory/bsc,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.865, Research for Mothers and Children, National Institutes of Health, HHS)

Dated: November 15, 2021.

**Melanie J. Pantoja,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2021–25161 Filed 11–17–21; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

**[1651–0139]**

### Electronic Visa Update System (EVUS)

**AGENCY:** U.S. Customs and Border Protection (CBP), Department of Homeland Security.

**ACTION:** 60-Day notice and request for comments; revision of an existing collection of information.

**SUMMARY:** The Department of Homeland Security, U.S. Customs and Border Protection will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

**DATES:** Comments are encouraged and must be submitted (no later than January 18, 2022) to be assured of consideration.

**ADDRESSES:** Written comments and/or suggestions regarding the item(s) contained in this notice must include the OMB Control Number 1651–0139 in the subject line and the agency name. Please use the following method to submit comments:

*Email:* Submit comments to: *CBP_PRA@cbp.dhs.gov.*

Due to COVID–19-related restrictions, CBP has temporarily suspended its ability to receive public comments by mail.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number 202–325–0056 or via email *CBP_PRA@cbp.dhs.gov.* Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/*.

**SUPPLEMENTARY INFORMATION:** CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

### Overview of This Information Collection

*Title:* Electronic Visa Update System (EVUS).

*OMB Number:* 1651–0139.

*Form Number:* N/A.

*Current Actions:* Revision of an existing information collection.

*Type of Review:* Revision.

*Affected Public:* Individuals.

*Abstract:* DHS developed the Electronic Visa Update System (EVUS) to assure robust screening of foreign nationals prior to travel to the United States. EVUS provides for robust traveler screening and verification to better identify foreign nationals who may be inadmissible to the United States. This results in enhanced national security, improved public safety, and a reduced number of delays upon arrival in the United States, all while facilitating legitimate travel.

Initially, the program is limited to nonimmigrant aliens presenting passports issued by the People's Republic of China (PRC) containing unrestricted, maximum validity B–1 (business visitor), B–2 (visitor for pleasure), or combination B–1/B–2 visas, generally valid for 10 years. PRC membership in EVUS became possible on November 12, 2014, when, in a reciprocal agreement, the U.S. Department of State expanded the validity of U.S. visitor visas issued to PRC nationals from one to ten years.

To ensure compliance with the Visa Waiver Program Improvement and Terrorist Travel Prevention Act of 2015, Public Law 114–113, 129 Stat. 2242, CBP will continuously update the application question with the list of nationals ineligible from traveling to the United States, as designated in accordance with section 217(a)(12) of the Immigration and Nationality Act, as amended (8 U.S.C. 1187(a)(12)).

*Recent Changes*

On May 31, 2019, the Department of State updated its immigrant and nonimmigrant visa application forms to request additional information, specifically social media identifiers, from most U.S. visa applicants worldwide. As a result, DHS is changing the EVUS application social media data field from optional to mandatory. National security is the top priority when adjudicating EVUS applications, and every prospective traveler to the United States undergoes extensive security screening. CBP is continually working to find mechanisms to improve our screening processes to protect U.S. visitors while supporting legitimate travel to the United States. DHS already requests information on contacts, travel history, and family members from all EVUS applicants. Changing the social medial field to mandatory in the EVUS application will enhance our vetting capabilities and assist in confirming applicants' identities. While the field is

mandatory, applicants will still have the ability to select ''none''.

*Type of Information Collection:* EVUS.

*Estimated Number of Respondents:* 3,595,904.

*Estimated Number of Annual Responses per Respondent:* 1.

*Estimated Number of Total Annual Responses:* 3,595,904.

*Estimated Time per Response:* 25 minutes.

*Estimated Total Annual Burden Hours:* 1,499,492.

Dated: November 15, 2021.

**Seth D. Renkema,**

*Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.*

[FR Doc. 2021–25146 Filed 11–17–21; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

**[1651–0111]**

### Arrival and Departure Record, Nonimmigrant Visa Waiver Arrival/ Departure, Electronic System for Travel Authorization (ESTA)

**AGENCY:** U.S. Customs and Border Protection (CBP), Department of Homeland Security.

**ACTION:** 60-Day notice and request for comments; revision of an existing collection of information.

**SUMMARY:** The Department of Homeland Security, U.S. Customs and Border Protection will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

**DATES:** Comments are encouraged and must be submitted (no later than January 18, 2022) to be assured of consideration.

**ADDRESSES:** Written comments and/or suggestions regarding the item(s) contained in this notice must include the OMB Control Number 1651–0111 in the subject line and the agency name. Please use the following method to submit comments:

*Email:* Submit comments to: *CBP_PRA@cbp.dhs.gov.*

Due to COVID–19-related restrictions, CBP has temporarily suspended its ability to receive public comments by mail.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number 202–325–0056 or via email *CBP_PRA@cbp.dhs.gov.* Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/.*

**SUPPLEMENTARY INFORMATION:** CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

#### Overview of This Information Collection

*Title:* Arrival and Departure Record, Nonimmigrant Visa Waiver Arrival/ Departure, Electronic System for Travel Authorization (ESTA).

*OMB Number:* 1651–0111.

*Form Number:* CBP Forms I–94 and I–94W.

*Current Actions:* Revision of an existing information collection.

*Type of Review:* Revision.

*Affected Public:* Individuals.

*Abstract:* Forms I–94 (Arrival/ Departure Record) and I–94W (Nonimmigrant Visa Waiver Arrival/ Departure Record) are used to document a traveler's admission into the United States. These forms are filled out by non-immigrants and are used to collect information on citizenship, residency, passport, and contact information. The data elements collected on these forms enable the Department of Homeland Security (DHS) to perform its mission related to the screening of noncitizen visitors for potential risks to national security and the determination of admissibility to the United States.

The Electronic System for Travel Authorization (ESTA) applies to non-immigrants seeking to travel to the United States under the Visa Waiver Program (VWP) and requires that VWP travelers provide information electronically to CBP before embarking on travel to the United States without a visa. Travelers who are entering the United States under the VWP in the air or sea environment, and who have a travel authorization obtained through ESTA, are not required to complete the paper Form I–94W. I–94 is provided for by 8 CFR 235.1(h), ESTA is provided for by 8 CFR 217.5.

On December 18, 2015, the President signed into law the Visa Waiver Program Improvement and Terrorist Travel Prevention Act of 2015 (''VWP Improvement Act'') as part of the Consolidated Appropriations Act, 2016, Public Law 114–113, 129 Stat. 2242. To meet the requirements of this new act, the Department of Homeland Security (DHS, or the Department) strengthened the security of the VWP through enhancements to the ESTA applications and to the Form I–94W, Form I–94 is not affected by this change. Many of the provisions of the new law became effective on the date of enactment of the VWP Improvement Act. The VWP Improvement Act generally makes certain nationals of VWP countries ineligible (with some exceptions) from traveling to the United States under the VWP. To ensure compliance with the VWP Improvement Act, CBP will continuously update the application question with the list of nationals ineligible from traveling to the United States, as designated in accordance with section 217(a)(12) of the Immigration and Nationality Act, as amended (8 U.S.C. 1187(a)(12)).

*Recent Changes*

1. *Mandatory Social Media Collection:* On May 31, 2019, the Department of State updated its immigrant and nonimmigrant visa application forms to request additional information,

including social media identifiers, from most U.S. visa applicants worldwide. In keeping with this change, CBP is amending the ESTA application to change social media collection from optional to mandatory. National security is CBP's top priority when adjudicating ESTA applications, and every prospective traveler to the United States undergoes extensive security screening. CBP is continually working to find mechanisms to improve our screening processes to protect U.S. citizens, while supporting legitimate travel to the United States. CBP already requests certain contact information, travel history and family member information from all ESTA applicants. Making social media a mandatory field in the ESTA application will enhance our vetting processes and assist in confirming applicants' identities. While the completion of the field is mandatory, applicants can still select ''none''.

2. *Biometric Information Collection:* CBP will begin collecting biometric data for identity confirmation on ESTA applications. ESTA applicants will be prompted to take a selfie or ''live'' photo to conduct a ''liveness'' test to determine if the ESTA application is interfacing with a physically present human being and not an inanimate object, or if it is a photo of someone other than the lawful passport holder. Respondents will be able to scan their passport biographic page, in order to submit biographic information, including passport photograph.

3. *ESTA Mobile Application (App):* CBP will implement the ESTA Mobile Application to provide an additional and more convenient option for intending VWP travelers to obtain an ESTA. The Mobile App will collect biometric data for confirmation of identity. This is another enhancement that will assist in preventing persons intending to travel to the United States under the VWP by fraud.

This new function will be accessible via mobile devices, *i.e.,* mobile phones, tablets. The portability of mobile devices will facilitate applying for an ESTA application, because an ESTA applicant will not be limited to applying on a desktop computer. The first phase will enable Android devices to use the ESTA App, and the second phase will follow with iOS. No implementation date has been set for iOS implementation.

The Mobile App will be very similar to the already established ESTA application website at *https://esta.cbp.dhs.gov,* but with Near Field Communication (NFC).

*The NFC:*

- Allows users to scan the passport e-Chip (embedded in the passport) to extract passenger data.
- A Mobile Device with NFC capability is required to scan the Passport e-Chip when applying for a new application using the ESTA Mobile App.
- Data on the e-Chip enables the NFC Scan.
- If the mobile device does not have NFC capability, the user can submit an ESTA application via the established website.

After determining if the mobile device has NFC capability:

- The applicant takes a selfie or ''live'' photo (another person may also take a photo of the applicant).
- The Mobile App will do a ''liveness'' test to determine that it is interfacing with a physically present human being and not an inanimate object, or if it is a photo of someone other than the lawful passport holder.
- If the passport photo does not match the ''liveness'' photo, a ''Third Party Acknowledgement'' screen will display, which requires confirmation.
- The applicant proceeds by completing the data fields the same as with the established ESTA application.
- When the applicant completes the application, he/she can review his/her responses.

The payment process will be the same as the established ESTA application, and the cost of each ESTA application will continue to be 14 USD, except in the case of a denial, the fee is 4 USD.

*Type of Information Collection:* I–94.
*Estimated Number of Respondents:* 4,387,550.
*Estimated Number of Annual Responses per Respondent:* 1.
*Estimated Number of Total Annual Responses:* 4,387,550.
*Estimated Time per Response:* 0.133 hours.
*Estimated Total Annual Burden Hours:* 583,544.

*Type of Information Collection:* I–94 Website.
*Estimated Number of Respondents:* 3,858,782.
*Estimated Number of Annual Responses per Respondent:* 1.
*Estimated Number of Total Annual Responses:* 3,858,782.
*Estimated Time per Response:* 0.066 hours.
*Estimated Total Annual Burden Hours:* 254,679.

*Type of Information Collection:* I–94W.
*Estimated Number of Respondents:* 941,291.
*Estimated Number of Annual Responses per Respondent:* 1.
*Estimated Number of Total Annual Responses:* 941,291.
*Estimated Time per Response:* 0.2667 hours.
*Estimated Total Annual Burden Hours:* 251,042.

*Type of Information Collection:* ESTA Website Application.
*Estimated Number of Respondents:* 15,000,000.
*Estimated Number of Annual Responses per Respondent:* 1.
*Estimated Number of Total Annual Responses:* 15,000,000.
*Estimated Time per Response:* 0.3833 hours.
*Estimated Total Annual Burden Hours:* 5,941,150.

*Type of Information Collection:* ESTA Mobile Application (App).
*Estimated Number of Respondents:* 500,000.
*Estimated Number of Annual Responses per Respondent:* 1.
*Estimated Number of Total Annual Responses:* 500,000.
*Estimated Time per Response:* 0.2142 hours.
*Estimated Total Annual Burden Hours:* 1,071,429.

Dated: November 15, 2021.

**Seth D. Renkema,**

*Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.*

[FR Doc. 2021–25147 Filed 11–17–21; 8:45 am]

BILLING CODE P

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Citizenship and Immigration Services

**[OMB Control Number 1615–0043]**

### Agency Information Collection Activities; Extension, Without Change, of a Currently Approved Collection: Application for Temporary Protected Status

**AGENCY:** U.S. Citizenship and Immigration Services, Department of Homeland Security.

**ACTION:** 60-Day notice.

**SUMMARY:** The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) invites the general public and other Federal agencies to comment upon this proposed extension of a currently approved collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of

the information collection, the categories of respondents, the estimated burden (*i.e.* the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

**DATES:** Comments are encouraged and will be accepted for 60 days until January 18, 2022.

**ADDRESSES:** All submissions received must include the OMB Control Number 1615–0043 in the body of the letter, the agency name and Docket ID USCIS–2007–0013. Submit comments via the Federal eRulemaking Portal website at *https://www.regulations.gov* under e-Docket ID number USCIS–2017–0013.

**FOR FURTHER INFORMATION CONTACT:** USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, telephone number (240) 721–3000 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *https://www.uscis.gov,* or call the USCIS Contact Center at 800–375–5283 (TTY 800–767–1833).

**SUPPLEMENTARY INFORMATION:**

## Comments

You may access the information collection instrument with instructions or additional information by visiting the Federal eRulemaking Portal site at: *https://www.regulations.gov* and entering USCIS–2007–0013 in the search box. All submissions will be posted, without change, to the Federal eRulemaking Portal at *https://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *https://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

## Overview of This Information Collection

(1) *Type of Information Collection:* Extension, Without Change, of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Application for Temporary Protected Status.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I–821; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. Form I–821 is necessary for USCIS to gather the information necessary to adjudicate TPS applications and determine if an applicant is eligible for TPS.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection I–821 Paper is 453,600 and the estimated hour burden per response is 2.41 hours. The estimated total number of respondents for the information collection I–821 Paper is 113,400 and the estimated hour burden per response is 1.92 hours. The estimated total number of respondents for the information collection I–821 Paper is 567,000 and the estimated hour burden per response is 1.17 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 1,974,294 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $73,401,836.

Dated: November 10, 2021.

**Jerry L Rigdon,**

*Deputy Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.*

[FR Doc. 2021–25194 Filed 11–17–21; 8:45 am]

**BILLING CODE 9111–97–P**

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## DEPARTMENT OF HOMELAND SECURITY

### U.S. Citizenship and Immigration Services

**[OMB Control Number 1615–0018]**

### Agency Information Collection Activities; Extension, Without Change, of a Currently Approved Collection: Application for Permission To Reapply for Admission Into the United States After Deportation or Removal

**AGENCY:** U.S. Citizenship and Immigration Services, Department of Homeland Security.

**ACTION:** 30-Day notice.

**SUMMARY:** The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The purpose of this notice is to allow an additional 30 days for public comments.

**DATES:** Comments are encouraged and will be accepted until December 20, 2021.

**ADDRESSES:** Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be submitted via the Federal eRulemaking Portal website at *http://www.regulations.gov* under e-Docket ID number USCIS–2005–0034. All submissions received must include the OMB Control Number 1615–0018 in the body of the letter, the agency name and Docket ID USCIS–2005–0034.

**FOR FURTHER INFORMATION CONTACT:** USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, Telephone number (240) 721–3000 (This is not a toll-free number; comments are not accepted via telephone message.). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about

the status of their individual cases can check Case Status Online, available at the USCIS website at *http://www.uscis.gov,* or call the USCIS Contact Center at (800) 375–5283; TTY (800) 767–1833.

**SUPPLEMENTARY INFORMATION:**

**Comments**

The information collection notice was previously published in the **Federal Register** on August 12, 2021, at 86 FR 444000, allowing for a 60-day public comment period. USCIS received 2 comments in connection with the 60-day notice.

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2005–0034 in the search box. The comments submitted to USCIS via this method are visible to the Office of Management and Budget and comply with the requirements of 5 CFR 1320.12(c). All submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

**Overview of This Information Collection**

(1) *Type of Information Collection Request:* Extension, Without Change, of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Application for Permission to Reapply for Admission into the United States after Deportation or Removal

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I–212; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. USCIS uses the data collected on Form I–212 to determine whether an alien is eligible for and should be granted the benefit of consent to reapply for admission into the United States. This form standardizes requests for consent to reapply and its data collection requirements ensure that, when filing the application, the alien provides the basic information that is required to assess eligibility for consent to reapply.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection I–212 (Paper) is 7,000 and the estimated hour burden per response is 2 hours. The estimated total number of respondents for the information collection I–212 (CBP e-SAFE) is 1,200 and the estimated hour burden per response is 2 hours. The estimated total number of respondents for the information collection of Biometrics is 350 and the estimated hour burden per response is 1.17 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 16,810 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $370,650.

Dated: November 10, 2021.

**Jerry L Rigdon,**

*Deputy Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.*

[FR Doc. 2021–25193 Filed 11–17–21; 8:45 am]

BILLING CODE 9111–97–P

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

**[Docket No. FR–7046–N–06]**

## Privacy Act of 1974; System of Records

**AGENCY:** Office of the Chief Financial Officer (OCFO), HUD.

**ACTION:** Notice of a Modified System of Records.

**SUMMARY:** Line of Credit Controls System (LOCCS), an Office of the Chief Financial Officer (OCFO) system, is a disbursement and cash management system that services the funding needs of HUD's grant, loan, and subsidy clients. Under the Privacy Act of 1974, the Department of Housing and Urban Development, the Office of the Chief Financial Officer proposes to update the system of records titled, Line of Credit Controls System. This system of records allows the Department of Housing and Urban Development OCFO's LOCCS to collect and maintain records on grantees. Because of a review of this system, information has been updated within the System Location section of the SORN and the authorities to collect information for LOCCS has been updated.

**DATES:** This notice action shall be applicable immediately, which will become effective December 20, 2021.

Comments will be accepted on or before: December 20, 2021.

**ADDRESSES:** You may submit comments, identified by docket number by one of these methods:

*Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions provided on that site to submit comments electronically.

*Fax:* 202–619–8365;

*Email: www.privacy@hud.gov;*

*Mail:* Attention: Privacy Office; LaDonne L. White; The Executive Secretariat; 451 Seventh Street SW, Room 10139; Washington, DC 20410–1001.

*Instructions:* All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov.* including any personal information provided.

*Docket:* For access to the docket to read background documents or comments received go to *http://www.regulations.gov.*

**FOR FURTHER INFORMATION CONTACT:** LaDonne White, Chief Privacy Officer, 451 Seventh Street SW, Room 10139, Washington, DC 20410, telephone

number 202–708–3559 (this is not a toll-free number).

**SUPPLEMENTARY INFORMATION:** The following are to be updated:

- The system location is being changed. LOCCS records are no longer in South Charleston, WV. It is at HUD Headquarters; Microsoft Azure Cloud US East Data Center. Microsoft is responsible for securing their data center per FedRAMP requirements.
- Routine uses previously included by reference are not explicitly listed in the SORN. This change adds no new routine uses, but merely reorganizes them. The routine uses included by reference to HUD's Appendix I are now explicitly listed.
- Remove instances of Program Accounting System (PAS) because it has been decommissioned. A new module has been added to LOCCS. LOCCS incorporated the entire Program Accounting System (PAS) functionality in this new Award Funding module. PAS users now access LOCCS to perform their daily tasks in the LOCCS Award Funding Module. However, no new Personally Identifiable Information (PII) is being collected, stored, maintained, or disclosed because of the PAS module being incorporated. Social Security Numbers have been removed from the system.
- Authority for Maintenance of the System: Replace ''Sec. 113 of the Budget and Accounting Act of 1951 (31 U.S.C.66a)'' with ''31 U.S.C. 3511''.
- Updated Categories of Individuals Covered by System.
- Updated Policies and Practices for Retention and Disposal of Records.
- Slight changes to the Record Access Procedures, Contesting Records Procedures, and Notification Procedures sections have been made. Minor non-substantive changes have been made to these sections to more accurately describe HUD's practices for accessing, contesting, and notifying.

**SYSTEM NAME AND NUMBER:**

Line of Credit Control System (LOCCS, A67).

**SECURITY CLASSIFICATION:**

Sensitive but Unclassified.

**SYSTEM LOCATION:**

HUD Headquarters, 451 7th Street SW, Washington, DC 20410 and Microsoft Azure Cloud US East Data Center.

**SYSTEM MANAGER(S):**

Sairah Ijaz, Assistant Chief Financial Officer for Systems, Office of the Chief Financial Officer, Department of Housing and Urban Development, 451 Seventh Street SW, Room 3100, Washington, DC 20410.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

- 31 U.S.C. 3511.
- The Chief Financial Officers Act of 1990 (31 U.S.C. 901, *et seq.*).
- Executive Order 9397, as amended by Executive Order 13478.
- Housing and Community Development Act of 1987, 42 U.S.C. 3543.

**PURPOSES OF THE SYSTEM:**

The system is to process and make grant, loan, and subsidy disbursements. LOCCS ensures that payments are made promptly thus achieving efficient cash management practices. It creates accounting transactions with the appropriate accounting classification elements to correctly record disbursements and collections to the grant/project level subsidiary.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

The Privacy Act allows HUD to disclose records from its systems of records to appropriate agencies, entities, and persons as a routine use, when the disclosure is compatible with the purpose for which the records were collected. The routine use statements and their conditions for disclosure are categorized below. The records maintained in this system may also be maintained for other purposes in another system or systems. In such cases, the routine uses for that system or those systems will apply.

(1) *General Service Administration Information Disclosure Routine Use:*

To the National Archives and Records Administration (NARA) and the General Services Administration (GSA) for records having sufficient historical or other value to warrant its continued preservation by the United States Government, or for inspection under authority of Title 44, Chapter 29, of the United States Code.

(2) *Congressional Inquiries Disclosure Routine Use:*

To a congressional office from the record of an individual, in response to an inquiry from the congressional office made at the request of that individual.

(3) *Health and Safety Prevention Disclosure Routine Use:*

To appropriate Federal, State, and local governments, or persons, under showing compelling circumstances affecting the health or safety or vital interest of an individual or data subject, including assisting such agencies or organizations in preventing the exposure to or transmission of a communicable or quarantinable disease, or to combat other significant public health threats, if upon such disclosure appropriate notice was transmitted to the last known address of such individual to identify the health threat or risk.

(4) *Prevention of Fraud, Waste, and Abuse Disclosure Routine Use:*

To Federal agencies, non-Federal entities, their employees, and agents (including contractors, their agents or employees; employees or contractors of the agents or designated agents); or contractors, their employees or agents with whom HUD has a contract, service agreement, grant, cooperative agreement, or computer matching agreement for: (1) Detection, prevention, and recovery of improper payments; (2) detection and prevention of fraud, waste, and abuse in major Federal programs administered by a Federal agency or non-Federal entity; (3) detection of fraud, waste, and abuse by individuals in their operations and programs, but only if the information shared is necessary and relevant to verify pre-award and prepayment requirements before the release of Federal funds, prevent and recover improper payments for services rendered under programs of HUD or of those Federal agencies and non-Federal entities to which HUD provides information under this routine use.

(5) *Research and Statistical Analysis Disclosure Routine Uses:*

(a) To contractors, grantees, experts, consultants, Federal agencies, and non-Federal entities, including, but not limited to, State and local governments and other research institutions or their parties, and entities and their agents with whom HUD has a contract, service agreement, grant, or cooperative agreement, when necessary to accomplish an agency function, related to a system of records, for statistical analysis and research supporting program operations, management, performance monitoring, evaluation, risk management, and policy development, or to otherwise support the Department's mission. Records under this routine use may not be used in whole or in part to make decisions that affect the rights, benefits, or privileges of specific individuals. The results of the matched information may not be disclosed in identifiable form.

(b) To a recipient who has provided the agency with advance, adequate written assurance that the record provided from the system of records will be used solely for statistical research or reporting purposes. Records under this condition will be disclosed or transferred in a form that does not identify an individual.

(6) *Information Sharing Environment Disclosure Routine Uses:*

To contractors, grantees, experts, consultants and their agents, or others performing or working under a contract, service, grant, or cooperative agreement with HUD, when necessary to accomplish an agency function related to a system of records. Disclosure requirements are limited to only those data elements considered relevant to accomplishing an agency function. Individuals provided information under these routine use conditions are subject to Privacy Act requirements and disclosure limitations imposed on the Department.

(7) *Data Testing for Technology Implementation Disclosure Routine Use:*

To contractors, experts and consultants with whom HUD has a contract, service agreement, or other assignment of the Department, when necessary to utilize data to test new technology and systems designed to enhance program operations and performance.

(8) *Data Breach Remediation Purposes Routine Use:*

(a) To appropriate agencies, entities, and persons when (1) HUD suspects or has confirmed there has breached the system of records; (2) HUD has determined that because of the suspected or confirmed breach there is a risk of harm to individuals, HUD, the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist with HUD's efforts to respond to the suspected or confirmed breach to prevent, minimize, or remedy such harm.

(b) To another Federal agency or Federal entity, when HUD 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.

(9) Disclosures for Law Enforcement Investigations Routine Uses:

(a) To appropriate Federal, State, local, tribal, or governmental agencies or multilateral governmental organizations responsible for investigating or prosecuting the violations of, or for enforcing or implementing, a statute, rule, regulation, order, or license, where HUD determines that the information would help to enforce civil or criminal laws when such records, either alone or in conjunction with other information, indicate a violation or potential violation of law.

(10) Court or Law Enforcement Proceedings Disclosure Routine Uses:

(a) To a court, magistrate, administrative tribunal, or arbitrator while presenting evidence, including disclosures to opposing counsel or witnesses in civil discovery, litigation, mediation, or settlement negotiations; or in connection with criminal law proceedings; or in response to a subpoena or to a prosecution request when such records to be released are specifically approved by a court provided order. Disclosures made pursuant to this routine use are limited to when HUD determines that use of such records is relevant and necessary to the litigation, provided, however, that in each case, HUD determines that the disclosure of the records is a use of the information contained in the records that is compatible with the purpose for which the records were collected.

(11) Department of Justice for Litigation Disclosure Routine Use:

To the Department of Justice (DOJ) when seeking legal advice for a HUD initiative or in response to DOJ's request for the information, after either HUD or DOJ determine that such information relates to DOJ's representatives of the United States or any other components in legal proceedings before a court or adjudicative body, provided that, in each case, the agency also determines before disclosure that disclosure of the records to DOJ is a use of the information in the records that is compatible with the purpose for which HUD collected the records. HUD on its own may disclose records in this system of records in legal proceedings before a court or administrative body after determining that disclosing the records to the court or administrative body is a use of the information in the records that is compatible with the purpose for which HUD collected the records.

(12) The U.S. Treasury Disclosure Routine Use:

To the U.S. Treasury for transactions such as disbursements of funds and related adjustments;

(13) The Internal Revenue Service Routine Use:

To the IRS for reporting payments for goods and services and for reporting of discharge indebtedness;

**DISCLOSURE TO CONSUMER REPORTING AGENCIES:**

Disclosures under 5 U.S.C. 552a(b)(12). Disclosures may be made from the system to consumer reporting agencies as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f) or the Federal Claims Collection Act of 1966, 31 U.S.C. 3701(a)(3)). The disclosure is limited to information to establish the identity of the individual, including name, social security number, and address; the amount, status, history of the claim, and the agency or program under which the claim arose solely to allow the consumer reporting agency to prepare a credit report.

**POLICIES AND PRACTICES FOR STORAGE OF RECORDS:**

Electronic files are stored on servers. Paper printouts or original input documents are stored in locked file cabinets at HUD or as imaged documents on magnetic media.

**POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:**

Records are retrieved by business partner name, tax ID number, schedule number, voucher number, and contract number.

**POLICIES AND PRACTICIES FOR RENTENTION AND DISPOSAL OF RECORDS:**

General Records Schedule 1:1; Financial Management and Reporting Records. This schedule covers records created by Federal agencies in carrying out the work of financial management. Temporary. Destroy 6 years after final payment or cancellation, but longer retention is authorized if required for business use.

**ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:**

All HUD employees have undergone background investigations. HUD buildings are guarded and monitored by security personnel, cameras, ID checks, and other physical security measures. Access is restricted to authorized personnel or contractors whose responsibilities require access. System users must take the mandatory security awareness training annually as mandated by the Federal Information Security Modernization Act (FISMA) (44 U.S.C. 3541, *et seq.*). Users must also sign a Rules of Behavior form certifying that they agree to comply with the requirements before they are granted access to the system. LOCCS resides on the Microsoft Azure Cloud, a FedRAMP certified Infrastructure-as-a-Service (IaaS). The system is limited to those with a business need to know. LOCCS Authorizing Officials authorize LOCCS access for users, and OCFO ensures the user is eligible for access (*e.g.,* suitability, System Security Administrator approval), which allow for segregation of duties. Also, system user recertifications is conducted semi-

annually for external users and quarterly for internal users.

**RECORD ACCESS PROCEDURES:**

Individuals seeking to determine whether this System of Records contains information on themselves should address written inquiries to the Department of Housing Urban and Development, 451 7th Street SW, Washington, DC. For verification, individuals should provide full name, current address, and telephone number. In addition, the requester must provide either a notarized statement or an unsworn declaration made under 28 U.S.C. 1746, in the following format:

If executed outside the United States: ''I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date). (Signature).''

If executed within the United States, its territories, possessions, or commonwealths: ''I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature).''

**CONTESTING RECORD PROCEDURES:**

The HUD rule for accessing, contesting, and appealing agency determinations by the individual concerned are published in 24 CFR part 16 or may be obtained from the system manager.

**NOTIFICATION PROCEDURES:**

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the Department of Housing Urban Development Chief Financial Officer, 451 7th Street SW, Washington, DC 20410–0001. For verification, individuals should provide full name, office or organization where assigned, if applicable, and current address and telephone number. In addition, the requester must provide either a notarized statement or an unsworn declaration made under 28 U.S.C. 1746, in the following format:

If executed outside the United States: ''I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date). (Signature).''

If executed within the United States, its territories, possessions, or commonwealths: ''I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature).''

**EXEMPTIONS PROMULGATED FOR THE SYSTEM:**

None.

**HISTORY:**

[Docket No. FR–5763–N–03]

**LaDonne L. White,**

*Departmental Privacy Officer.*

[FR Doc. 2021–25114 Filed 11–17–21; 8:45 am]

**BILLING CODE 4210–67–P**

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## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

**[Docket No. FR–7038–N–21]**

## 60-Day Notice of Proposed Information Collection: Housing Counseling Notice of Funding Opportunity (NOFO), OMB Control No.: 2502–0621

**AGENCY:** Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

**ACTION:** Notice.

**SUMMARY:** HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

**DATES:** *Comments Due Date:* January 18, 2022.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

**FOR FURTHER INFORMATION CONTACT:** Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. This is not a toll-free number.

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

**SUPPLEMENTARY INFORMATION:** This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

### A. Overview of Information Collection

*Title of Information Collection:* Housing Counseling Notice of Funding Opportunity (NOFO).

*OMB Approval Number:* 2502–0621.

*OMB Expiration Date:* 02/28/2022.

*Type of Request:* Revision of a currently approved collection.

*Form Numbers:* HUD–9906–L; HUD–9906–P; NOFO 9906 Charts (A2, B, E).

*Description of the need for the information and proposed use:* This information is collected in connection with HUD's Housing Counseling Program and will be used by HUD to determine that the Housing Counseling grant applicant meets the requirements of the Notice of Funding Opportunity (NOFO). Information collected is also used to assign points for awarding grant funds on a competitive and equitable basis. HUD's Office of Housing Counseling will also use the information to provide housing counseling services through private or public organizations with special competence and knowledge in counseling low and moderate-income families. The information is collected from housing counseling agencies that participate in HUD's Housing Counseling Program. The information is collected via the Form 9906 (grant application chart).

*Respondents:* Not-for-profit institutions; State, Local or Tribal Government.

*Estimated Number of Respondents:* 300.

*Estimated Number of Responses:* 300.

*Frequency of Response:* 1.

*Average Hours per Response:* 40.

*Total Estimated Burden:* 12,000 hours.

### B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

### C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35.

**Janet M. Golrick,**

*Acting, Chief of Staff for the Office of Housing, Federal Housing Administration.*

[FR Doc. 2021–25143 Filed 11–17–21; 8:45 am]

BILLING CODE 4210–67–P

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

**[Docket No. FR–7046–N–09]**

## Privacy Act of 1974; System of Records

**AGENCY:** Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

**ACTION:** Notice of a modified system of records.

**SUMMARY:** Home Equity Conversion Mortgage loan servicing is provided by the Home Equity Reverse Mortgage Information Technology (HERMIT). Under the Privacy Act of 1974, as amended, the Department of the Housing and Urban Development (HUD) is issuing a public notice of its intent to modify the Deputy Assistant Secretary for Finance and Budget, Federal Housing Administration, Office Systems and Technology, Office of Housing Privacy Act system of records, Home Equity Reverse Mortgage Information Technology (HERMIT), this system of records is being revised to make clarifying changes within system of records, system location, system manager, authority for maintenance of the system, purpose of the system, categories of individuals covered by the system, categories of records in the system, records source categories, routine uses of records maintained in the system, retrieval of records, retention and deposal of records, records access, contesting of records, and notification sections.

**DATES:** This notice action shall be applicable immediately, which will become effective December 20, 2021.

Comments will be accepted on or before: December 20, 2021.

**ADDRESSES:** You may submit comments, identified by docket number by one method:

*Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions provided on that site to submit comments electronically;

*Fax:* 202–619–8365;

*Email: www.privacy@hud.gov;*

*Mail:* Attention: Privacy Office; LaDonne White, Chief Privacy Officer; The Executive Secretariat; 451 Seventh Street SW, Room 10139; Washington, DC 20410–0001.

*Instructions:* All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov.* including any personal information provided.

*Docket:* For access to the docket to read background documents or comments received go to *http://www.regulations.gov.*

**FOR FURTHER INFORMATION CONTACT:** LaDonne White, Chief Privacy Officer, 451 Seventh Street SW, Room 10139, Washington, DC 20410, telephone number 202–708–3559 (this is not a toll-free number).

**SUPPLEMENTARY INFORMATION:** The Department of Housing and Urban Development (HUD), Office Systems and Technology, Office of Housing maintains the ''Home Equity Reverse Mortgage Information Technology'' system of records. HUD is publishing this revised notice to establish a new and modified routine use and to reflect updated information in the sections being revised. The modification of the system of records will have no undue impact on the privacy of individuals and updates follow the records collected.

The previous SORN updates include:

1. *System Number:* Updated to classify new system of records number designation to alignment with HUD's system of records inventory.

2. *System Location:* Replaced former locations with locations of where the system is maintained. HERMIT is maintained at: The business service providers, Reverse Market Insight, Inc. at these primary locations: 2101 Gaithersburg Road, Rockville MD 20850; and 4100 Smith School Road, Austin Texas 78744.

3. *System Manager:* Identified new system manager expected to operate under this system of records.

4. *Authority for Maintenance of the System:* Listed existing HUD authority and missing authority section that permits the collection of social security numbers: The Housing and Community Development Act of 1987 (42 U.S.C. 3543(a)); and The Debt Collection Act of 1982, Public Law 97–365.

5. *Purpose of the System:* Applied non-substantive changes to identify system functions with clarity and conciseness for public awareness.

6. *Categories of Individuals Covered:* Added existing system user groups and purpose the user group serves.

7. *Categories of Records in the System:* Removed ''Loan Production HERMIT loan production records include personally identifiable information (PII) data pertaining to HECM Housing Counseling data: Full name of HECM housing counselor, HECM Certificate of Counseling, HECM counselor ID numbers, and borrowers' full names, property addresses, birthdates, Social Security numbers, and phone numbers.'' These records were not collected and determined not needed for HERMIT's business process. These records instead were incorporated under the HUD loan underwriting and origination process.

8. *Records Source Categories:* Updated to cover all record sources for system programs.

9. *Routine Use of Records in System:*

(a) Added new routine uses to facilitate data sharing to support agency dispute resolution process between HUD and General Service Administration.

(b) Updated routine use for breach remediation efforts to extend agency data sharing when relevant for breach remediation efforts to appropriate agencies.

(c) Removed routine use ''To housing counselors to comply with new HECM housing counseling policies to include training and certification'', these records were determined not needed for HERMIT business process.

(d) Reorganized routine uses and incorporated HUD's 2015 blanket routine uses publication as part of this system of records.

10. *Records Retention and Disposition:* Updated to describe retention and disposal requirements.

11. *Policy and Practice for Retrieval of Records:* Updated to include minor changes and format.

12. *Records Access, Contesting, and Notification Procedures:* Updated to include Federal requirements and HUD office to which the individuals' request should be directed.

**SYSTEM NAME AND NUMBER:**

Home Equity Reverse Mortgage Information Technology (HERMIT), HOU–31.

**SECURITY CLASSIFICATION:**

Unclassified.

**SYSTEM LOCATION:**

The systems are hosted by the business service providers, Reverse Market Insight, Inc. at these primary locations: 2101 Gaithersburg Road,

Rockville MD 20850; and 4100 Smith School Road, Austin Texas 78744.

**SYSTEM MANAGER(S):**

Juanita Johnson, System Manager, Office of Systems and Technology, 451 Seventh Street SW, Room 2242, Washington, DC 20410, telephone number (202) 402–5348.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 255 of the National Housing Act of 1934 (12 U.S.C. 1715z–20) covers the Federal Housing Administration (FHA) reverse mortgage program for the elderly, the Home Equity Conversion Mortgage (HECM) program. The Housing and Community Development Act of 1987 (42 U.S.C. 3543(a)) and the Debt Collection Act of 1982, Public Law 97–365.

**PURPOSES OF THE SYSTEM:**

HERMIT is a conversion mortgage loan servicing technology, operated by Federal Housing Administration (FHA) for Home Equity Conversion Mortgage (HECM) Programs including insurance Endorsed loans and Secretary-held Assigned Notes. HECM Program personnel operate HERMIT to collect, store, present, and deliver core reverse mortgage data, including all borrower and loan characteristics required to manage HECM Program obligations and performance such as loan setup, servicing actions, compliance monitoring, default management, asset sale transfers, claims processing, payment reporting's, and lender portfolio management. Records collected are utilized to analyze and assess the health of the program, its impact on FHA operations, and program participants compliance with specific Federal requirements.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

HECM mortgagors (homeowners) including borrower, co-borrower, and non-borrowing spouse; FHA-approved HECM business partners including mortgagee (lender) originators, servicers, and investors; and HECM personnel for Home Equity Conversion Mortgages insured under HUD's HECM mortgage insurance program.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Categories of records in HERMIT include:

*System Users:* Full name (first, middle, last), telephone number, email address, user id, user passcode, lender id.

*Borrowers (Mortgagors):* Full names (first, middle, last), property address, social security numbers (SSNs), driver license, telephone number, email address, marital status, gender, birth, and death dates including death notification details; financial account information including bank accounts and routing numbers, debits and credits to HUD accounts based on transaction events; and details about the mortgage loan, including loan application and appraisal documents.

*Non-Borrower Spouses:* Full name (first, middle, last), SSN, date of birth; and details about the mortgage loan including loan application documentation.

*FHA-approved HECM business partners:* (mortgagees/investors): Full name (first, middle, last), SSN, tax identification number (TIN), lender id; organization name; and banking information (institutional information, routings account numbers, and account types); telephone number, fax number, email address, and FHA Case Number (For HECM loans reported to HUD, the FHA case number represents the lender requested case number).

*Borrowers' property inspections:* Full name (first, middle, last), SSN; property inspections; property address, annual occupancy certification and recording of assigned notes.

*Borrowers' claims information:* Full name (first, middle, last), property address, SSN, driver license, email address, date and death dates, gender, marital status; assisted living and healthcare details; disposition information including deed-in-lieu, short sale, foreclosure, and appraisal claim; property protection and preservation details; loan application and payment details; financial account information including bank accounts and routing numbers, debits and credits to HUD accounts based on transaction events.

*Borrowers of Investors (Purchasers) asset sales information:* Full name (first, middle, last), property address, SSN, birth, and death dates) and loan balance details

*Borrowers' death indications:* Full name (first, middle, last), social security number, date of birth, and date of death.

**RECORD SOURCE CATEGORIES:**

Records in this system are provided on behalf of the borrowers (mortgagors) from individuals (FHA HECM approved mortgagee and Business Service Provider) and HUD personnel.

*Existing HUD information systems:* F17/Computerized Homes Underwriting Management System (CHUMS), A80S/ Single Family Acquired Asset Management; Single Family Asset Sales by Secure File Transfer Protocol, P269/ Reporting and Feedback System. Information is also shared with Federal information systems Social Security Administration Death Master File (DMF), and U.S. Department of Treasury's *Pay.gov* and Secure Payment System.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:**

Besides those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information in this system may be disclosed outside of HUD as a routine use under 5 U.S.C. 552a(b)(3):

*General Service Administration Information Disclosure Routine Use:*

(a) To the National Archives and Records Administration (NARA) and the General Services Administration (GSA) for records having sufficient historical or other value to warrant its continued preservation by the United States Government, or for inspection under authority of Title 44, Chapter 29, of the United States Code.

(a) To the National Archives and Records Administration, Office of Government Information Services (OGIS), to the extent to fulfill its responsibilities in 5 U.S.C. 552(h), to review administrative agency policies, procedures, and compliance with the Freedom of Information Act (FOIA), and to facilitate OGIS's offering of mediation service to resolve disputes between persons making FOIA requests and administrative agencies.

(2) *Congressional Inquiries Disclosure Routine Use:*

To a congressional office from the record of an individual, in response to an inquiry from the congressional office made at the request of that individual.

(3) *Health and Safety Prevention Disclosure Routine Use:*

To appropriate Federal, State, and local governments, or persons, under showing compelling circumstances affecting the health or safety or vital interest of an individual or data subject, including assisting such agencies or organizations in preventing the exposure to or transmission of a communicable or quarantinable disease, or to combat other significant public health threats, if upon such disclosure appropriate notice was transmitted to the last known address of such individual to identify the health threat or risk.

(4) *Prevention of Fraud, Waste, and Abuse Disclosure Routine Use:*

To Federal agencies, non-Federal entities, their employees, and agents (including contractors, their agents or employees; employees or contractors of the agents or designated agents); or contractors, their employees or agents

with whom HUD has a contract, service agreement, grant, cooperative agreement, or computer matching agreement for: (1) Detection, prevention, and recovery of improper payments; (2) detection and prevention of fraud, waste, and abuse in major Federal programs administered by a Federal agency or non-Federal entity; (3) detection of fraud, waste, and abuse by individuals in their operations and programs, but only if the information shared is necessary and relevant to verify pre-award and prepayment requirements before the release of Federal funds, prevent and recover improper payments for services rendered under programs of HUD or of those Federal agencies and non-Federal entities to which HUD provides information under this routine use.

(5) *Research and Statistical Analysis Disclosure Routine Uses:*

(a) To contractors, grantees, experts, consultants, Federal agencies, and non-Federal entities, including, but not limited to, State and local governments and other research institutions or their parties, and entities and their agents with whom HUD has a contract, service agreement, grant, or cooperative agreement, when necessary to accomplish an agency function, related to a system of records, for statistical analysis and research supporting program operations, management, performance monitoring, evaluation, risk management, and policy development, or to otherwise support the Department's mission. Records under this routine use may not be used in whole or in part to make decisions that affect the rights, benefits, or privileges of specific individuals. The results of the matched information may not be disclosed in identifiable form.

(b) To a recipient who has provided the agency with advance, adequate written assurance that the record provided from the system of records will be used solely for statistical research or reporting purposes. Records under this condition will be disclosed or transferred in a form that does not identify an individual.

(6) *Information Sharing Environment Disclosure Routine Uses:*

(a) To contractors, grantees, experts, consultants and their agents, or others performing or working under a contract, service, grant, or cooperative agreement with HUD, when necessary to accomplish an agency function related to a system of records. Disclosure requirements are limited to only those data elements considered relevant to accomplishing an agency function. Individuals provided information under these routine use conditions are subject to Privacy Act requirements and disclosure limitations imposed on the Department.

(b) To FHA-approved HECM servicing mortgagees to give notice of miscalculations or other errors in subsidy computation, to pay claims, or for compliance or other servicing-related functions.

(c) To taxing authorities, insurance companies, homeowners' associations, or condominium associations for maintaining the property while HUD is the servicer of record to ensure property taxes, insurance payments, and/or homeowners/condominium association fees are current.

(d) To the U.S. Department of the Treasury for collection and disbursement transactions (*Pay.gov,* Automated Clearing House (ACH), Secure Payment System (SPS)).

(e) To title insurance companies or financial institutions to allow HUD to respond to inquiries for payoff figures on HECM assigned loans.

(f) To recorders' offices for recording legal documents and responses to bankruptcy courts or other legal responses required during the servicing of the insured loan to allow HUD to release mortgage liens, respond to bankruptcies or deaths of mortgagors to protect the interest of the Secretary of HUD.

(g) To the Federal Bureau of Investigation to investigate possible fraud revealed while servicing efforts to allow HUD to protect the interests of the Secretary of HUD.

(h) To an Administrative Law Judge and to the interested parties to the extent necessary for conducting administrative proceedings where HUD is a party.

(i) To welfare agencies for fraud investigation to allow HUD to respond to state government inquiries when a HECM mortgagor is committed to a nursing home.

(j) To requestors, as required by the FOIA, records that have been frequently requested'' and disclosed under the FOIA within the meaning of that Act, as determined by the HUD, are provided to the public for routine inspection and copying.

(7) *Data Testing for Technology Implementation Disclosure Routine Use:*

To contractors, experts and consultants with whom HUD has a contract, service agreement, or other assignment of the Department, when necessary to utilize data to test new technology and systems designed to enhance program operations and performance.

(8) *Data Breach Remediation Purposes Routine Use:*

To appropriate agencies, entities, and persons when:

To another Federal agency or Federal entity, when HUD 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.

To appropriate agencies, entities, and persons when (1) HUD suspects or has confirmed there has breached the system of records, (2) the HUD has determined that because of the suspected or confirmed breach there is a risk of harm to individuals, the HUD (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 with the HUD's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

(9) *Disclosures for Law Enforcement Investigations Routine Uses:*

(a) To appropriate Federal, State, local, tribal, or governmental agencies or multilateral governmental organizations responsible for investigating or prosecuting the violations of, or for enforcing or implementing, a statute, rule, regulation, order, or license, where HUD determines that the information would help to enforce civil or criminal laws.

(b) To third parties during a law enforcement investigation, to the extent to obtain information pertinent to the investigation, disclosed such information is appropriate to the proper performance of the official duties of the officer making the disclosure.

(10) *Court or Law Enforcement Proceedings Disclosure Routine Uses:*

(a) To a court, magistrate, administrative tribunal, or arbitrator while presenting evidence, including disclosures to opposing counsel or witnesses in civil discovery, litigation, mediation, or settlement negotiations; or in connection with criminal law proceedings; or in response to a subpoena or to a prosecution request when such records to be released are specifically approved by a court provided order.

(b) To appropriate Federal, State, local, tribal, or governmental agencies or multilateral governmental organizations

responsible for investigating or prosecuting the violations of, or for enforcing or implementing, a statute, rule, regulation, order, or license, where HUD determines that the information would help to enforce civil or criminal laws.

(c) To third parties during a law enforcement investigation to the extent to obtain information pertinent to the investigation, provided disclosure is appropriate to the proper performance of the official duties of the officer making the disclosure.

(d) To another agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States for a civil or criminal law enforcement activity if the activity is authorized by law, and if the head of the agency or instrumentality has made a written request to the agency that maintains the record, specifying the portion desired and the law enforcement activity for which the record is sought.

(11) *Department of Justice for Litigation Disclosure Routine Use:*

To the Department of Justice (DOJ) when seeking legal advice for a HUD initiative or in response to DOJ's request for the Start Printed Page 81840information, after either HUD or DOJ determine that such information relates to DOJ's representatives of the United States or any other components in legal proceedings before a court or adjudicative body, provided that, in each case, the agency also determines before disclosure that disclosure of the records to DOJ is a use of the information in the records compatible with the purpose for which HUD collected the records. HUD on its own may disclose records in this system of records in legal proceedings before a court or administrative body after determining that disclosing the records to the court or administrative body is a use of the information in the records compatible with the purpose for which HUD collected the records.

**POLICIES AND PRACTICES FOR STORAGE OF RECORDS:**

Paper and Electronic.

**POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:**

Records are retrieved by name, Social Security Number, Tax Identification Number, FHA case number, location and contact information (home address, telephone number, personal email address).

**POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:**

The policies and practices for retention and disposal of records includes:

GRS 5.2, item 20, Collections, Disbursements, Servicing, and Asset management records. This schedule covers records created by FHA and its approved business partners to administer HECM Program loans granted, serviced, assigned, or claims related submission. Destroy upon verification of successful creation of the final document or file, or when no longer needed for business use, whichever is later.

GRS 1.1, item 010, HECM Premiums, Notes, and Claims Records. This schedule covers records created by FHA and its approved business partners to perform financial management responsibilities. Destroy 6 years after final payment or cancellation, but longer retention is authorized if required for business use.

GRS 3.2, item 031, Correspondence, Emails, Non-financial Transactions, and Reports. This schedule supports user account management and administration. Destroy 6 years after password is altered or user account is terminated, but longer retention is authorized if required for business use.

**ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:**

FHA ensures the protection of program participants' PII and mortgagee business sensitive information by ensuring HERMIT's compliance with Federal requirements and HUD's security and privacy standards.

*Administrative Controls:* Data backups secured off-site; access granted only to authorized personnel; periodic security audits; regular monitoring of users' security practices. HUD access is safeguarded according to rules and policies, including all applicable automated processes according to security and privacy safeguard policies.

*Physical Controls:* Key card, controlled access, security guards, and identification badges and secure data physical methods are used to ensure only authorized users have access to PII; Periodic security audits, regular monitoring of system users' behavior are conducted; Primary and recovery facilities control physical access to information system output devices to prevent unauthorized individuals from obtaining the output.

*Technical Controls:* Biometrics, firewalls, role-based access controls, virtual private network, use of privileged (Elevated Roles), external certificate authority certificates, PIV cards and intrusion detection system. The system sends and receives data through HUD Security File Transfer Protocol (SFTP), which encrypts the data. SSNs are encrypted during transmission to protect session information and at rest. System incorporates least privilege access, user identification and passwords.

**RECORD ACCESS PROCEDURES:**

Individuals seeking to determine whether this System of Records contains information on themselves should address written inquiries to the Department of Housing Urban and Development 451 7th Street, SW Washington, DC, 20410–0001. For verification, individuals should provide full name, current address, and telephone number. In addition, the requester must provide either a notarized statement or an unsworn declaration made under 28 U.S.C. 1746, in the following format:

If executed outside the United States: ''I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (Date). (Signature)

If executed within the United States, its territories, possessions, or commonwealths: ''I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (Date). (Signature).''

**CONTESTING RECORD PROCEDURES:**

The HUD rule for accessing, contesting, and appealing agency determinations by the individual concerned are published in 24 CFR part 16 or may be obtained from the system manager.

**NOTIFICATION PROCEDURES:**

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the Department of Housing Urban Development Office of Systems and Technology, 451 7th street SW, Washington, DC 20410–0001. For verification, individuals should provide full name, office or organization where assigned, if applicable, and current address and telephone number. In addition, the requester must provide either a notarized statement or an unsworn declaration made under 28 U.S.C. 1746, in the following format:

If eLadoxecuted outside the United States: ''I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. executed on (Date). (Signature).''

If executed within the United States, its territories, possessions, or commonwealths: ''I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. executed on (Date). (Signature).''

**EXEMPTIONS PROMULGATED FOR THE SYSTEM:**

None.

**HISTORY:**

The SORN History includes HSNG/HWAT.01:

- 81 FR–33690 (May 27, 2016)
- 77 FR–61620 (October 10, 2012)

**LaDonne L. White,**

*Departmental Privacy Officer.*

[FR Doc. 2021–25117 Filed 11–17–21; 8:45 am]

**BILLING CODE 4210–67–P**

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

**[Docket No. FR–7046–N–01]**

## Privacy Act of 1974; System of Records

**AGENCY:** Office of the Chief Financial Officer (OCFO), HUD.

**ACTION:** Notice of a new system of records.

**SUMMARY:** The Payroll Data Analytics Project was created to analyze payroll disbursement data. For the HUD employees in the collection, the HUD Office of the Chief Financial Officer (OCFO) collects the first five letters of the first name and the last 4 digits of Social Security Numbers (SSN) from the Department of Treasury, Administrative Resource Center (ARC). This is collected as part of the payroll data used to identify questionable payroll transactions that may require further review by HUD management. If needed, OCFO will request HUD employees' Standard Form 50 (SF–50) from HUD's Office of the Chief Human Capital Officer (OCHCO) for potential outliers that require justification. HUD OCHCO sends the SF–50 to HUD OCFO via encrypted email. The SF–50 includes Personally Identifiable Information (PII) such as full name, date of birth, SSN, pay grade, salary, veterans' preference, and all other data included in the SF–50 template.

**DATES:** This notice action shall be applicable immediately, which will become effective December 20, 2021.

*Comments will be accepted on or before:* December 20, 2021.

**ADDRESSES:** You may submit comments, identified by docket number [FR–7046–N–01] by one of the following methods:

*Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions provided on that site to submit comments electronically;

*Fax:* 202–619–8365;

*Email: privacy@hud.gov;*

*Mail:* Attention: Privacy Office; Chief Privacy Officer, Mr. LaDonne White, The Executive Secretariat; 451 Seventh Street SW, Room 10139, Washington, DC 20410–0001.

*Instructions:* All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov.* including any personal information provided.

*Docket:* For access to the docket to read background documents or comments received go to *http://www.regulations.gov.*

**FOR FURTHER INFORMATION CONTACT:** LaDonne White, Chief Privacy Officer, The Privacy Office, 451 Seventh Street SW, Room 10139, Washington, DC 20410–1000; telephone number 202–708–3054 (this is not a toll-free number).

**SUPPLEMENTARY INFORMATION:** HUD OCFO is creating a system of records for the Payroll Data Analytics Project to collect HUD employees' PII from the Treasury ARC and HUD OCHCO. The PII that Treasury has is initially collected for payroll purposes. HUD OCFO will collect from Treasury only the first five digits of the first name and the last four digits of the Social Security Number (SSN) for all individuals within HUD's payroll. HUD OCFO will use R Script to review and identify any questionable payroll transactions and/or outliers (*e.g.,* mismatch of Employee Name and SSN, fraudulent transactions). An R Script is a set of instructions that tells the computer what to do. If any are identified, HUD OCFO will request SF–50s from OCHCO for the specified employee(s) for justification and further review.

**SYSTEM NAME AND NUMBER:**

Payroll Data Analytics Project.

**SECURITY CLASSIFICATION:**

Unclassified.

**SYSTEM LOCATION:**

Records collected by HUD OCFO are maintained at the Department of Housing and Urban Development Local Area Network (LAN), which resides at the National Center for Critical Information Processing and Storage (NCCIPS), Stennis Space Center, MS and at the Mid-Atlantic Data Center, Clarksville, VA.

**SYSTEM MANAGER(S):**

Director, OCFO Financial Policy and Procedures Division, 451 7th St. SW, Washington, DC 20410–0001.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

5 U.S.C. 6101–6133; 5 U.S.C. 6301–6387; 44 U.S.C. 3101; 5 U.S.C. 5501–5597; 5 CFR part 630; 31 U.S.C. 3512(b); 31 U.S.C. 3351 *et seq.*—Payment Integrity Information Act (PIIA) of 2019; Executive Order 13478; OMB Circular No. A 123, Appendix A, Management of Reporting and Data Integrity Risk.

**PURPOSE(S) OF THE SYSTEM:**

Identification and Validation—Payroll data is collected for reviewing and identifying questionable payroll transactions and/or outliers (*e.g.,* mismatch of Employee Name and SSN) that may require further review by HUD Management to comply with OMB Circular No. A 123, Appendix A, ''Management of Reporting and Data Integrity Risk.''

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

All HUD employees from the previous fiscal year.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

The following data is collected from Treasury ARC: First five characters of HUD employee's first name; last four digits of HUD employee's SSN. If further review needs to be done on an individual's payroll accounting, the SF–50 is collected from HUD OCHCO, which includes: Full name, date of birth, SSN, pay grade, salary, veterans preference, and all other data included in the SF–50 template.

**RECORD SOURCE CATEGORIES:**

These records contain information obtained from the Department of Treasury, Administrative Resource Center (ARC), which serves as the HR shared service provider for HUD. Note: HUD OCFO is not the initial collector of the information from individuals.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:**

In addition, the Privacy Act allows HUD to disclose records from its systems of records, from the following headings (1)–(14), to appropriate agencies, entities, and persons, when the records being disclosed are compatible with the purpose for which the system was developed. The routine use statements specified in this notice shall not be used to construe, limit, or waive any other routine use condition or exemption specified in the text of an individual system of records, and may

overlap in some cases. The routine use statements and their conditions for disclosure are categorized below.

*(1) Department of Treasury for Payroll Adjustments/Corrections Disclosure Routine Use:*

To the Department of Treasury's Administrative Resource Center (ARC), for the purpose of adjusting any payroll transactional error findings.

*(2) General Service Administration Information Disclosure Routine Use:*

To the National Archives and Records Administration (NARA) and the General Services Administration (GSA) for records having sufficient historical or other value to warrant its continued preservation by the United States Government, or for inspection under authority of Title 44, Chapter 29, of the United States Code.

*(3) Congressional Inquiries Disclosure Routine Use:*

To a congressional office from the record of an individual, in response to an inquiry from the congressional office made at the request of that individual.

*(4) Health and Safety Prevention Disclosure Routine Use:*

To appropriate Federal, State, and local governments, or persons, pursuant to a showing of compelling circumstances affecting the health or safety or vital interest of an individual or data subject, including assisting such agencies or organizations in preventing the exposure to or transmission of a communicable or quarantinable disease, or to combat other significant public health threats, if upon such disclosure appropriate notice was transmitted to the last known address of such individual to identify the health threat or risk.

*(5) Consumer Reporting Agency Disclosure Routine Use:*

To a consumer reporting agency, when trying to collect a claim owed on behalf of the Government, in accordance with 31 U.S.C. 3711(e).

*(6) Computer Matching Program Disclosure Routine Use:*

To Federal, State, and local agencies, their employees, and agents for the purpose of conducting computer matching programs as regulated by the Privacy Act of 1974, as amended (5 U.S.C. 552a).

*(7) Prevention of Fraud, Waste, and Abuse Disclosure Routine Use:*

To Federal agencies, non-Federal entities, their employees, and agents (including contractors, their agents or employees; employees or contractors of the agents or designated agents); or contractors, their employees or agents with whom HUD has a contract, service agreement, grant, cooperative agreement, or computer matching agreement for the purpose of: (1) Detection, prevention, and recovery of improper payments; (2) detection and prevention of fraud, waste, and abuse in major Federal programs administered by a Federal agency or non-Federal entity; (3) detection of fraud, waste, and abuse by individuals in their operations and programs, but only to the extent that the information shared is necessary and relevant to verify pre-award and prepayment requirements prior to the release of Federal funds, prevent and recover improper payments for services rendered under programs of HUD or of those Federal agencies and non-Federal entities to which HUD provides information under this routine use.

*(8) Research and Statistical Analysis Disclosure Routine Uses:*

(a) To contractors, grantees, experts, consultants, Federal agencies, and non-Federal entities, including, but not limited to, State and local governments and other research institutions or their parties, and entities and their agents with whom HUD has a contract, service agreement, grant, or cooperative agreement, when necessary to accomplish an agency function, related to a system of records, for the purposes of statistical analysis and research in support of program operations, management, performance monitoring, evaluation, risk management, and policy development, or to otherwise support the Department's mission. Records under this routine use may not be used in whole or in part to make decisions that affect the rights, benefits, or privileges of specific individuals. The results of the matched information may not be disclosed in identifiable form.

(b) To a recipient who has provided the agency with advance, adequate written assurance that the record provided from the system of records will be used solely for statistical research or reporting purposes. Records under this condition will be disclosed or transferred in a form that does not identify an individual.

*(9) Information Sharing Environment Disclosure Routine Uses:*

To contractors, grantees, experts, consultants and their agents, or others performing or working under a contract, service, grant, or cooperative agreement with HUD, when necessary to accomplish an agency function related to a system of records. Disclosure requirements are limited to only those data elements considered relevant to accomplishing an agency function. Individuals provided information under these routine use conditions are subject to Privacy Act requirements and disclosure limitations imposed on the Department.

*(10) Data Testing for Technology Implementation Disclosure Routine Use:*

To contractors, experts and consultants with whom HUD has a contract, service agreement, or other assignment of the Department, when necessary to utilize relevant data for the purpose of testing new technology and systems designed to enhance program operations and performance.

*(11) Data Breach Remediation Purposes Routine Use:*

(a) To appropriate agencies, entities, and persons when (1) HUD suspects or has confirmed that there has been a breach of the system of records; (2) HUD has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, HUD (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.

(b) To another Federal agency or Federal entity, when HUD determines that information from this systems of record 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.

*(12) Disclosures for Law Enforcement Investigations Routine Uses:*

(a) To appropriate Federal, State, local, tribal, or governmental agencies or multilateral governmental organizations responsible for investigating or prosecuting the violations of, or for enforcing or implementing, a statute, rule, regulation, order, or license, where HUD determines that the information would assist in the enforcement of civil or criminal laws.

(b) To third parties during the course of a law enforcement investigation, to the extent necessary to obtain information pertinent to the investigation, provided the disclosure of such information is appropriate to the proper performance of the official duties of the officer making the disclosure.

*(13) Court or Law Enforcement Proceedings Disclosure Routine Uses:*

(a) To a court, magistrate, administrative tribunal, or arbitrator in the course of presenting evidence, including disclosures to opposing

counsel or witnesses in the course of civil discovery, litigation, mediation, or settlement negotiations; or in connection with criminal law proceedings; or in response to a subpoena or to a prosecution request when such records to be released are specifically approved by a court provided order.

(b) To appropriate Federal, State, local, tribal, or governmental agencies or multilateral governmental organizations responsible for investigating or prosecuting the violations of, or for enforcing or implementing, a statute, rule, regulation, order, or license, where HUD determines that the information would assist in the enforcement of civil or criminal laws.

(c) To third parties while a law enforcement investigation to the extent necessary to obtain information pertinent to the investigation, provided disclosure is appropriate to the proper performance of the official duties of the officer making the disclosure.

(d) To another agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States for a civil or criminal law enforcement activity if the activity is authorized by law, and if the head of the agency or instrumentality has made a written request to the agency that maintains the record, specifying the particular portion desired and the law enforcement activity for which the record is sought.

*(14) Department of Justice for Litigation Disclosure Routine Use:*

To the Department of Justice (DOJ) when seeking legal advice for a HUD initiative or in response to DOJ's request for the information, after either HUD or DOJ determine that such information is relevant to DOJ's representatives of the United States or any other components in legal proceedings before a court or adjudicative body, provided that, in each case, the agency also determines prior to disclosure that disclosure of the records to DOJ is a use of the information contained in the records that is compatible with the purpose for which HUD collected the records. HUD on its own may disclose records in this system of records in legal proceedings before a court or administrative body after determining that the disclosure of the records to the court or administrative body is a use of the information contained in the records that is compatible with the purpose for which HUD collected the records.

**POLICIES AND PRACTICES FOR STORAGE OF RECORDS:**

General Records

Records will be stored on a shared drive (J:/Drive) in a restricted folder with restricted access to specific staff. The shared drive is a part of the HUD Local Area Network (LAN).

**POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:**

Designated OCFO Financial Management staff members will pull records from the restricted shared drive folder (J:/Drive).

**POLICIES AND PRACTICIES FOR RENTENTION AND DISPOSAL OF RECORDS**

Destroy 6 years after final payment or cancellation, but longer retention is authorized if required for business use.

**ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:**

Users must log into their workstation with their PIV (ID) badge and a PIN number to log into the computer and access the HUD network. The data is stored on the HUD LAN resides at the Stennis and Clarksville Data Centers. Both data centers are managed by the OCIO Infrastructure and Operations Office (IOO) and are secured by security guards with ID badges and cameras. Files are stored on a shared drive folder J:/Drive in a restricted folder with restricted access to specific staff and the files are encrypted at rest. All OCFO staff must complete annual IT Security Awareness/Privacy Awareness Training, and electronically sign the Enterprise Rules of Behavior.

**RECORD ACCESS PROCEDURES:**

Individuals seeking to determine whether this System of Records contains information on themselves should address written inquiries to the Department of Housing Urban and Development 451 7th Street SW, Washington, DC. For verification purposes, individuals should provide full name, current address, and telephone number. In addition, the requester must provide either a notarized statement or an unsworn declaration made in accordance with 28 U.S.C. 1746, in the following format:

If executed outside the United States: ''I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date). (Signature).''

If executed within the United States, its territories, possessions, or commonwealths: ''I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature).''

**CONTESTING RECORD PROCEDURES:**

The HUD rule for accessing, contesting, and appealing agency determinations by the individual concerned are published in 24 CFR part 16 or may be obtained from the system manager.

**NOTIFICATION PROCEDURES:**

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the Department of Housing Urban Development Chief Financial Officer, 451 7th Street SW, Washington, DC 20410–0001. For verification purposes, individuals should provide full name, office or organization where currently assigned, if applicable, and current address and telephone number. In addition, the requester must provide either a notarized statement or an unsworn declaration made in accordance with 28 U.S.C. 1746, in the following format:

If executed outside the United States: ''I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date). (Signature).''

If executed within the United States, its territories, possessions, or commonwealths: ''I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature).''

**EXEMPTIONS PROMULGATED FOR THE SYSTEM:**

N/A.

**HISTORY:**

N/A.

**LaDonne L. White,**

*Departmental Privacy Officer.*

[FR Doc. 2021–25109 Filed 11–17–21; 8:45 am]

BILLING CODE 4210–67–P

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

**[Docket No. FWS–R4–ES–2021–0121; FXES11140400000–212–FF04EF4000]**

### Receipt of Incidental Take Permit Application and Proposed Habitat Conservation Plan for the Scrub-Jay, Volusia County, FL; Categorical Exclusion

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of availability; request for comment and information.

**SUMMARY:** We, the Fish and Wildlife Service (Service), announce receipt of an application from Maury L. Carter and Associates Inc. (applicant) for an incidental take permit (ITP) under the

Endangered Species Act. The applicant requests the ITP to take the federally listed scrub-jay incidental to construction in Volusia County, Florida. We request public comment on the application, which includes the applicant's proposed habitat conservation plan (HCP), and the Service's preliminary determination that this HCP qualifies as ''low-effect,'' categorically excluded, under the National Environmental Policy Act. To make this determination, we used our environmental action statement and low-effect screening form, both of which are also available for public review.

**DATES:** We must receive your written comments on or before December 20, 2021.

**ADDRESSES:**

*Obtaining Documents:* You may obtain copies of the documents online in Docket No. FWS–R4–ES–2021–0121 at *http://www.regulations.gov.*

*Submitting Comments:* If you wish to submit comments on any of the documents, you may do so in writing by any of the following methods:

- *Online: http://www.regulations.gov.* Follow the instructions for submitting comments on Docket No. FWS–R4–ES–2021–0121.
- *U.S. Mail:* Public Comments Processing, Attn: Docket No. FWS–R4–ES–2021–0121; U.S. Fish and Wildlife Service, MS: JAO/1N, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

**FOR FURTHER INFORMATION CONTACT:** Erin M. Gawera, by telephone at 904–731–3121 or via email at *erin_gawera@fws.gov.* Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

**SUPPLEMENTARY INFORMATION:** We, the Fish and Wildlife Service, announce receipt of an application from Maury L. Carter and Associates Inc. (applicant) (Howland Property) for an incidental take permit (ITP) under the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*). The applicant requests the ITP to take the federally listed scrub-jay (*Aphelocoma coerulescens*) incidental to the construction of a mixed-use commercial development (project) in Volusia County, Florida. We request public comment on the application, which includes the applicant's proposed habitat conservation plan (HCP), and the Service's preliminary determination that this HCP qualifies as ''low-effect,'' categorically excluded, under the National Environmental Policy Act (NEPA; 42 U.S.C. 4231 *et seq.*). To make this determination, we used our environmental action statement and low-effect screening form, which are also available for public review.

## Project

Maury L. Carter and Associates Inc. requests a 10-year ITP to take scrub-jays by converting approximately 2.20 acres of occupied scrub-jay foraging and sheltering habitat incidental to the construction of a mixed-use commercial development located on a 36.69-acre parcel in Section 4, Township 19 South, Range 30 East, Volusia County, Florida. The applicant proposes to mitigate for take of the scrub-jays by the contribution of $67,438.80 to the Florida Scrub-jay Conservation Fund (Fund) administered by The Nature Conservancy for the purchase of 4.40 acres, twice as much habitat as would be destroyed. The Service would require the applicant to make this contribution to the Fund within 30 days following the issuance of the incidental take permit by the Service and prior to engaging in activities associated with the project.

## Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, be aware that your entire comment—including your personal identifying information—may be made available to the public. While you may request that we withhold your personal identifying information, we cannot guarantee that we will be able to do so.

## Our Preliminary Determination

The Service has made a preliminary determination that the applicant's project, including land clearing, infrastructure building, landscaping, and the proposed mitigation measure, would individually and cumulatively have a minor or negligible effect on scrub-jays and the environment. Therefore, we have preliminarily concluded that the ITP for this project would qualify for categorical exclusion and the HCP is low effect under our NEPA regulations at 43 CFR 46.205 and 46.210. A low-effect HCP is one that would result in (1) minor or negligible effects on federally listed, proposed, and candidate species and their habitats; (2) minor or negligible effects on other environmental values or resources; and (3) impacts that, when considered together with the impacts of other past, present, and reasonably foreseeable similarly situated projects, would not result in significant cumulative effects to environmental values or resources over time.

## Next Steps

The Service will evaluate the application and the comments received to determine whether to issue the requested permit. We will also conduct an intra-Service consultation pursuant to section 7 of the ESA to evaluate the effects of the proposed take. After considering the preceding findings, we will determine whether the permit issuance criteria of section 10(a)(1)(B) of the ESA have been met. If met, the Service will issue ITP number PER0017037 to Maury L. Carter and Associates Inc.

## Authority

The Service provides this notice under section 10(c) of the ESA (16 U.S.C. 1531 *et seq.*) and its implementing regulations (50 CFR 17.32) and NEPA (42 U.S.C. 4321 *et seq.*) and its implementing regulations (40 CFR 1506.6 and 43 CFR 46.305).

**Robert L. Carey,**

*Division Manager, Environmental Review, Florida Ecological Services Field Office.*

[FR Doc. 2021–25119 Filed 11–17–21; 8:45 am]

**BILLING CODE 4333–15–P**

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## DEPARTMENT OF THE INTERIOR

## Fish and Wildlife Service

**[FWS–R8–ES–2020–N174; FXES11140800000–212–FF08EVEN00]**

## Endangered and Threatened Wildlife and Plants; Draft Habitat Conservation Plan and Draft Categorical Exclusion for the Central California Distinct Population Segment of the California Tiger Salamander; Churchill Family Properties Residential Development Project, San Benito County, California

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of availability; request for comments.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service), announce the availability of a draft habitat conservation plan (HCP) and draft categorical exclusion for activities associated with an application for an incidental take permit (ITP) under the Endangered Species Act of 1973, as amended. The ITP would authorize take of the Central California distinct population segment of the California tiger salamander incidental to activities associated with construction adjacent to the City of Hollister in San Benito County, California. The applicant developed the draft HCP as part of their application for an ITP. The Service

prepared a draft low-effect screening form and environmental action statement (CatEx) in accordance with the National Environmental Policy Act to evaluate the potential effects to the natural and human environment resulting from issuing an ITP to the applicant. We invite public comment on these documents.

**DATES:** Written comments should be received on or before December 20, 2021.

**ADDRESSES:**

*Obtaining Documents:* You may download a copy of the draft HCP and draft CatEx at *http://www.fws.gov/ventura/,* or you may request copies of the documents by U.S. mail (below) or by phone (see **FOR FURTHER INFORMATION CONTACT**).

*Submitting Written Comments:* Please send us your written comments using one of the following methods:

- *U.S. Mail:* Stephen P. Henry, Field Supervisor, Ventura Fish and Wildlife Office, U.S. Fish and Wildlife Service, 2493 Portola Road, Suite B, Ventura, CA 93003.
- *Email: mark_ogonowski@fws.gov.*

**FOR FURTHER INFORMATION CONTACT:** Mark Ogonowski, Senior Fish and Wildlife Biologist, by email (see **ADDRESSES**), via phone at (805) 677–3350, via the Federal Relay Service at 1–800–877–8339 for TTY assistance, or by mail (see **ADDRESSES**).

**SUPPLEMENTARY INFORMATION:** We, the U.S. Fish and Wildlife Service, announce the availability of a draft HCP and draft CatEx for activities associated with an application for an ITP under section 10(a)(1)(B) of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*). The ITP would authorize take of the Central California distinct population segment (DPS) of the California tiger salamander (*Ambystoma californiense*) incidental to activities associated with the subdivision of two adjoining parcels and construction of residential housing over a 23.5-acre project site adjacent to the City of Hollister in San Benito County, California. The site would be fully developed with single- and multi-family housing, rights of way for streets and utilities, and public open space lots. The applicant developed the draft HCP as part of their application for an ITP. The Service prepared a draft CatEx in accordance with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) to evaluate the potential effects to the natural and human environment resulting from issuing an ITP to the applicant. We invite public comment on all of these documents.

## Background

The Service listed the Central California DPS of the California tiger salamander as threatened on August 4, 2004 (69 FR 47212). Section 9 of the ESA prohibits ''take'' of fish and wildlife species listed as endangered (16 U.S.C. 1538), where take is defined to include the following activities: ''to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct'' (16 U.S.C. 1532). The take prohibitions of Section 9 are extended to species listed as threatened at the discretion the Secretary of the Department of the Interior.

Under section 10(a)(1)(B) of the ESA (16 U.S.C. 1539(a)(1)(B)), we may issue permits to authorize take of listed fish and wildlife species that is incidental to, and not the purpose of, carrying out an otherwise lawful activity. Regulations governing incidental take permits for threatened species are in the Code of Federal Regulations (CFR) at 50 CFR 17.32. Issuance of an ITP also must not jeopardize the existence of federally listed fish, wildlife, or plant species, pursuant to section 7 of the ESA and 50 CFR 402.02. The permittee would receive assurances under our ''No Surprises'' regulations (50 CFR 17.32(b)(5)).

The Service designated critical habitat for the Central California DPS of the California tiger salamander on August 23, 2005 (70 CFR 49380). The project site encompasses 2.3 acres of California tiger salamander critical habitat unit EB 15A, representing approximately .09 percent of this unit and .001 percent of critical habitat designated for the species rangewide. The area of critical habitat overlapping the project site is fragmented from the remainder of unit EB 15A by Fairview Road, which is moderately trafficked.

## Proposed Activities

The applicant has applied for a permit for incidental take of the Central California DPS of the California tiger salamander. The take would occur in association with the construction of residential housing over a 23.5-acre project site adjacent to the City of Hollister in San Benito County, California.

The HCP includes avoidance and minimization measures for the Central California DPS of the California tiger salamander and mitigation for unavoidable loss of habitat. As mitigation, the applicant proposes to purchase credits from a Service-approved conservation bank. The Service in collaboration with the applicant determined the required mitigation using a habitat model based on the methodology in *Calculating Biologically Accurate Mitigation Credits: Insights from the California tiger Salamander* (Searcy and Shaffer 2008). The method assigns a value to habitat that scales with the reproductive value of the individuals estimated to be occupying an area, which is a function of (1) distance to each known or potential breeding pond within dispersal distance of the site, and (2) surrounding land-use. A mitigation ratio of 1:1 (reproductive value lost: Reproductive value conserved) is then applied to determine the amount of mitigation required to offset impacts to California tiger salamander habitat based on the per-credit habitat value of mitigation credits at the chosen conservation bank.

## 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 view, we cannot guarantee that we will be able to do so.

## Authority

We provide this notice under section 10(c) of the ESA (16 U.S.C. 1531 *et seq.*) and its implementing regulations (50 CFR 17.32) and NEPA (42 U.S.C. 4321 *et seq.*) and its implementing regulations (40 CFR 1506.6).

**Stephen Henry,**

*Field Supervisor, Ventura Fish and Wildlife Office, Ventura, California.*

[FR Doc. 2021–25120 Filed 11–17–21; 8:45 am]

BILLING CODE 4333–15–P

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# DEPARTMENT OF THE INTERIOR

## Office of Natural Resources Revenue

**[Docket No. ONRR–2011–0021; DS63644000 DRT000000.CH7000 223D1113RT, OMB Control Number 1012–0002]**

## Agency Information Collection Activities: Indian Oil and Gas Valuation

**AGENCY:** Office of Natural Resources Revenue (''ONRR''), Interior.

**ACTION:** Notice of information collection; request for comment.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995 (''PRA''), ONRR is proposing to renew

an information collection. Through this Information Collection Request (''ICR''), ONRR seeks renewed authority to collect information for the collection, verification, and disbursement of oil and gas royalties owed to Indian lessors. ONRR uses forms ONRR–4109, ONRR–4110, ONRR–4295, ONRR–4393, ONRR–4410, and ONRR–4411 as part of these information collection requirements.

**DATES:** Interested persons are invited to submit written comments on or before December 20, 2021.

**ADDRESSES:** All comment submissions must (1) reference ''OMB Control Number 1012–0002'' in the subject line; (2) be sent to ONRR before the close of the comment period listed under **DATES**; and (3) be sent through one of the following two methods:

• *Electronically via the Federal eRulemaking Portal:* Please visit *https://www.regulations.gov.* In the Search Box, enter the Docket ID Number for this ICR renewal (''ONRR–2011–0021'') to locate the document and click the ''Comment Now!'' button. Follow the prompts to submit your comment prior to the close of the comment period.

• *Email Submissions:* Please email your comments to *ONRR_RegulationsMailbox@onrr.gov* with the Control Number (''OMB Control Number 1012–0002'') listed in the subject line of your email. Email submissions must be postmarked on or before the close of the comment period.

*Docket:* To access the docket to view ICR publications in the **Federal Register**, go to *https://www.regulations.gov* and search ''ONRR–2011–0021.'' The docket will display renewal notices recently published in the **Federal Register**, publications associated with prior renewals, and applicable public comments received for this ICR.

*OMB ICR Data:* You may also view information collection review data for this ICR, including past OMB approvals, at *https://www.reginfo.gov/public/do/PRASearch.* Under the ''OMB Control Number'' heading enter ''1012–0002'' and click the ''Search'' button located at the bottom of the page. To view the ICR renewal or OMB approval status, click on the most recent entry. On the ''View ICR—OIRA Conclusion'' page, check the box next to ''All'' to display all available ICR information provided by OMB.

**FOR FURTHER INFORMATION CONTACT:** To request additional information about this ICR, please contact Linda Miller, Reference & Reporting Management, ONRR, by telephone (303) 231–3626, or by email to *Linda.Miller@onrr.gov.* Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

**SUPPLEMENTARY INFORMATION:** Pursuant to the PRA, 44 U.S.C. 3501, *et seq.,* and 5 CFR 1320.5, all information collections, as defined in 5 CFR 1320.3, require approval by OMB. ONRR 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 its continuing effort to reduce paperwork and respondent burdens, ONRR is inviting the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information in accordance with the PRA and 5 CFR 1320.8(d)(1). This helps ONRR to assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand ONRR's information collection requirements and provide the requested data in the desired format.

ONRR is especially interested in public comments addressing the following:

(1) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of ONRR's 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.

ONRR published a notice, with a 60-day public comment period soliciting comments on this collection of information, in the **Federal Register** on April 21, 2021 (86 FR 20708). ONRR received seven comments from companies regarding the 60-Day Notice. Two commenters stated their general agreement with the contents of the ICR. A third commenter stated that the company had recently issued its first Indian royalty payment in February and it is still getting familiar with ONRR's reporting and payments processes. A fourth commenter stated that the company did not have any feedback in response to the 60-Day Notice. Three other commenters declined to provide any comments.

Comments that you submit in response to this 30-Day Notice are a matter of public record. ONRR will include or summarize each comment in its 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 in formation—may be made publicly available at any time. While you can ask ONRR in your comment to withhold information from public review, ONRR cannot guarantee that it will be able to do so.

*Abstract: (a) General Information:* ONRR collects, accounts for, and verifies natural resource and energy revenues due to states, American Indians, and the U.S. Treasury. *See* U.S. Department of the Interior Departmental Manual, 112 DM 34.3 (Sept. 9, 2020). ONRR collects various information for this purpose. The information collections that ONRR covers in this ICR are found at 30 CFR part 1202, subparts C and J, which pertain to Indian oil and gas royalties; part 1206, subparts B and E, which govern the valuation of oil and gas produced from leases on Indian lands; and part 1207, which pertains to recordkeeping. These records are essential to ensure that Indian Tribes and individual Indian mineral owners receive all royalties and other revenues owed on the minerals removed from their lands. All data reported is subject to subsequent audit and adjustment.

*(b) Information Collections:* This ICR covers the paperwork requirements under 30 CFR parts 1202, 1206, and 1207 as follows:

(1) *Indian Oil:* Regulations at 30 CFR part 1206, subpart B, govern the valuation for royalty purposes of oil produced from Indian oil and gas leases (Tribal and allotted). These regulations require a lessee to file form ONRR–4110, *Oil Transportation Allowance Report,* when its oil transportation allowance includes costs incurred under non-arm's-length or no-contract transportation situations. ONRR and Tribal audit personnel use the information collected on this form to help verify that the lessee correctly reported its transportation allowance within regulatory allowance limitations and reported and paid the correct amount of royalties.

(2) *Indian Gas:* Regulations at 30 CFR part 1206, subpart E, govern the valuation for royalty purposes of natural gas produced from Indian oil and gas leases (Tribal and allotted). These regulations require reporting on ONRR forms 4109, 4295, 4410, and 4411 as follows:

• A lessee must file form ONRR–4109, *Gas Processing Allowance Report,* when its processing allowance includes costs incurred under non-arm's-length or no-contract processing situations. ONRR and Tribal audit personnel use the information collected on this form to verify that the lessee correctly reported its processing allowance within regulatory allowance limitations and reported and paid the correct amount of royalties.

• A lessee must file form ONRR–4295, *Gas Transportation Allowance Report,* when its gas transportation allowance includes costs incurred under non-arm's-length or no-contract transportation situations. ONRR and Tribal audit personnel use the information collected on this form to verify that a lessee correctly reported its transportation allowance within regulatory allowance limitations and reported and paid the correct amount of royalties.

• A lessee must file form ONRR–4410, *Accounting for Comparison [Dual Accounting],* to certify for an Indian oil and gas lease when dual accounting is not required (part A) or to make an election for actual dual accounting as defined in 30 CFR 1206.176 or alternative dual accounting as defined in 30 CFR 1206.173 when dual accounting is required (part B).

• A lessee uses form ONRR–4411, *Safety Net Report,* when it sells gas production from an Indian oil or gas lease in an ONRR-designated index zone beyond the first index pricing point. The safety net calculation establishes the minimum value, for royalty purposes, of natural gas production from Indian oil and gas leases. This reporting requirement helps ensure that Indian lessors receive all royalties due and aids ONRR compliance efforts.

(3) *Indian Oil and Gas:* Regulations at 30 CFR 1206.56(b)(2) and 1206.177(c)(2) and (c)(3) allow a lessee to submit form ONRR–4393, *Request to Exceed Regulatory Allowance Limitation,* to request to exceed the 50-percent-of-royalty-value-transportation-allowance limitation for Indian oil and gas leases. This form and other documentation required by the regulations provide ONRR with data necessary to approve or deny the request.

The requirement to report is mandatory for form ONRR–4410, *Accounting for Comparison [Dual Accounting],* and for form ONRR–4411, *Safety Net Report,* when applicable. A lessee uses ONRR forms 4109, 4110, 4295, and 4393 in order to obtain the benefit of a transportation or processing allowance.

*Title of Collection:* Indian Oil and Gas Valuation, 30 CFR parts 1202, 1206, and 1207.

*OMB Control Number:* 1012–0002.

*Bureau Form Numbers:* Forms ONRR–4109, ONRR–4110, ONRR–4295, ONRR–4393, ONRR–4410, and ONRR–4411.

*Type of Review:* Extension of a currently approved collection.

*Respondents/Affected Public:* Businesses.

*Total Estimated Number of Annual Respondents:* 146 Indian lessees.

*Total Estimated Number of Annual Responses:* 146.

*Estimated Completion Time per Response:* 8.85 hours.

*Total Estimated Number of Annual Burden Hours:* 1,299 hours.

*Respondent's Obligation:* Required to obtain or retain a benefit.

*Frequency of Collection:* Annual and on occasion.

*Total Estimated Annual Non-Hour Burden Cost:* ONRR identified no ''non-hour cost'' burden associated with this collection of information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the PRA (44 U.S.C. 3501, *et seq.*).

**Kimbra G. Davis,**

*Director, Office of Natural Resources Revenue.*

[FR Doc. 2021–24341 Filed 11–17–21; 8:45 am]

**BILLING CODE 4335–30–P**

## INTERNATIONAL TRADE COMMISSION

**[Investigation No. 337–TA–1218]**

## Certain Variable Speed Wind Turbine Generators and Components Thereof; Commission Determination To Review in Part a Final Initial Determination Finding a Violation of Section 337 as to One Patent and No Violation as to Another Patent; Schedule for Filing Written Submissions on Remedy, the Public Interest, and Bonding

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission has determined to review in part a final initial determination (''Final ID'') issued by the presiding administrative law judge (''ALJ'') finding a violation of section 337 of the Tariff Act of 1930. The Commission requests briefing from the parties, interested government agencies, and interested persons on the issues of remedy, the public interest, and bonding based on the schedule set forth below.

**FOR FURTHER INFORMATION CONTACT:** Robert Needham, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708–5468. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server (*http://www.usitc.gov*). Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

**SUPPLEMENTARY INFORMATION:** On September 8, 2020, the Commission instituted this investigation based on a complaint filed on behalf of General Electric Company of Boston, Massachusetts (''GE''). 85 FR 55492–93 (Sept. 8, 2020). The complaint alleged violations of section 337 of the Tariff Act of 1930, as supplemented and amended, 19 U.S.C. 1337, based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain variable speed wind turbine generators and components thereof by reason of infringement of one or more of claims 1, 3, 6, 7, 12, 15–16, 21–24, 29, 30, and 33–38 of U.S. Patent No. 6,921,985 (''the '985 patent'') and claims 1 and 2 of the U.S. Patent No. 7,629,705 (''the '705 patent''). *Id.* at 55493; Order No. 10 (Dec. 2, 2020), *unreviewed by* Comm'n Notice (Dec. 22, 2020). *Id.* The Commission's notice of investigation named as respondents Siemens Gamesa Renewable Energy Inc. of Orlando, Florida; Siemens Gamesa Renewable Energy A/S of Brande, Denmark; and Gamesa Electric, S.A.U. of Zamudio, Spain (collectively, ''SGRE''). *Id.* at 26493; 85 FR 55493. The Office of Unfair Import Investigations is not a party to the investigation. *Id.*

The Commission subsequently terminated the investigation with respect to claims 3, 7, 15, 16, 21–24, 36, and 38 of the '985 patent and claim 2 of the '705 patent based on GE's partial withdrawal of the complaint. Order No. 20 (Mar. 30, 2021), *unreviewed by* Comm'n Notice (Apr. 15, 2021) (terminating the investigation with

respect to claims 3, 7, 36, and 38 of the '985 patent and claim 2 of the '705 patent); Order No. 24 (Apr. 26, 2021), *unreviewed by* Comm'n Notice (May 17, 2021) (terminating the investigation with respect to claims 15, 16, and 21–24 of the '985 patent). Accordingly, at the time of the Final ID, the remaining asserted claims were claims 1, 6, 12, 29, 30, 33–35, and 37 of the '985 patent and claim 1 of the '705 patent.

The Commission also issued a summary determination that GE satisfied the economic prong of the domestic industry requirement with respect to both asserted patents. Order No. 23 (Apr. 26, 2021), *unreviewed by* Comm'n Notice (May 26, 2021).

On September 10, 2021, the ALJ issued the Final ID finding a violation of section 337 with respect to claims 1, 6, 12, 29, 30, 33–35, and 37 of the '985 patent and finding no violation with respect to claim 1 of the '705 patent. Final ID at 147. The Final ID found that GE showed that SGRE induced infringement of claims 1, 6, 12, 29, 30, 33–35, and 37 of the '985 patent and claim 1 of the '705 patent, and that GE showed that it satisfied the technical prong of the domestic industry requirement with respect to both patents. The Final ID also found that SGRE showed that claim 1 of the '705 patent is directed to ineligible subject matter but failed to show that any asserted claim of the '985 patent is invalid or ineligible.

On September 22, 2021, GE filed a petition for review of several issues, including the Final ID's finding that claim 1 of the '705 patent is directed to ineligible subject matter and is not infringed by SGRE's full-converter turbines, as well as the Final ID's finding that GE failed to demonstrate contributory infringement. On September 24, 2021, SGRE filed a petition for review of several issues, including the Final ID's findings that SGRE's products satisfied several limitations of claims 1, 6, and 12 of the '985 patent, its findings that all of SGRE's accused products satisfied claims 29, 30, 33–35, and 37 of the '985 patent, its reliance on licensed activity, and its refusal to adjudicate infringement by products named in the complaint but for which no infringement evidence was presented. SGRE also contingently petitioned for review of the Final ID's finding that SGRE's products practice a limitation of claim 1 of the '705 patent and that claim 1 is not invalid as anticipated. SGRE did not petition for review any issue regarding the Final ID's finding that SGRE violated section 337 via its full-converter turbines with earlier software with respect to claims 29, 30, 33–35, and 37 of the '985 patent. GE and SGRE opposed each other's petitions on September 30, 2021, and October 4, 2021, respectively.

Having examined the record of this investigation, including the ALJ's final ID, the petition for review, and the responses thereto, the Commission has determined to review the Final ID in part. Specifically, the Commission has determined to review the following issues: (1) The Final ID's finding that the accused products satisfy the limitation ''a second mode of operation comprising the low voltage event'' of claims 1, 6, and 12 of the '985 patent; (2) the Final ID's finding that the accused turbines having a doubly-fed induction generator (''DFIG'') satisfy the limitation ''turbine controller causes the blade pitch control system to vary the pitch of the one or more blades'' of claims 1, 6, and 12 of the '985 patent; (3) the Final ID's finding that certain full-converter turbines with later software and DFIG Products infringe claims 29, 30, 33–35, and 37 of the '985 patent; and (4) the Final ID's finding that the accused products satisfy the limitation ''during the entire duration of and subsequent to a zero voltage fault that lasts for an undetermined period of time'' of claim 1 of the '705 patent. The Commission declines to review the remainder of the ID, including the Final ID's finding that SGRE violated section 337 via its full-converter turbines with earlier software with respect to claims 29, 30, 33–35, and 37 of the '985 patent, its findings that GE satisfied the technical prong of the domestic industry requirement with respect to both asserted patents, and its finding that claim 1 of the '705 patent is directed to ineligible matter under 35 U.S.C. 101. The Commission has determined to take no position on whether GE showed that the accused products satisfy the limitation ''during the entire duration of and subsequent to a zero voltage fault that lasts for an undetermined period of time,'' and therefore affirms the Final ID's finding of no violation as to claim 1 of the '705 patent based on 35 U.S.C. 101.

In connection with the final disposition of this investigation, the Commission may (1) issue an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) issue a cease and desist order that could result in the respondent being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone Lines,* Inv. No. 337–TA–360, USITC Pub. No. 2843, Comm'n Op. at 7–10 (December 1994).

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or a cease and desist order would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

The Commission requests full briefing on remedy and the public interest, including in particular briefing on the following remedy and public interest issues:

1. If the Commission were to issue a remedy only with respect to articles that infringe claims 29, 30, 33–35, and 37 of the '985 patent, please provide the identity and volume of the products that would be impacted. Please address the extent to which the software version and licensed activity affect which products are covered by the remedy. Please discuss whether and to what extent remedial order(s) directed to the affected products you have identified in response to this question would affect each of the four public interest considerations. Please also address whether and to what extent SGRE's requested remedy exemptions would be necessary or appropriate in order to mitigate the identified adverse impacts on each public interest consideration.

2. Please explain the feasibility, including in terms of costs and time commitments or delays, of developing alternative contracts for the supply of wind turbine generators in the United States if SGRE is unable to fulfill its existing contract volumes due to remedial orders issued in this investigation.

3. Please describe whether and to what extent it is possible to switch providers for components and service. Please elaborate on the extent to which non-accused or non-infringing components can be used to build or service existing SGRE wind towers.

4. Please describe what, if any, additional costs a wind turbine operator would incur if the proposed remedy requires switching providers for wind turbine components and

service. Please address the extent to which wind turbine operators have already paid for components potentially covered by a remedy, and related service, through warranty and other contractual provisions. Please also address whether switching providers would cause delays or compatibility issues. Please explain how such additional costs, if any, would affect one or more of the four public interest considerations.

5. Please explain what products, if any, are still subject to the license agreement between the parties or whether SGRE otherwise retains the right under patent exhaustion principles to import components for the purpose of repairing products sold under the license. Please explain how the Commission or Customs and Border Protection could ascertain whether imported products are covered by the license or are otherwise authorized.

6. Please address whether SGRE's proven domestic inventories of products and components that are accused of infringing (a) claims 1, 6, and 12 of the '985 patent and (b) claims 29, 30, 33–35, and 37 of the '985 patent are commercially significant within an appropriate context and whether SGRE has other significant business operations in the United States. Please address the various product categories separately: Full-converter turbines using the earlier software, full-converter turbines using the later software, and DFIG turbines.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve, disapprove, or take no position on the Commission's action. *See* Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

*Written Submissions:* The Commission requests that the parties to the investigation file written submissions on the remedy and public interest issues identified in this notice. The Commission encourages parties to the investigation, interested government agencies, and any other interested parties to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the recommended determination by the ALJ on remedy and bonding, which issued on September 10, 2021. The Commission further requests that GE submit proposed remedial orders, state the date when the '985 patent expires, provide the HTSUS subheadings under which the subject articles are imported, and supply a list of known importers of the subject article. The written submissions, exclusive of any exhibits, must not exceed 40 pages, and must be filed no later than close of business on December 7, 2021. Reply submissions must not exceed 20 pages, and must be filed no later than the close of business on December 14, 2021. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (March 19, 2020). Submissions should refer to the investigation number (Inv. No. 337–TA–1218) in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf*). Persons with questions regarding filing should contact the Secretary, (202) 205–2000.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. A redacted non-confidential version of the document must also be filed simultaneously with any confidential filing. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

The Commission vote for this determination took place on November 12, 2021.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: November 12, 2021.

**Lisa Barton,**

*Secretary to the Commission.*

[FR Doc. 2021–25134 Filed 11–17–21; 8:45 am]

**BILLING CODE 7020–02–P**

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## INTERNATIONAL TRADE COMMISSION

**[Investigation No. 731–TA–1070B (Third Review)]**

## Certain Tissue Paper Products From China

### Determination

On the basis of the record [1] developed in the subject five-year review, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that revocation of the antidumping duty order on certain tissue paper products from China would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

### Background

The Commission instituted this review on June 1, 2021 (86 FR 29289) and determined on September 7, 2021 that it would conduct an expedited review (86 FR 54238, September 30, 2021).

The Commission made this determination pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)). It completed and filed its determination in this review on November 4, 2021. The views of the Commission are contained in USITC Publication 5236 (November 2021), entitled *Certain Tissue Paper Products from China: Investigation No. 731–TA–1070B (Third Review).*

By order of the Commission.

Issued: November 18, 2021.

**Katherine Hiner,**

*Supervisory Attorney.*

[FR Doc. 2021–25196 Filed 11–17–21; 8:45 am]

**BILLING CODE 7020–02–P**

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[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

## DEPARTMENT OF JUSTICE

**[OMB Number 1105–0091]**

### Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension Without Change, of a Previously Approved Collection; Assumption of Concurrent Federal Criminal Jurisdiction in Certain Areas of Indian Country

**AGENCY:** Office of Tribal Justice, Department of Justice.

**ACTION:** 30-Day notice.

**SUMMARY:** The Department of Justice, Office of Tribal Justice, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

**DATES:** Comments are encouraged and will be accepted for 30 days until December 20, 2021.

**FOR FURTHER INFORMATION CONTACT:** 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:** Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Office of Tribal Justice, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

**Overview of This Information Collection**

1. *Type of Information Collection:* Extension of a currently approved collection.

2. *The Title of the Form/Collection:* Request to the Attorney General for Assumption of Concurrent Federal Criminal Jurisdiction.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* No form. The applicable component within the Department of Justice is the Office of Tribal Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* The Department of Justice published a rule to establish the procedures for an Indian tribe whose Indian country is subject to State criminal jurisdiction under Public Law 280 (18 U.S.C. 1162(a)) to request that the United States accept concurrent criminal jurisdiction within the tribe's Indian country, and for the Attorney General to decide whether to consent to such a request. The purpose of the collection is to provide information from the requesting tribe sufficient for the Attorney General to make a decision whether to consent to the request.

6. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* Fewer than 350 respondents; 80 hours.

5. *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated maximum 28,000 annual total burden hours associated with this collection (up to 350 respondents × 80 hours = 28,000 hours). Fewer than 350 Indian tribes are eligible for the assumption of concurrent criminal jurisdiction by the United States. The Department of Justice does not know how many eligible tribes will, in fact, make such a request. The information collection will require Indian tribes seeking assumption of concurrent criminal jurisdiction by the United States to provide certain information relating to public safety within the Indian country of the tribe.

If additional information is required please contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, Suite 3E.405B, Washington, DC 20530.

Dated: November 15, 2021.

**Melody Braswell,**

*Department Clearance Officer for PRA, U.S. Department of Justice.*

[FR Doc. 2021–25157 Filed 11–17–21; 8:45 am]

**BILLING CODE 4410–A5–P**

## DEPARTMENT OF LABOR

### Employee Benefits Security Administration

### Agency Information Collection Activities; Request for Public Comment

**AGENCY:** Employee Benefits Security Administration (EBSA), Department of Labor.

**ACTION:** Notice.

**SUMMARY:** The Department of Labor (the Department), in accordance with the Paperwork Reduction Act of 1995 (PRA 95) provides the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the reporting burden on the public and helps the public understand the Department's information collection requirements and provide the requested data in the desired format. Currently, the Employee Benefits Security Administration (EBSA) is soliciting comments on Patient Protection and Affordable Care Act Patient Protection Notice. A copy of the information collection request (ICR) may be obtained by contacting the office listed in the **ADDRESSES** section of this notice.

**DATES:** Written comments must be submitted to the office shown in the **ADDRESSES** section on or before January 18, 2022.

**ADDRESSES:** James Butikofer, Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW, Room N–5718, Washington, DC 20210, or *ebsa.opr@dol.gov.*

**SUPPLEMENTARY INFORMATION:**

**I. Current Actions**

This notice requests public comment pertaining to the Department's request for extension of OMB's approval of the Application. After considering comments received in response to this notice, the Department intends to submit an ICR to OMB for continuing approval. No change to the existing ICR is proposed or made at this time. The Department notes that an agency may not conduct or sponsor, and a person is not required to respond to, an

information collection unless it displays a valid OMB control number. A summary of the ICR and the current burden estimates follows:

*Agency:* Employee Benefits Security Administration, Department of Labor.

*Title:* Patient Protection and Affordable Care Act Patient Protection Notice.

*Type of Review:* Extension of a currently approved collection of information.

*OMB Number:* 1210–0142.

*Affected Public:* Business or other for-profit; Not-for-profit institutions.

*Respondents:* 56,543.

*Frequency of Responses:* On occasion.

*Responses:* 256,262.

*Estimated Total Burden Hours:* 7,068.

*Estimated Total Burden Cost (Operating and Maintenance):* $3,203.

*Description:* The Patient Protection and Affordable Care Act (the Affordable Care Act) was enacted on March 23, 2010. Section 2719A of the Public Health Service Act (the PHS Act), as added by the Affordable Care Act, and the Department's 2015 final regulations (29 CFR 2590.715–2719A) provide that if a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer must permit each participant, beneficiary, or enrollee to designate any participating primary care provider who is available to accept the participant, beneficiary, or enrollee.

The statute and the 2015 final regulations impose a requirement for the designation of a pediatrician similar to the requirement for the designation of a primary care physician. Specifically, if a plan or issuer requires or provides for the designation of a participating primary care provider for a child by a participant, beneficiary, or enrollee, the plan or issuer must permit the designation of a physician (allopathic or osteopathic) who specializes in pediatrics as the child's primary care provider if the provider participates in the network of the plan or issuer. The statute and the 2015 final regulations also provide that a group health plan, or a health insurance issuer may not require authorization or referral by the plan, issuer, or any person (including a primary care provider) for a female participant, beneficiary, or enrollee who seeks obstetrical or gynecological care provided by an in-network health care professional who specializes in obstetrics or gynecology.

On December 27, 2020, the Consolidated Appropriations Act, 2021 (CAA), which includes the No Surprises Act, was signed into law. The No Surprises Act provides Federal protections against surprise billing and limits out-of-network cost sharing under many of the circumstances in which surprise bills arise most frequently. The CAA added provisions applicable to group health plans and health insurance issuers in the group and individual markets in a new Part D of title XXVII of the Public Health Service Act (PHS Act) and also added new provisions to part 7 of the Employee Retirement Income Security Act (ERISA), and Subchapter B of chapter 100 of the Internal Revenue Code (Code).

The No Surprises Act expanded the patient protections related to emergency services to provide additional protections. In addition, the No Surprises Act added reorganized part 7 of ERISA and added a section 722 that includes provisions which mirror those related to choice of healthcare professional that are currently applicable under section 2719A of the PHS Act (which is incorporated by reference through ERISA section 715). The patient protections under the No Surprises Act apply generally to all group health plans and health insurance coverage and a result of the recodification of this provision is that it now applies to grandfathered health plans. The 2021 interim final regulations ''Requirements Related to Surprise Billing; Part I'' add a sunset clause to the current patient protection provisions codified in the 2015 final regulations, and re-codify the provisions related to choice of health care professional in a new section. Accordingly, the 2015 final regulations and 2021 interim final regulations requires plans and issuers to provide a notice to participants (in the individual market, primary subscribers) of these rights when applicable. The notice must be provided whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage, or in the individual market, provides a primary subscriber with a policy, certificate, or contract of health insurance.

On September 10, 2021, the Office of Management and Budget (OMB) approved the information collection request (OMB Control Number 1210–0142) under the emergency procedures for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35) and 5 CFR 1320.13. The approval is scheduled to expire on March 31, 2022.

## II. Focus of Comments

The Department is particularly interested in comments that:

- Evaluate whether the collections of information are necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the collections of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* by permitting electronic submissions of responses.
- Evaluate the effectiveness of the additional demographic questions.

Comments submitted in response to this notice will be summarized and/or included in the ICR for OMB approval of the information collection; they will also become a matter of public record.

Comments submitted in response to this notice will be summarized and/or included in the ICR for OMB approval of the information collection; they will also become a matter of public record.

Signed at Washington, DC, this 11th day of November, 2021.

**Ali Khawar,**

*Acting Assistant Secretary, Employee Benefits Security Administration, U.S. Department of Labor.*

[FR Doc. 2021–25162 Filed 11–17–21; 8:45 am]

BILLING CODE P

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## DEPARTMENT OF LABOR

### Office of Workers' Compensation Programs

### Agency Information Collection Activities; Comment Request; Uniform Billing Form

**ACTION:** Notice.

**AGENCY:** Office of Workers' Compensation Programs.

**SUMMARY:** The Department of Labor (DOL) is soliciting comments concerning a proposed extension for the authority to conduct the information collection request (ICR) titled, ''Uniform Billing Form''. This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the

Paperwork Reduction Act of 1995 (PRA).

**DATES:** Consideration will be given to all written comments received by January 18, 2022.

**ADDRESSES:** A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained for free by contacting Anjanette Suggs by telephone at 202–354–9660 or by email at *suggs.anjanette@dol.gov.*

Submit written comments about this ICR by mail or courier to the U.S. Department of Labor, Office of Workers' Compensation Programs, Room S3323, 200 Constitution Avenue NW, Washington, DC 20210; or by email at *suggs.anjanette@dol.gov.* Please note that comments submitted after the comment period will not be considered.

**FOR FURTHER INFORMATION CONTACT:** Anjanette Suggs by telephone at 202–354–9660 or by email at *suggs.anjanette@dol.gov.*

**SUPPLEMENTARY INFORMATION:** The DOL, as part of continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to the Office of Management and Budget (OMB) for final approval. This program helps to ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed.

The Office of Workers' Compensation Programs (OWCP) is the agency responsible for administration of the Federal Employees' Compensation Act, 5 U.S.C. 8101 *et seq.,* the Black Lung Benefits Act, 30 U.S.C. 901 *et seq.,* and the Energy Employees Occupational Illness Compensation Program Act of 2000, 42 U.S.C. 7384 *et seq.* All three of these statutes require that OWCP pay for medical treatment of beneficiaries; this medical treatment can include inpatient/outpatient hospital services, as well as services provided by nursing homes, skilled nursing facilities and home health aides in the home. In order to determine whether billed amounts are appropriate, OWCP needs to identify the patient, the specific services that were rendered and their relationship to the work-related injury or illness. The regulations implementing these statutes require the use of Form OWCP–04 or UB–04 for the submission of medical bills from institutional providers (20 CFR 10.801, 30.701, 725.405, 725.406, 725.701 and 725.704). The Uniform Billing Form, known as the paper UB–04, has been approved by the American Hospital Association, the Centers for Medicare and Medicaid Services and the Civilian Health and Medical Program of Uniformed Services by various other government health care providers, and the private sector, to request payment to institutional providers of medical services. The paper UB–04 form has been designed by the National Uniform Billing Committee and is neither a government-printed form nor distributed by OWCP. However, this collection includes the paper UB–04 form as a collection instrument, with detailed instructions prepared by OWCP to ensure that it obtains only the information needed to consider requests for payment from institutional providers using this billing form. This information collection is currently approved for use through March 31, 2022.

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. Written comments will receive consideration, and be summarized and included in the request for OMB approval of the final ICR. In order to help ensure appropriate consideration, comments should mention OMB No. 1240–0019.

Submitted comments will also be a matter of public record for this ICR and posted on the internet, without redaction. The DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

The DOL is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

*Agency:* DOL–OWCP.

*Type of Review:* Revision of currently approved collection.

*Title of Collection:* Uniform Billing Form.

*Form:* OWCP–04, Uniform Billing Form.

*OMB Control Number:* 1240–0019.

*Affected Public:* Private Sector: Business or other for-profit institutions; not for-profit.

*Estimated Number of Respondents:* 6,077.

*Frequency:* On occasion.

*Total Estimated Annual Responses:* 190,970.

*Estimated Average Time per Response:* 1–7 minutes.

*Estimated Total Annual Burden Hours:* 29,466.

*Total Federal Cost:* $1,981,286.

*Total Estimated Annual Other Cost Burden:* 0.

(*Authority:* 44 U.S.C. 3506(c)(2)(A))

**Anjanette Suggs,**

*Agency Clearance Officer.*

[FR Doc. 2021–25163 Filed 11–17–21; 8:45 am]

**BILLING CODE 4510–CH–P**

## NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

**[Notice (21–078)]**

## Notice of Intent To Grant an Exclusive, Co-Exclusive or Partially Exclusive Patent License

**AGENCY:** National Aeronautics and Space Administration.

**ACTION:** Notice of intent to grant exclusive, co-exclusive or partially exclusive patent license.

**SUMMARY:** NASA hereby gives notice of its intent to grant an exclusive, co-exclusive or partially exclusive patent license to practice the inventions described and claimed in the patents and/or patent applications listed in **SUPPLEMENTARY INFORMATION** below.

**DATES:** The prospective exclusive, co-exclusive or partially exclusive license may be granted unless NASA receives written objections including evidence and argument, no later than December 3, 2021 that establish that the grant of the license would not be consistent with the requirements regarding the licensing of federally owned inventions as set forth in the Bayh-Dole Act and implementing regulations. Competing applications completed and received by NASA no later than December 3, 2021 will also be treated as objections to the grant of the

contemplated exclusive, co-exclusive or partially exclusive license. Objections submitted in response to this notice will not be made available to the public for inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act.

*Objections and Further Information:* Written objections relating to the prospective license or requests for further information may be submitted to Agency Counsel for Intellectual Property, NASA Headquarters at Email: *hq-patentoffice@mail.nasa.gov.* Questions may be directed to Phone: (202) 358–3437.

**SUPPLEMENTARY INFORMATION:** NASA intends to grant an exclusive, co-exclusive, or partially exclusive patent license in the United States to practice the inventions described and claimed in U.S. Patent Application Serial No. 16/104,824 entitled ''Cryogenic Flux Capacitor for Solid-State Storage and On-Demand Supply of Fluid Commodities,'' filed on August 17, 2018, to Hyperion Companies, Inc., having its principal place of business in Orange, California. The fields of use may be limited. NASA has not yet made a final determination to grant the requested license and may deny the requested license even if no objections are submitted within the comment period.

This notice of intent to grant an exclusive, co-exclusive or partially exclusive patent license is issued in accordance with 35 U.S.C. 209(e) and 37 CFR 404.7(a)(1)(i). The patent rights in these inventions have been assigned to the United States of America as represented by the Administrator of the National Aeronautics and Space Administration. The prospective license will comply with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Information about other NASA inventions available for licensing can be found online at *http://technology.nasa.gov.*

**Helen M. Galus,**

*Agency Counsel for Intellectual Property.*

[FR Doc. 2021–25144 Filed 11–17–21; 8:45 am]

**BILLING CODE 7510–13–P**

## NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

**[Notice (21–077)]**

### Notice of Intent To Grant a Partially Exclusive Patent License

**AGENCY:** National Aeronautics and Space Administration.

**ACTION:** Notice of intent to grant partially exclusive patent license.

**SUMMARY:** NASA hereby gives notice of its intent to grant a partially exclusive patent license to practice the inventions described and claimed in the patents and/or patent applications listed in **SUPPLEMENTARY INFORMATION** below.

**DATES:** The prospective partially exclusive license may be granted unless NASA receives written objections including evidence and argument, no later than December 3, 2021 that establish that the grant of the license would not be consistent with the requirements regarding the licensing of federally owned inventions as set forth in the Bayh-Dole Act and implementing regulations. Competing applications completed and received by NASA no later than December 3, 2021 will also be treated as objections to the grant of the contemplated exclusive, co-exclusive or partially exclusive license. Objections submitted in response to this notice will not be made available to the public for inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act.

*Objections and Further Information:* Written objections relating to the prospective license or requests for further information may be submitted to Agency Counsel for Intellectual Property, NASA Headquarters at Email: *hq-patentoffice@mail.nasa.gov.* Questions may be directed to Phone: (202) 358–3437.

**SUPPLEMENTARY INFORMATION:** NASA intends to grant an exclusive, co-exclusive, or partially exclusive patent license in the United States to practice the inventions described and claimed in: U.S. Patent No. 8,939,178 titled ''Variable-Aperture Reciprocating Reed Valve,'' and U.S. Patent Application No. 17/314,201 titled ''Motion Absorbing System and Method for a Structure,'' to SEA.O.G, LLC, having its principal place of business in New Bedford, MA. The fields of use may be limited. NASA has not yet made a final determination to grant the requested license and may deny the requested license even if no objections are submitted within the comment period.

This notice of intent to grant a partially exclusive patent license is issued in accordance with 35 U.S.C. 209(e) and 37 CFR 404.7(a)(1)(i). The patent rights in these inventions have been assigned to the United States of America as represented by the Administrator of the National Aeronautics and Space Administration. The prospective license will comply with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Information about other NASA inventions available for licensing can be found online at *http://technology.nasa.gov.*

**Helen M. Galus,**

*Agency Counsel for Intellectual Property.*

[FR Doc. 2021–25137 Filed 11–17–21; 8:45 am]

**BILLING CODE 7510–13–P**

## NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

### National Endowment for the Humanities

### Meeting of Humanities Panel

**AGENCY:** National Endowment for the Humanities; National Foundation on the Arts and the Humanities.

**ACTION:** Notice of meeting.

**SUMMARY:** The National Endowment for the Humanities (NEH) will hold fourteen meetings, by videoconference, of the Humanities Panel, a federal advisory committee, during December 2021. The purpose of the meetings is for panel review, discussion, evaluation, and recommendation of applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965.

**DATES:** See **SUPPLEMENTARY INFORMATION** for meeting dates. The meetings will open at 8:30 a.m. and will adjourn by 5:00 p.m. on the dates specified below.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Voyatzis, Committee Management Officer, 400 7th Street SW, Room 4060, Washington, DC 20506; (202) 606–8322; *evoyatzis@neh.gov.*

**SUPPLEMENTARY INFORMATION:** Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. App.), notice is hereby given of the following meetings:

1. Date: December 1, 2021

This video meeting will discuss applications on the topic of U.S. History, for the Humanities Collections and Reference Resources grant program, submitted to the Division of Preservation and Access.

2. Date: December 1, 2021

This video meeting will discuss applications on the topics of History and Culture, for the Infrastructure and Capacity Building Challenge Grants program, submitted to the Office of Challenge Programs.

3. Date: December 1, 2021

This video meeting will discuss applications for the Dialogues on the

Experience of War grant program, submitted to the Division of Education Programs.

4. Date: December 2, 2021

This video meeting will discuss applications for the Dialogues on the Experience of War grant program, submitted to the Division of Education Programs.

5. Date: December 2, 2021

This video meeting will discuss applications on the topics of History and Culture, for the Infrastructure and Capacity Building Challenge Grants program, submitted to the Office of Challenge Programs.

6. Date: December 2, 2021

This video meeting will discuss applications on the topic of Art History, for the Humanities Collections and Reference Resources grant program, submitted to the Division of Preservation and Access.

7. Date: December 3, 2021

This video meeting will discuss applications for the Dialogues on the Experience of War grant program, submitted to the Division of Education Programs.

8. Date: December 6, 2021

This video meeting will discuss applications on the topic of Higher Education, for the Infrastructure and Capacity Building Challenge Grants program, submitted to the Office of Challenge Programs.

9. Date: December 7, 2021

This video meeting will discuss applications on the topic of Digital, for the Infrastructure and Capacity Building Challenge Grants program, submitted to the Office of Challenge Programs.

10. Date: December 8, 2021

This video meeting will discuss applications for the Dynamic Language Infrastructure—Documenting Endangered Languages Fellowships, submitted to the Division of Research Programs.

11. Date: December 9, 2021

This video meeting will discuss applications on the topic of Museums, for the Infrastructure and Capacity Building Challenge Grants program, submitted to the Office of Challenge Programs.

12. Date: December 10, 2021

This video meeting will discuss applications for Fellowship Programs at Independent Research Institutions, submitted to the Division of Research Programs.

13. Date: December 13, 2021

This video meeting will discuss applications on the topic of Higher Education, for the Infrastructure and Capacity Building Challenge Grants program, submitted to the Office of Challenge Programs.

14. Date: December 14, 2021

This video meeting will discuss applications on the topic of Museums, for Infrastructure and Capacity Building Challenge Grants programs, submitted to the Office of Challenge Programs.

Because these meetings will include review of personal and/or proprietary financial and commercial information given in confidence to the agency by grant applicants, the meetings will be closed to the public pursuant to sections 552b(c)(4) and 552b(c)(6) of Title 5, U.S.C., as amended. I have made this determination pursuant to the authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee Meetings dated April 15, 2016.

Dated: November 12, 2021.

**Samuel Roth,**

*Attorney-Advisor, National Endowment for the Humanities.*

[FR Doc. 2021–25131 Filed 11–17–21; 8:45 am]

**BILLING CODE 7536–01–P**

## NATIONAL SCIENCE FOUNDATION

### Sunshine Act Meetings

The National Science Board hereby gives notice of a change in a previously scheduled closed teleconference meeting of the External Engagement Committee's Subcommittee on Honorary Awards pursuant to the National Science Foundation Act and the Government in the Sunshine Act.

**FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT:** 86 FR 62851, November 12, 2021.

**PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING:** The National Science Board's Subcommittee on Honorary Awards was scheduled for November 16, 2021, from 11:00 a.m.–12:00 p.m. EST.

**CHANGES IN THE MEETING:** The new date and time is November 23, 2021, from 3:00–4:00 p.m. EST.

**CONTACT PERSON FOR MORE INFORMATION:** Chris Blair, 703/292–7000, *cblair@nsf.gov.*

**Chris Blair,**

*Executive Assistant to the National Science Board Office.*

[FR Doc. 2021–25223 Filed 11–16–21; 11:15 am]

**BILLING CODE P**

## NATIONAL SCIENCE FOUNDATION

### Notice of Permits Issued Under the Antarctic Conservation Act of 1978

**AGENCY:** National Science Foundation.

**ACTION:** Notice of permits issued.

**SUMMARY:** The National Science Foundation (NSF) is required to publish notice of permits issued under the Antarctic Conservation Act of 1978. This is the required notice.

**FOR FURTHER INFORMATION CONTACT:** Polly Penhale, ACA Permit Officer, Office of Polar Programs, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314; 703–292–8030; email: *ACApermits@nsf.gov.*

**SUPPLEMENTARY INFORMATION:** On October 13, 2021, the National Science Foundation published a notice in the **Federal Register** of permit applications received. The permits were issued on November 12, 2021, to:

1. Quixote Expeditions—Permit No. 2022–012
2. Scenic USA—Permit No. 2022–013

**Erika N. Davis,**

*Program Specialist, Office of Polar Programs.*

[FR Doc. 2021–25110 Filed 11–17–21; 8:45 am]

**BILLING CODE 7555–01–P**

## OCCUPATIONAL SAFETY AND HEALTH REVIEW COMMISSION

### Privacy Act of 1974; System of Records

**AGENCY:** Occupational Safety and Health Review Commission.

**ACTION:** Notice of a new system of records.

**SUMMARY:** In accordance with the Privacy Act of 1974, as amended, the Occupational Safety and Health Review Commission (OSHRC) is providing notice of a new Privacy Act system of records, designated as Reasonable Accommodation Records, OSHRC–9.

**DATES:** Comments must be received by OSHRC on or before December 20, 2021. The new system of records will become effective on that date, without any further notice in the **Federal Register**, unless comments or government

approval procedures necessitate otherwise.

**ADDRESSES:** You may submit comments by any of the following methods:

- *Email: rbailey@oshrc.gov.* Include ''PRIVACY ACT SYSTEM OF RECORDS'' in the subject line of the message.
- *Fax:* (202) 606–5417.
- *Mail:* One Lafayette Centre, 1120 20th Street NW, Ninth Floor, Washington, DC 20036–3457.
- *Hand Delivery/Courier:* same as mailing address.

*Instructions:* All submissions must include your name, return address, and email address, if applicable. Please clearly label submissions as ''PRIVACY ACT SYSTEM OF RECORDS.''

**FOR FURTHER INFORMATION CONTACT:** Ron Bailey, Attorney-Advisor, Office of the General Counsel, via telephone at (202) 606–5410, or via email at *rbailey@oshrc.gov.*

**SUPPLEMENTARY INFORMATION:** The Privacy Act of 1974, 5 U.S.C. 552a(e)(4), requires federal agencies such as OSHRC to publish in the **Federal Register** notice of any new or modified system of records.

In accordance Executive Order 14043, ''Executive Order on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees'' (Sept. 9, 2021), each agency is required to ''implement, to the extent consistent with applicable law, a program to require COVID–19 vaccination for all of its Federal employees, with exceptions only as required by law.'' The Safer Federal Workforce Task Force—created by the president to provide federal agencies with guidance on issues related to the COVID–19 pandemic—subsequently issued guidance regarding reasonable accommodation requests, for both medical and religious reasons, that may constitute ''legally required exception[s] to the vaccination requirement.'' More specifically, under certain circumstances, federal law—such as section 501 of the Rehabilitation Act of 1973, 29 U.S.C. 791; and Title VII of the Civil Rights Act of 1964, 42 U.S.C. 2000e *et seq.*—may require an agency to provide a reasonable accommodation for an employee or applicant who, because of a disability or a sincerely held religious belief, practice, or observance, requests and is granted an exception from the COVID–19 vaccine mandate.

In the event that an employee or applicant requests a reasonable accommodation, records supporting that request may be collected and maintained by the agency, in accordance with 29 CFR part 1614. The agency may also collect and maintain records concerning requests for reasonable accommodations made in other circumstances that are unrelated to the vaccine mandate set forth in Executive Order 14043.

The notice for OSHRC–9, provided below in its entirety, is as follows.

**SYSTEM NAME AND NUMBER:**

Reasonable Accommodation Records.

**SECURITY CLASSIFICATION:**

Unclassified.

**SYSTEM LOCATION:**

The Office of the Executive Director maintains the records in this system. The office is located at 1120 20th Street NW, Ninth Floor, Washington, DC 20036–3457.

**SYSTEM MANAGER(S):**

Human Resources Specialist, 1120 20th Street NW, Ninth Floor, Washington, DC 20036–3457; (202) 606–5100.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 501 of the Rehabilitation Act of 1973, 29 U.S.C. 791; Title VII of the Civil Rights Act of 1964, 42 U.S.C. 2000e *et seq.;* 29 CFR part 1614; E.O. 13548; E.O. 13164.

**PURPOSE(S) OF THE SYSTEM:**

This system is maintained for the purpose of considering, deciding, and implementing requests for reasonable accommodations made by OSHRC employees and applicants.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

This system of records covers current and former OSHRC employees and applicants who have requested reasonable accommodations.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

This system of records may include the employee's or applicant's name; contact information, including mailing and email addresses, and phone numbers; employment information; information concerning disabilities, including descriptions of disabilities and how they affect major life activities, medical records, and medical opinions; and information concerning religious beliefs, practices and observances.

**RECORD SOURCE CATEGORIES:**

Information contained in the system is obtained from OSHRC employees and applicants requesting reasonable accommodations, as well as their medical providers.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:**

In addition to disclosures generally permitted under 5 U.S.C. 552a(b), all or a portion of the records or information contained in this system of records may be disclosed as a routine use pursuant to 5 U.S.C. 552a(b)(3) under the circumstances or for the purposes described below, to the extent such disclosures are compatible with the purposes for which the information was collected, and to the extent disclosure of any medical and/or genetic information is in compliance with Section 501 of the Rehabilitation Act of 1973 and Title II of the Genetic Information Nondiscrimination Act (GINA) of 2008. With respect to medical and genetic information protected under the Rehabilitation Act and/or GINA, records will be withheld or redacted to comply with the specific confidentiality and disclosure requirements set forth by the U.S. Equal Employment Opportunity Commission at 29 CFR part 1630 (Rehabilitation Act) and 29 CFR part 1635 (GINA). With these limitations, records may be disclosed as a routine use:

(1) To the Department of Justice (DOJ), or to a court or adjudicative body before which OSHRC is authorized to appear, when any of the following entities or individuals—(a) OSHRC, or any of its components; (b) any employee of OSHRC in his or her official capacity; (c) any employee of OSHRC in his or her individual capacity where DOJ (or OSHRC where it is authorized to do so) has agreed to represent the employee; or (d) the United States, where OSHRC determines that litigation is likely to affect OSHRC or any of its components—is a party to litigation or has an interest in such litigation, and OSHRC determines that the use of such records by DOJ, or by a court or other tribunal, or another party before such tribunal, is relevant and necessary to the litigation.

(2) To an appropriate agency, whether federal, state, local, or foreign, charged with investigating or prosecuting a violation or enforcing or implementing a law, rule, regulation, or order, when a record, either on its face or in conjunction with other information, indicates a violation or potential violation of law, which includes civil, criminal or regulatory violations, and such disclosure is proper and consistent with the official duties of the person making the disclosure.

(3) To a federal, state, or local agency maintaining civil, criminal or other relevant enforcement information, such as current licenses, if necessary to

obtain information relevant to an OSHRC decision concerning the hiring, appointment, or retention of an employee; the issuance, renewal, suspension, or revocation of a security clearance; the execution of a security or suitability investigation; the letting of a contract; or the issuance of a license, grant or other benefit.

(4) To a federal, state, or local agency, in response to that agency's request for a record, and only to the extent that the information is relevant and necessary to the requesting agency's decision in the matter, if the record is sought in connection with the hiring, appointment, or retention of an employee; the issuance, renewal, suspension, or revocation of a security clearance; the execution of a security or suitability investigation; the letting of a contract; or the issuance of a license, grant or other benefit by the requesting agency.

(5) To an authorized appeal grievance examiner, formal complaints manager, equal employment opportunity investigator, arbitrator, or other duly authorized official engaged in investigation or settlement of a grievance, complaint, or appeal filed by an employee, only to the extent that the information is relevant and necessary to the case or matter.

(6) To OPM in accordance with the agency's responsibilities for evaluation and oversight of federal personnel management.

(7) To officers and employees of a federal agency for the purpose of conducting an audit, but only to the extent that the record is relevant and necessary to this purpose.

(8) To OMB in connection with the review of private relief legislation at any stage of the legislative coordination and clearance process, as set forth in Circular No. A–19.

(9) To a Member of Congress or to a person on his or her staff acting on the Member's behalf when a written request is made on behalf and at the behest of the individual who is the subject of the record.

(10) To the National Archives and Records Administration (NARA) for records management inspections and such other purposes conducted under the authority of 44 U.S.C. 2904 and 2906.

(11) To appropriate agencies, entities, and persons when: (a) OSHRC suspects or has confirmed that there has been a breach of the system of records; (b) OSHRC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, OSHRC, the Federal Government, or national security; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with OSHRC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

(12) To NARA, Office of Government Information Services (OGIS), to the extent necessary to fulfill its responsibilities in 5 U.S.C. 552(h), to review administrative agency policies, procedures and compliance with FOIA, and to facilitate OGIS' offering of mediation services to resolve disputes between persons making FOIA requests and administrative agencies.

(13) To another federal agency or federal entity, when OSHRC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (a) responding to a suspected or confirmed breach or (b) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

(14) To medical professionals, when the requester has signed a limited release, authorizing OSHRC to seek additional information directly from the medical provider, or when OSHRC has determined that medical information must be reviewed by other medical experts to make a reasonable accommodation determination.

**POLICIES AND PRACTICES FOR STORAGE OF RECORDS:**

Records are stored on paper in locked file cabinets at OSHRC's National Office in Washington, DC, and electronically on an access-restricted shared OSHRC drive.

**POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:**

Records are retrieved manually or electronically by an individual's name.

**POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:**

Records are retained and disposed of in accordance with NARA's General Records Schedule 2.1, Item 140 (applicants); and General Records Schedule 2.3, Item 20 (employees).

**ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:**

Paper records are maintained in offices and locked file cabinets. During duty hours, the records are under surveillance of personnel charged with their custody. After duty hours, the offices are accessible only using an office key or access card. Access to electronic records maintained on an OSHRC shared drive is restricted to personnel who require access to perform their official functions.

**RECORD ACCESS PROCEDURES:**

Individuals who wish to gain access to their records should notify: Privacy Officer, OSHRC, 1120 20th Street NW, Ninth Floor, Washington, DC 20036–3457. For an explanation on how such requests should be drafted, refer to 29 CFR 2400.4 (procedures for requesting notification of and access to personal records).

**CONTESTING RECORD PROCEDURES:**

Individuals who wish to contest their records should notify: Privacy Officer, OSHRC, 1120 20th Street NW, Ninth Floor, Washington, DC 20036–3457. For an explanation on the specific procedures for contesting the contents of a record, refer to 29 CFR 2400.6 (procedures for amending personal records), and 29 CFR 2400.7 (procedures for appealing).

**NOTIFICATION PROCEDURES:**

Individuals interested in inquiring about their records should notify: Privacy Officer, OSHRC, 1120 20th Street NW, Ninth Floor, Washington, DC 20036–3457. For an explanation on how such requests should be drafted, refer to 29 CFR 2400.4 (procedures for requesting notification of and access to personal records).

**EXEMPTIONS PROMULGATED FOR THE SYSTEM:**

None.

**HISTORY:**

None.

**Nadine N. Mancini,**

*Senior Agency Official for Privacy.*

[FR Doc. 2021–25166 Filed 11–17–21; 8:45 am]

BILLING CODE 7600–01–P

## RAILROAD RETIREMENT BOARD

### 2022 Railroad Experience Rating Proclamations, Monthly Compensation Base and Other Determinations

**AGENCY:** Railroad Retirement Board.

**ACTION:** Notice.

**SUMMARY:** As required by the Railroad Unemployment Insurance Act (Act), the Railroad Retirement Board (RRB) hereby publishes its notice for calendar year 2022 of account balances, factors used in calculating experience-based employer contribution rates, computation of amounts related to the monthly compensation base, and the maximum daily benefit rate for days of unemployment or sickness.

**DATES:** The balance in notice (1) and the determinations made in notices (3) through (7) are based on data as of June 30, 2021. The balance in notice (2) is based on data as of September 30, 2021. The determinations made in notices (5) through (7) apply to the calculation, under section 8(a)(1)(C) of the Act, of employer contribution rates for 2022. The determinations made in notices (8) through (11) are effective January 1, 2022. The determination made in notice (12) is effective for registration periods beginning after June 30, 2022.

**ADDRESSES:** Secretary to the Board, Railroad Retirement Board, 844 N Rush Street, Chicago, Illinois 60611–1275.

**FOR FURTHER INFORMATION CONTACT:** Michael J. Rizzo, Bureau of the Actuary and Research, Railroad Retirement Board, 844 N Rush Street, Chicago, Illinois 60611–1275, telephone (312) 751–4771.

**SUPPLEMENTARY INFORMATION:** The RRB is required by section 8(c)(1) of the Railroad Unemployment Insurance Act (Act) (45 U.S.C. 358(c)(1)) as amended by Public Law 100–647, to proclaim by October 15 of each year certain system-wide factors used in calculating experience-based employer contribution rates for the following year. The RRB is further required by section 8(c)(2) of the Act (45 U.S.C. 358(c)(2)) to publish the amounts so determined and proclaimed. The RRB is required by section 12(r)(3) of the Act (45 U.S.C. 362(r)(3)) to publish by December 11, 2021, the computation of the calendar year 2022 monthly compensation base (section 1(i) of the Act) and amounts described in sections 1(k), 2(c), 3 and 4(a–2)(i)(A) of the Act which are related to changes in the monthly compensation base. Also, the RRB is required to publish, by June 11, 2022, the maximum daily benefit rate under section 2(a)(3) of the Act for days of unemployment and days of sickness in registration periods beginning after June 30, 2022. Pursuant to section 8(c)(2) and section 12(r)(3) of the Railroad Unemployment Insurance Act (Act) (45 U.S.C. 358(c)(2) and 45 U.S.C. 362(r)(3), respectively), the Board gives notice of the following:

1. The accrual balance of the Railroad Unemployment Insurance (RUI) Account, as of June 30, 2021, is ($46,213,371.39);

2. The September 30, 2021, balance of any new loans to the RUI Account, including accrued interest, is $105,399,084.73;

3. The system compensation base is $3,778,489,820.38 as of June 30, 2021;

4. The cumulative system unallocated charge balance is ($465,529,620.69) as of June 30, 2021;

5. The pooled credit ratio for calendar year 2022 is zero;

6. The pooled charged ratio for calendar year 2022 is zero;

7. The surcharge rate for calendar year 2022 is 3.5 percent;

8. The monthly compensation base under section 1(i) of the Act is $1,755 for months in calendar year 2022;

9. The amount described in sections 1(k) and 3 of the Act as ''2.5 times the monthly compensation base'' is $4,387.50 for base year (calendar year) 2022;

10. The amount described in section 4(a–2)(i)(A) of the Act as ''2.5 times the monthly compensation base'' is $4,387.50 with respect to disqualifications ending in calendar year 2022;

11. The amount described in section 2(c) of the Act as ''an amount that bears the same ratio to $775 as the monthly compensation base for that year as computed under section 1(i) of this Act bears to $600'' is $2,267 for months in calendar year 2022;

12. The maximum daily benefit rate under section 2(a)(3) of the Act is $85 with respect to days of unemployment and days of sickness in registration periods beginning after June 30, 2022.

**Surcharge Rate**

A surcharge is added in the calculation of each employer's contribution rate, subject to the applicable maximum rate, for a calendar year whenever the balance to the credit of the RUI Account on the preceding June 30 is less than the greater of $100 million or the amount that bears the same ratio to $100 million as the system compensation base for that June 30 bears to the system compensation base as of June 30, 1991. If the RUI Account balance is less than $100 million (as indexed), but at least $50 million (as indexed), the surcharge will be 1.5 percent. If the RUI Account balance is less than $50 million (as indexed), but greater than zero, the surcharge will be 2.5 percent. The maximum surcharge of 3.5 percent applies if the RUI Account balance is less than zero.

The ratio of the June 30, 2021 system compensation base of $3,778,489,820.38 to the June 30, 1991 system compensation base of $2,763,287,237.04 is 1.36738945. Multiplying 1.36738945 by $100 million yields $136,738,945.00. Multiplying $50 million by 1.36738945 produces $68,369,472.50. The Account balance on June 30, 2021, was ($46,213,371.39). Accordingly, the surcharge rate for calendar year 2022 is 3.5 percent.

**Monthly Compensation Base**

For years after 1988, section 1(i) of the Act contains a formula for determining the monthly compensation base. Under the prescribed formula, the monthly compensation base increases by approximately two-thirds of the cumulative growth in average national wages since 1984. The monthly compensation base for months in calendar year 2022 shall be equal to the greater of (a) $600 or (b) $600 [1 + {(A − 37,800)/56,700}], where A equals the amount of the applicable base with respect to tier 1 taxes for 2022 under section 3231(e)(2) of the Internal Revenue Code of 1986. Section 1(i) further provides that if the amount so determined is not a multiple of $5, it shall be rounded to the nearest multiple of $5.

Using the calendar year 2022 tier 1 tax base of $147,000 for A above produces the amount of $1,755.56, which must then be rounded to $1,755. Accordingly, the monthly compensation base is determined to be $1,755 for months in calendar year 2022.

**Amounts Related to Changes in Monthly Compensation Base**

For years after 1988, sections 1(k), 3, 4(a–2)(i)(A) and 2(c) of the Act contain formulas for determining amounts related to the monthly compensation base.

Under section 1(k), remuneration earned from employment covered under the Act cannot be considered subsidiary remuneration if the employee's base year compensation is less than 2.5 times the monthly compensation base for months in such base year. Under section 3, an employee shall be a ''qualified employee'' if his/her base year compensation is not less than 2.5 times the monthly compensation base for months in such base year. Under section 4(a–2)(i)(A), an employee who leaves work voluntarily without good cause is disqualified from receiving unemployment benefits until he has been paid compensation of not less than 2.5 times the monthly compensation base for months in the calendar year in which the disqualification ends.

Multiplying 2.5 by the calendar year 2022 monthly compensation base of $1,755 produces $4,387.50. Accordingly, the amount determined under sections 1(k), 3 and 4(a–2)(i)(A) is $4,387.50 for calendar year 2022.

Under section 2(c), the maximum amount of normal benefits paid for days of unemployment within a benefit year and the maximum amount of normal benefits paid for days of sickness within a benefit year shall not exceed an

employee's compensation in the base year. In determining an employee's base year compensation, any money remuneration in a month not in excess of an amount that bears the same ratio to $775 as the monthly compensation base for that year bears to $600 shall be taken into account.

The calendar year 2022 monthly compensation base is $1,755. The ratio of $1,755 to $600 is 2.92500000. Multiplying 2.92500000 by $775 produces $2,267. Accordingly, the amount determined under section 2(c) is $2,267 for months in calendar year 2022.

**Maximum Daily Benefit Rate**

Section 2(a)(3) contains a formula for determining the maximum daily benefit rate for registration periods beginning after June 30, 1989, and after each June 30 thereafter. Legislation enacted on October 9, 1996, revised the formula for indexing maximum daily benefit rates. Under the prescribed formula, the maximum daily benefit rate increases by approximately two-thirds of the cumulative growth in average national wages since 1984. The maximum daily benefit rate for registration periods beginning after June 30, 2022, shall be equal to 5 percent of the monthly compensation base for the base year immediately preceding the beginning of the benefit year. Section 2(a)(3) further provides that if the amount so computed is not a multiple of $1, it shall be rounded down to the nearest multiple of $1.

The calendar year 2021 monthly compensation base is $1,710. Multiplying $1,710 by 0.05 yields $85.50. Accordingly, the maximum daily benefit rate for days of unemployment and days of sickness beginning in registration periods after June 30, 2022, is determined to be $85.

By Authority of the Board.

**Stephanie Hillyard,**

*Secretary to the Board.*

[FR Doc. 2021–25154 Filed 11–17–21; 8:45 am]

**BILLING CODE 7905–01–P**

## SECURITIES AND EXCHANGE COMMISSION

**[SEC File No. 270–638, OMB Control No. 3235–0687]**

## Proposed Collection; Comment Request

*Upon Written Request Copies Available From:* Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

*Extension:*
Rule 239

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Rule 239 (17 CFR 230.239) provides exemptions under the Securities Act of 1933 (15 U.S.C. 77a *et seq.*), the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) and the Trust Indenture Act of 1939 (U.S.C. 77aaa *et seq.*) for security-based swaps issued by certain clearing agencies satisfying certain conditions. The purpose of the information required by Rule 239 is to make certain information about security-based swaps that may be cleared by the registered or the exempt clearing agencies available to eligible contract participants and other market participants. We estimate that each registered or exempt clearing agency issuing security-based swaps in its function as a central counterparty will spend approximately 2 hours each time it provides or update the information in its agreements relating to security-based swaps or on its website. We estimate that each registered or exempt clearing agency will provide or update the information approximately 20 times per year. In addition, we estimate that 75% of the 2 hours per response (1.5 hours) is prepared internally by the clearing agency for a total annual reporting burden of 180 hours (1.5 hours per response × 20 times × 6 respondents).

Written 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 imposed by the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

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 control number.

Please direct your written comment to David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.*

Dated: November 15, 2021.

**J. Matthew DeLesDernier,**

*Assistant Secretary.*

[FR Doc. 2021–25170 Filed 11–17–21; 8:45 am]

**BILLING CODE 8011–01–P**

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–93558; File No. SR–NASDAQ–2021–088]**

## Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Equity 7, Section 118 of the Fee Schedule

November 12, 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 November 1, 2021, The Nasdaq Stock Market LLC (''Nasdaq'' 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 Equity 7, Section 118(a), as described further below.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/nasdaq/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

**II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change**

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

*A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

1. Purpose

The purpose of the proposed rule change is to amend the Exchange's schedule of credits, at Equity 7, Section 118(a). Specifically, the Exchange proposes to amend the criteria for two existing credits of $0.0029 per share executed with respect to its schedule of credits for displayed quotes/orders (other than Supplemental Orders or Designated Retail Orders) that provide liquidity in Tapes A, B and C.

The Exchange proposes to amend two existing credits in Tapes A, B and C of $0.0029 per share executed. One of the existing credits applies to members (i) with shares of liquidity provided in all securities through one or more of its Nasdaq Market Center MPIDs that represent more than 0.675% of Consolidated Volume during the month. The other credit applies to members (i) with shares of liquidity accessed in all securities through one or more of its Nasdaq Market Center MPIDs that represent more than 0.80% of Consolidated Volume during the month, and (ii) with shares of liquidity provided in all securities through one or more of its Nasdaq Market Center MPIDs that represent more than 0.60% of Consolidated Volume.

The Exchange proposes to amend the credits in all three Tapes by also requiring a member to execute an average daily volume (''ADV'') of at least 350,000 shares of Midpoint Extended Life Orders (''M–ELOs'')[3] during the month. The proposed amendments will increase the extent to which members engage in M–ELO activity on the Exchange and grow the extent of such activity over time. From time to time, the Exchange believes it is reasonable to recalibrate the criteria for credits such as these to ensure that the credits remain appropriately challenging for participants to attain in light of changes to their levels of activity on the Exchange.

2. Statutory Basis

The Exchange believes that its proposals are consistent with Section 6(b) of the Act,[4] in general, and further the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[5] in particular, in that they provide for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The proposals are also consistent with Section 11A of the Act relating to the establishment of the national market system for securities.

The Proposals Are Reasonable

The Exchange's proposals are reasonable in several respects. As a threshold matter, the Exchange is subject to significant competitive forces in the market for equity securities transaction services that constrain its pricing determinations in that market. The fact that this market is competitive has long been recognized by the courts. In *NetCoalition* v. *Securities and Exchange Commission,* the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . .''[6]

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.''[7]

Numerous indicia demonstrate the competitive nature of this market. For example, clear substitutes to the Exchange exist in the market for equity security transaction services. The Exchange is only one of several equity venues to which market participants may direct their order flow. Competing equity exchanges offer similar tiered pricing structures to that of the Exchange, including schedules of rebates and fees that apply based upon members achieving certain volume thresholds.

Within this environment, market participants can freely and often do shift their order flow among the Exchange and competing venues in response to changes in their respective pricing schedules. Within the foregoing context, the proposals represent reasonable attempts by the Exchange to increase its liquidity and market share relative to its competitors.

The Exchange believes that it is reasonable to amend the credit of $0.0029 per share executed, which applies to members (i) with shares of liquidity provided in all securities through one or more of its Nasdaq Market Center MPIDs that represent more than 0.675% of Consolidated Volume during the month, and the credit of $0.0029 per share executed, which applies to members (i) with shares of liquidity accessed in all securities through one or more of its Nasdaq Market Center MPIDs that represent more than 0.80% of Consolidated Volume during the month, and (ii) with shares of liquidity provided in all securities through one or more of its Nasdaq Market Center MPIDs that represent more than 0.60% of Consolidated Volume. The proposed additional requirement of executing an ADV of at least 350,000 shares of M–ELOs during the month will encourage members that currently qualify for the credit to increase the extent to which members engage in M–ELO activity.

From time to time, the Exchange believes it is reasonable to recalibrate the criteria for credits such as this one to ensure that the credits remain appropriately challenging for participants to attain in light of changes to their levels of activity on the Exchange. The Exchange has limited resources at its disposal to devote to incentives and it periodically reassesses the allocation of those resources when they prove to be ineffective.

[3] Pursuant to Equity 4, Rule 4702(b)(14), a ''Midpoint Extended Life Order'' is an Order Type with a Non-Display Order Attribute that is priced at the midpoint between the NBBO and that will not be eligible to execute until a minimum period of 10 milliseconds has passed after acceptance of the Order by the System.

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(4) and (5).

[6] *NetCoalition* v. *SEC,* 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[7] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

Additionally, these proposals are reasonable because they will provide extra incentives to members to engage in substantial amounts of MELO-related activity on the Exchange during a month. The Exchange believes that if such incentives are effective, then any ensuing increase in M–ELOs and executions on the Exchange will improve the quality of the M–ELO market, and the market overall, to the benefit of M–ELO and all market participants.

The Exchange notes that those market participants that are dissatisfied with the proposals are free to shift their order flow to competing venues that offer more generous pricing or less stringent qualifying criteria.

The Proposals Are Equitable Allocations of Credits

The Exchange believes that it is an equitable allocation to modify the eligibility requirements for its transaction credits because the proposals will encourage members to increase the extent to which they add liquidity to the Exchange. To the extent that the Exchange succeeds in increasing the levels of liquidity and activity on the Exchange, including in segments for which there is an observed need or demand, such as non-displayed, MELO, and Tape B securities, then the Exchange will experience improvements in its market quality, which stands to benefit all market participants. The Exchange also believes it is equitable to recalibrate or revise existing criteria for its credits to ensure that the credits remain appropriately challenging for participants to attain in light of changes to their levels of activity on the Exchange.

Any participant that is dissatisfied with the proposals is free to shift their order flow to competing venues that provide more generous pricing or less stringent qualifying criteria.

The Proposals Are Not Unfairly Discriminatory

The Exchange believes that its proposals are not unfairly discriminatory. As an initial matter, the Exchange believes that nothing about its volume-based tiered pricing model is inherently unfair; instead, it is a rational pricing model that is well-established and ubiquitous in today's economy among firms in various industries—from co-branded credit cards to grocery stores to cellular telephone data plans—that use it to reward the loyalty of their best customers that provide high levels of business activity and incent other customers to increase the extent of their business activity. It is also a pricing model that the Exchange and its competitors have long employed with the assent of the Commission. It is fair because it incentivizes customer activity that increases liquidity, enhances price discovery, and improves the overall quality of the equity markets.

The Exchange believes that its proposals to amend the qualifying criteria for its transaction credits are not unfairly discriminatory because these credits are available to all members. Moreover, these proposals stand to improve the overall market quality of the Exchange, to the benefit of all market participants, by incentivizing members to increase the extent of their liquidity provision or activity on the Exchange, including in segments for which there is an observed need or demand, such as non-displayed, M–ELO, and Tape B securities. The Exchange also believes it is not unfairly discriminatory to recalibrate or revise existing criteria for its credits to ensure that the credits remain appropriately challenging for participants to attain in light of changes to their levels of activity on the Exchange.

Any participant that is dissatisfied with the proposals is free to shift their order flow to competing venues that provide more generous pricing or less stringent qualifying criteria.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange does not believe that the proposed rule changes will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Intramarket Competition

The Exchange does not believe that its proposals will place any category of Exchange participant at a competitive disadvantage.

As noted above, Nasdaq's proposals to amend transaction credits are intended to have market-improving effects, to the benefit of all members. Any member may elect to achieve the levels of liquidity or activity required in order to qualify for the amended credits.

The Exchange notes that its members are free to trade on other venues to the extent they believe that the proposed qualification criteria for or amounts of these credits are not attractive. As one can observe by looking at any market share chart, price competition between exchanges is fierce, with liquidity and market share moving freely between exchanges in reaction to credit changes. The Exchange notes that its pricing tier structure is consistent with broker-dealer fee practices as well as the other industries, as described above.

Intermarket Competition

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 credit levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its credits to remain competitive with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their own credits in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which credit changes in this market may impose any burden on competition is extremely limited.

The proposed amended credits are reflective of this competition because, even as one of the largest U.S. equities exchanges by volume, the Exchange has less than 20% market share, which in most markets could hardly be categorized as having enough market power to burden competition. Moreover, as noted above, price competition between exchanges is fierce, with liquidity and market share moving freely between exchanges in reaction to credit changes. This is in addition to free flow of order flow to and among off-exchange venues which comprises upwards of 44% of industry volume.

The Exchange's proposals to amend its transaction credits are pro-competitive in that the Exchange intends for the changes to increase liquidity addition and activity on the Exchange, thereby rendering the Exchange a more attractive and vibrant venue to market participants.

In sum, if the changes proposed herein are unattractive to market participants, it is likely that the Exchange will lose market share as a result. Accordingly, the Exchange does not believe that the proposed changes will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets.

*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

Pursuant to Section 19(b)(3)(A)(ii) of the Act,[8] the Exchange has designated this proposal as establishing or changing a due, fee, or other charge imposed by the self-regulatory organization on any person, whether or not the person is a member of the self-regulatory organization, which renders the proposed rule change effective upon filing.

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–NASDAQ–2021–088 on the subject line.

*Paper Comments*

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2021–088. 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–NASDAQ–2021–088 and should be submitted on or before December 9, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

**J. Matthew DeLesDernier,**

*Assistant Secretary.*

[FR Doc. 2021–25130 Filed 11–17–21; 8:45 am]

**BILLING CODE 8011–01–P**

[8] 15 U.S.C. 78s(b)(3)(A)(ii).

[9] 17 CFR 200.30–3(a)(12).

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## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–93559; File No. SR–CboeBZX–2021–019]**

## Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Order Disapproving 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

November 12, 2021.

## I. Introduction

On March 1, 2021, Cboe BZX Exchange, Inc. (''BZX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares (''Shares'') of the VanEck Bitcoin Trust (''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]

On April 28, 2021, pursuant to Section 19(b)(2) of the Exchange Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] On June 16, 2021, the Commission instituted proceedings under Section 19(b)(2)(B) of the Exchange Act[6] to determine whether to approve or disapprove the proposed rule change.[7] On September 8, 2021, the Commission designated a longer period for Commission action on the proposed rule change.[8]

This order disapproves the proposed rule change. The Commission concludes that BZX has not met its burden under the Exchange Act and the Commission's Rules of Practice to demonstrate that its proposal is consistent with the requirements of Exchange Act Section 6(b)(5), in particular, the requirement that the rules of a national securities exchange be ''designed to prevent fraudulent and manipulative acts and practices'' and ''to protect investors and the public interest.''[9]

When considering whether BZX's proposal to list and trade the Shares is designed to prevent fraudulent and manipulative acts and practices, the Commission applies the same standard used in its orders considering previous proposals to list bitcoin[10]-based

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 91326 (Mar. 15, 2021), 86 FR 14987 (''Notice''). Comments on the proposed rule change can be found at: *https://www.sec.gov/comments/sr-cboebzx-2021-019/srcboebzx2021019.htm.*

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 91695, 86 FR 24066 (May 5, 2021).

[6] 15 U.S.C. 78s(b)(2)(B).

[7] *See* Securities Exchange Act Release No. 92196, 86 FR 32985 (June 23, 2021).

[8] *See* Securities Exchange Act Release No. 92894, 86 FR 51203 (Sept. 14, 2021). On September 30, 2021, the Exchange filed Amendment No. 1 to the proposed rule change and withdrew it on October 1, 2021. On October 1, 2021, the Exchange filed Amendment No. 2 to the proposed rule change; and on November 4, 2021, the Exchange filed Amendment No. 3 to the proposed rule change. As discussed below, *see* Section III.E, *infra,* the Commission views these amendments as untimely. These amendments also do not materially alter the substance of the proposed rule change, and therefore they are not subject to notice and comment. Furthermore, even if these amendments had been timely filed, they would not alter the Commission's conclusion that the Exchange's proposal is not consistent with the Exchange Act. *See* Section III.E.

[9] 15 U.S.C. 78f(b)(5).

[10] Bitcoins are digital assets that are issued and transferred via a decentralized, open-source protocol used by a peer-to-peer computer network through which transactions are recorded on a public transaction ledger known as the ''bitcoin blockchain.'' The bitcoin protocol governs the creation of new bitcoins and the cryptographic system that secures and verifies bitcoin transactions. *See, e.g.,* Notice, 86 FR 14988.

commodity trusts and bitcoin-based trust issued receipts.[11] As the Commission has explained, an exchange that lists bitcoin-based exchange-traded products (''ETPs'') can meet its obligations under Exchange Act Section 6(b)(5) by demonstrating that the exchange has a comprehensive surveillance-sharing agreement with a regulated market of significant size related to the underlying or reference bitcoin assets.[12]

The standard requires such surveillance-sharing agreements since they ''provide a necessary deterrent to manipulation because they facilitate the availability of information needed to fully investigate a manipulation if it were to occur.'' [13] The Commission has emphasized that it is essential for an exchange listing a derivative securities product to enter into a surveillance-sharing agreement with markets trading the underlying assets for the listing exchange to have the ability to obtain information necessary to detect, investigate, and deter fraud and market manipulation, as well as violations of exchange rules and applicable federal securities laws and rules.[14] The hallmarks of a surveillance-sharing agreement are that the agreement provides for the sharing of information about market trading activity, clearing activity, and customer identity; that the parties to the agreement have reasonable ability to obtain access to and produce requested information; and that no existing rules, laws, or practices would impede one party to the agreement from obtaining this information from, or producing it to, the other party.[15]

In the context of this standard, the terms ''significant market'' and ''market of significant size'' include a market (or group of markets) as to which (a) there is a reasonable likelihood that a person attempting to manipulate the ETP would also have to trade on that market to successfully manipulate the ETP, so that a surveillance-sharing agreement would assist in detecting and deterring misconduct, and (b) it is unlikely that trading in the ETP would be the predominant influence on prices in that market.[16] A surveillance-sharing agreement must be entered into with a ''significant market'' to assist in detecting and deterring manipulation of the ETP, because a person attempting to manipulate the ETP is reasonably likely to also engage in trading activity on that ''significant market.'' [17]

Consistent with this standard, for the commodity-trust ETPs approved to date for listing and trading, there has been in *every* case at least one significant, regulated market for trading futures on the underlying commodity—whether gold, silver, platinum, palladium, or copper—and the ETP listing exchange has entered into surveillance-sharing agreements with, or held Intermarket Surveillance Group (''ISG'') membership in common with, that market.[18] Moreover, the surveillance-sharing agreements have been consistently present whenever the Commission has approved the listing and trading of derivative securities, even where the underlying securities were also listed on national securities exchanges—such as options based on an index of stocks traded on a national securities exchange—and were thus subject to the Commission's direct regulatory authority.[19]

Listing exchanges have also attempted to demonstrate that other means besides surveillance-sharing agreements will be sufficient to prevent fraudulent and manipulative acts and practices, including that the bitcoin market as a whole or the relevant underlying bitcoin market is ''uniquely'' and ''inherently'' resistant to fraud and manipulation.[20] In response, the Commission has agreed that, if a listing exchange could establish that the underlying market inherently possesses a unique resistance to manipulation beyond the protections that are utilized by traditional commodity or securities markets, it would not necessarily need to enter into a surveillance-sharing agreement with a regulated significant market.[21] Such resistance to fraud and manipulation, however, must be novel and beyond those protections that exist in traditional commodity markets or equity markets for which the Commission has long required surveillance-sharing agreements in the context of listing

[11] *See* Order Setting Aside Action by Delegated Authority and Disapproving a Proposed Rule Change, as Modified by Amendments No. 1 and 2, To List and Trade Shares of the Winklevoss Bitcoin Trust, Securities Exchange Act Release No. 83723 (July 26, 2018), 83 FR 37579 (Aug. 1, 2018) (SR–BatsBZX–2016–30) (''Winklevoss Order''); Order Disapproving a Proposed Rule Change, as Modified by Amendment No. 1, To Amend NYSE Arca Rule 8.201–E (Commodity-Based Trust Shares) and To List and Trade Shares of the United States Bitcoin and Treasury Investment Trust Under NYSE Arca Rule 8.201–E, Securities Exchange Act Release No. 88284 (Feb. 26, 2020), 85 FR 12595 (Mar. 3, 2020) (SR–NYSEArca–2019–39) (''USBT Order''). *See also* Order Disapproving a Proposed Rule Change, as Modified by Amendment No. 1, Relating to the Listing and Trading of Shares of the SolidX Bitcoin Trust Under NYSE Arca Equities Rule 8.201, Securities Exchange Act Release No. 80319 (Mar. 28, 2017), 82 FR 16247 (Apr. 3, 2017) (SR–NYSEArca–2016–101) (''SolidX Order''). The Commission also notes that orders were issued by delegated authority on the following matters: Order Disapproving a Proposed Rule Change To List and Trade the Shares of the ProShares Bitcoin ETF and the ProShares Short Bitcoin ETF, Securities Exchange Act Release No. 83904 (Aug. 22, 2018), 83 FR 43934 (Aug. 28, 2018) (NYSEArca–2017–139) (''ProShares Order''); Order Disapproving a Proposed Rule Change To List and Trade the Shares of the GraniteShares Bitcoin ETF and the GraniteShares Short Bitcoin ETF, Securities Exchange Act Release No. 83913 (Aug. 22, 2018), 83 FR 43923 (Aug. 28, 2018) (SR–CboeBZX–2018–001) (''GraniteShares Order'').

[12] *See* USBT Order, 85 FR 12596. *See also* Winklevoss Order, 83 FR 37592 n.202 and accompanying text (discussing previous Commission approvals of commodity-trust ETPs); GraniteShares Order, 83 FR 43925–27 nn.35–39 and accompanying text (discussing previous Commission approvals of commodity-futures ETPs).

[13] *See* Amendment to Rule Filing Requirements for Self-Regulatory Organizations Regarding New Derivative Securities Products, Securities Exchange Act Release No. 40761 (Dec. 8, 1998), 63 FR 70952, 70959 (Dec. 22, 1998) (''NDSP Adopting Release''). *See also* Winklevoss Order, 83 FR 37594; ProShares Order, 83 FR 43936; GraniteShares Order, 83 FR 43924; USBT Order, 85 FR 12596.

[14] *See* NDSP Adopting Release, 63 FR 70959.

[15] *See* Winklevoss Order, 83 FR 37592–93; Letter from Brandon Becker, Director, Division of Market Regulation, Commission, to Gerard D. O'Connell, Chairman, Intermarket Surveillance Group (June 3, 1994), *available at https://www.sec.gov/divisions/marketreg/mr-noaction/isg060394.htm.*

[16] *See* Winklevoss Order, 83 FR 37594. This definition is illustrative and not exclusive. There could be other types of ''significant markets'' and ''markets of significant size,'' but this definition is an example that will provide guidance to market participants. *See id.*

[17] *See* USBT Order, 85 FR 12597.

[18] *See* Winklevoss Order, 83 FR 37594.

[19] *See* USBT Order, 85 FR 12597; Securities Exchange Act Release No. 33555 (Jan. 31, 1994), 59 FR 5619, 5621 (Feb. 7, 1994) (SR–Amex–93–28) (order approving listing of options on American Depository Receipts). The Commission has also required a surveillance-sharing agreement in the context of index options even when (i) all of the underlying index component stocks were either registered with the Commission or exempt from registration under the Exchange Act; (ii) all of the underlying index component stocks traded in the U.S. either directly or as ADRs on a national securities exchange; and (iii) effective international ADR arbitrage alleviated concerns over the relatively smaller ADR trading volume, helped to ensure that ADR prices reflected the pricing on the home market, and helped to ensure more reliable price determinations for settlement purposes, due to the unique composition of the index and reliance on ADR prices. *See* Securities Exchange Act Release No. 26653 (Mar. 21, 1989), 54 FR 12705, 12708 (Mar. 28, 1989) (SR–Amex–87–25) (stating that ''surveillance-sharing agreements between the exchange on which the index option trades and the markets that trade the underlying securities are necessary'' and that ''[t]he exchange of surveillance data by the exchange trading a stock index option and the markets for the securities comprising the index is important to the detection and deterrence of intermarket manipulation.''). And the Commission has required a surveillance-sharing agreement even when approving options based on an index of stocks traded on a national securities exchange. *See* Securities Exchange Act Release No. 30830 (June 18, 1992), 57 FR 28221, 28224 (June 24, 1992) (SR–Amex–91–22) (stating that surveillance-sharing agreements ''ensure the availability of information necessary to detect and deter potential manipulations and other trading abuses'').

[20] *See* USBT Order, 85 FR 12597.

[21] *See* Winklevoss Order, 83 FR 37580, 37582–91 (addressing assertions that ''bitcoin and bitcoin [spot] markets'' generally, as well as one bitcoin trading platform specifically, have unique resistance to fraud and manipulation); *see also* USBT Order, 85 FR 12597.

derivative securities products. No listing exchange has satisfied its burden to make such demonstration.[22]

Here, BZX contends that approval of the proposal is consistent with Section 6(b)(5) of the Exchange Act, in particular Section 6(b)(5)'s requirement that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices and to protect investors and the public interest.[23] As discussed in more detail below, BZX asserts that the proposal is consistent with Section 6(b)(5) of the Exchange Act because the Exchange has a comprehensive surveillance-sharing agreement with a regulated market of significant size,[24] and there exist other means to prevent fraudulent and manipulative acts and practices that are sufficient to justify dispensing with the requisite surveillance-sharing agreement.[25]

Although BZX recognizes the Commission's focus on potential manipulation of bitcoin ETPs in prior disapproval orders, BZX argues that such manipulation concerns have been sufficiently mitigated, and that the growing and quantifiable investor protection concerns should be the central consideration of the Commission.[26] Specifically, as discussed in more detail below, the Exchange asserts that the significant increase in trading volume in bitcoin futures on the Chicago Mercantile Exchange (''CME''), the growth of liquidity in the spot market for bitcoin, and certain features of the Shares and the Benchmark (as defined herein) mitigate potential manipulation concerns to the point that the investor protection issues that have arisen from the rapid growth of over-the-counter (''OTC'') bitcoin funds, including premium volatility and management fees, should be the central consideration as the Commission determines whether to approve this proposal.[27]

Further, BZX believes that the proposal would give U.S. investors access to bitcoin in a regulated and transparent exchange-traded vehicle that would act to limit risk to U.S. investors. According to BZX, the proposed listing and trading of the Shares would mitigate risk by: (i) Reducing premium volatility; (ii) reducing management fees through meaningful competition; (iii) reducing risks associated with investing in operating companies that are imperfect proxies for bitcoin exposure; and (iv) providing an alternative to custodying spot bitcoin.[28]

In the analysis that follows, the Commission examines whether the proposed rule change is consistent with Section 6(b)(5) of the Exchange Act by addressing: In Section III.B.1 assertions that other means besides surveillance-sharing agreements will be sufficient to prevent fraudulent and manipulative acts and practices; in Section III.B.2 assertions that BZX has entered into a comprehensive surveillance-sharing agreement with a regulated market of significant size related to bitcoin; and in Section III.C assertions that the proposal is consistent with the protection of investors and the public interest. As discussed further below, BZX repeats various assertions made in prior bitcoin-based ETP proposals that the Commission has previously addressed and rejected—and more importantly, BZX does not respond to the Commission's reasons for rejecting those assertions but merely repeats them. The Commission concludes that BZX has not established that other means to prevent fraudulent and manipulative acts and practices are sufficient to justify dispensing with the requisite surveillance-sharing agreement. The Commission further concludes that BZX has not established that it has a comprehensive surveillance-sharing agreement with a regulated market of significant size related to bitcoin. As a result, the Commission is unable to find that the proposed rule change is consistent with the statutory requirements of Exchange Act Section 6(b)(5).

The Commission again emphasizes that its disapproval of this proposed rule change does not rest on an evaluation of whether bitcoin, or blockchain technology more generally, has utility or value as an innovation or an investment. Rather, the Commission is disapproving this proposed rule change because, as discussed below, BZX has not met its burden to demonstrate that its proposal is consistent with the requirements of Exchange Act Section 6(b)(5).

## II. Description of the Proposed Rule Change

As described in more detail in the Notice,[29] the Exchange proposes to list and trade the Shares of the Trust under BZX Rule 14.11(e)(4), which governs the listing and trading of Commodity-Based Trust Shares on the Exchange.

The investment objective of the Trust is for the Shares to reflect the performance of the MVIS® CryptoCompare Bitcoin Benchmark Rate (''Benchmark''), less the expenses of the Trust's operations.[30] The Benchmark will be used to calculate the Trust's net asset value (''NAV''). The Benchmark is designed to be a U.S. dollar price for bitcoin, and there is no component other than bitcoin in the Benchmark.[31]

The Benchmark is derived from trade prices of bitcoin on certain bitcoin spot platforms. The current platform composition of the Benchmark is Bitstamp, Coinbase, Gemini, itBit, and Kraken.[32] The Benchmark is calculated using a methodology that captures trade prices and sizes from the aforementioned platforms. The methodology examines twenty three-minute periods leading up to 4:00 p.m. E.T. and calculates an equal-weighted average of the volume-weighted median price of these twenty three-minute periods, removing the highest and lowest contributed prices.[33]

Each Share represents a fractional undivided beneficial interest in the Trust's net assets. The Trust's assets will consist of bitcoin held by the Custodian on behalf of the Trust. The Trust generally does not intend to hold cash or cash equivalents. However, there may be situations where the Trust will unexpectedly hold cash on a temporary basis.[34]

[22] *See supra* note 11.

[23] *See* Notice, 86 FR 14993–95.

[24] *See id.* at 14994–95.

[25] *See id.* at 14995.

[26] *See id.* at 14990.

[27] *See id.* at 14994.

[28] *See id.* at 14990.

[29] *See* Notice, *supra* note 3. *See also* draft Registration Statement on Form S–1, dated December 30, 2020, submitted to the Commission by VanEck Digital Assets, LLC (''Sponsor'') on behalf of the Trust, and Amendment No. 1 thereto, filed June 4, 2021 (''Amended Registration Statement'').

[30] Delaware Trust Company is the trustee, and State Street Bank and Trust Company will be the administrator (''Administrator'') and transfer agent. Van Eck Securities Corporation will be the marketing agent in connection with the creation and redemption of Shares. Van Eck Securities Corporation provides assistance in the marketing of the Shares. A third-party regulated custodian (''Custodian'') will be responsible for custody of the Trust's bitcoin. *See* Notice, 86 FR 14995. The Amended Registration Statement indicates that Gemini Trust Company, LLC is the Custodian. *See* Amended Registration Statement at (i).

[31] *See* Notice, 86 FR 14995–96.

[32] According to BZX, the Benchmark constituents are the same constituent platforms as the CME CF Bitcoin Reference Rate and are selected using a methodology that utilizes a combination of qualitative and quantitative metrics to analyze a data set across eight categories of evaluation: Legal/regulation, ''know-your-customer''/transaction risk, data provision, security, team/platform, asset quality/diversity, market quality, and negative events. Based on these evaluations, the top five platforms by rank are selected for inclusion in the Benchmark, and the constituent platforms are reassessed on a semi-annual basis. *See id.* at 14996 n.65.

[33] *See id.* at 14996.

[34] *See id.* at 14995.

The Administrator will determine the NAV and NAV per Share of the Trust on each day that the Exchange is open for regular trading, as promptly as practical after 4:00 p.m. E.T. The NAV of the Trust is the aggregate value of the Trust's assets less its estimated accrued but unpaid liabilities (which include accrued expenses). In determining the Trust's NAV, the Administrator values the bitcoin held by the Trust based on the price set by the Benchmark as of 4:00 p.m. E.T.[35]

The Trust will provide information regarding the Trust's bitcoin holdings, as well as an Intraday Indicative Value (''IIV'') per Share updated every 15 seconds, as calculated by the Exchange or a third-party financial data provider during the Exchange's Regular Trading Hours (9:30 a.m. to 4:00 p.m. E.T.). The IIV will be calculated by using the prior day's closing NAV per Share as a base and updating that value during Regular Trading Hours to reflect changes in the value of the Trust's bitcoin holdings during the trading day.[36]

When the Trust sells or redeems its Shares, it will do so in ''in-kind'' transactions in blocks of 50,000 Shares. When creating the Shares, authorized participants will deliver, or facilitate the delivery of, bitcoin to the Trust's account with the Custodian in exchange for the Shares, and, when redeeming the Shares, the Trust, through the Custodian, will deliver bitcoin to such authorized participants.[37]

## III. Discussion

### *A. The Applicable Standard for Review*

The Commission must consider whether BZX's proposal is consistent with the Exchange Act. Section 6(b)(5) of the Exchange Act requires, in relevant part, that the rules of a national securities exchange be designed ''to prevent fraudulent and manipulative acts and practices'' and ''to protect investors and the public interest.'' [38] Under the Commission's Rules of Practice, the ''burden to demonstrate that a proposed rule change is consistent with the Exchange Act and the rules and regulations issued thereunder . . . is on the self-regulatory organization ['SRO'] that proposed the rule change.'' [39]

The description of a proposed rule change, its purpose and operation, its effect, and a legal analysis of its consistency with applicable requirements must all be sufficiently detailed and specific to support an affirmative Commission finding,[40] and any failure of an SRO to provide this information may result in the Commission not having a sufficient basis to make an affirmative finding that a proposed rule change is consistent with the Exchange Act and the applicable rules and regulations.[41] Moreover, ''unquestioning reliance'' on an SRO's representations in a proposed rule change is not sufficient to justify Commission approval of a proposed rule change.[42]

### *B. Whether BZX Has Met Its Burden To Demonstrate That the Proposal Is Designed To Prevent Fraudulent and Manipulative Acts and Practices*

#### (1) Assertions That Other Means Besides Surveillance-Sharing Agreements Will Be Sufficient To Prevent Fraudulent and Manipulative Acts and Practices

As stated above, the Commission has recognized that a listing exchange could demonstrate that other means to prevent fraudulent and manipulative acts and practices are sufficient to justify dispensing with a comprehensive surveillance-sharing agreement with a regulated market of significant size, including by demonstrating that the bitcoin market as a whole or the relevant underlying bitcoin market is uniquely and inherently resistant to fraud and manipulation.[43] Such resistance to fraud and manipulation must be novel and beyond those protections that exist in traditional commodities or securities markets.[44]

BZX asserts that bitcoin is resistant to price manipulation. According to BZX, the geographically diverse and continuous nature of bitcoin trading render it difficult and prohibitively costly to manipulate the price of bitcoin.[45] Fragmentation across bitcoin platforms, the relatively slow speed of transactions, and the capital necessary to maintain a significant presence on each trading platform make manipulation of bitcoin prices through continuous trading activity challenging.[46] To the extent that there are bitcoin platforms engaged in or allowing wash trading or other activity intended to manipulate the price of bitcoin on other markets, such pricing does not normally impact prices on other platforms because participants will generally ignore markets with quotes that they deem non-executable.[47] BZX further argues that the linkage between the bitcoin markets and the presence of arbitrageurs in those markets means that the manipulation of the price of bitcoin on any single venue would require manipulation of the global bitcoin price in order to be effective.[48] Arbitrageurs must have funds distributed across multiple trading platforms in order to take advantage of temporary price dislocations, thereby making it unlikely that there will be strong concentration of funds on any particular bitcoin trading venue.[49] As a result, BZX concludes that the potential for manipulation on a bitcoin trading platform would require overcoming the liquidity supply of such arbitrageurs who are effectively eliminating any cross-market pricing differences.[50]

Several commenters share BZX's view that the nature of the bitcoin market makes it resistant to price manipulation.[51] One commenter, in

[35] *See id.* at 14996.

[36] *See id.*

[37] *See id.* at 14995.

[38] 15 U.S.C. 78f(b)(5). Pursuant to Section 19(b)(2) of the Exchange Act, 15 U.S.C. 78s(b)(2), the Commission must disapprove a proposed rule change filed by a national securities exchange if it does not find that the proposed rule change is consistent with the applicable requirements of the Exchange Act. Exchange Act Section 6(b)(5) states that an exchange shall not be registered as a national securities exchange unless the Commission determines that ''[t]he rules of the exchange are 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 are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers, or to regulate by virtue of any authority conferred by this title matters not related to the purposes of this title or the administration of the exchange.'' 15 U.S.C. 78f(b)(5).

[39] Rule 700(b)(3), Commission Rules of Practice, 17 CFR 201.700(b)(3).

[40] *See id.*

[41] *See id.*

[42] *Susquehanna Int'l Group, LLP* v. *Securities and Exchange Commission,* 866 F.3d 442, 447 (D.C. Cir. 2017) (''Susquehanna'').

[43] *See* USBT Order, 85 FR 12597 n.23. The Commission is not applying a ''cannot be manipulated'' standard. Instead, the Commission is examining whether the proposal meets the requirements of the Exchange Act and, pursuant to its Rules of Practice, places the burden on the listing exchange to demonstrate the validity of its contentions and to establish that the requirements of the Exchange Act have been met. *See id.*

[44] *See id.* at 12597.

[45] *See* Notice, 86 FR 14994 n.54.

[46] *See id.*

[47] *See id.*

[48] *See id.*

[49] *See id.*

[50] *See id.*

[51] *See* letters from: Bryan B. Solstin, dated June 17, 2021; Anthony Ellis, dated June 17, 2021 (''Ellis Letter''); Courtney Rye, dated June 17, 2021 (''Rye Letter''); and Frank Rose, dated June 17, 2021 (''Rose Letter''). These commenters assert that, in addition to arbitrage, bitcoin's large market capitalization, liquidity, decentralized design, finite quantity, and transparent public ledger make it less susceptible to fraud and manipulation. Another commenter remarks that, unlike other commodities on which exchange-traded funds are based, bitcoin

particular, agrees that arbitrage would very quickly close any bitcoin price disparities between trading platforms.[52]

As with the previous proposals, the Commission here concludes that the record does not support a finding that the bitcoin market is inherently and uniquely resistant to fraud and manipulation. BZX asserts that, because of how bitcoin trades occur, including through continuous means and through fragmented platforms, arbitrage across the bitcoin platforms essentially helps to keep global bitcoin prices aligned with one another, thus hindering manipulation. The Exchange, however, does not provide any data or analysis to support its assertions, either in terms of how closely bitcoin prices are aligned across different bitcoin trading venues or how quickly price disparities may be arbitraged away.[53] Likewise, the commenter who concurs with BZX that arbitrage would very quickly close any bitcoin price disparities between trading platforms provides no empirical evidence to substantiate the commenter's claim. As stated above, ''unquestioning reliance'' on an SRO's representations in a proposed rule change is not sufficient to justify Commission approval of a proposed rule change.[54]

Further, efficient price arbitrage is not sufficient to support the finding that a market is uniquely and inherently resistant to manipulation such that the Commission can dispense with surveillance-sharing agreements.[55] The Commission has stated, for example, that even for equity options based on securities listed on national securities exchanges, the Commission relies on surveillance-sharing agreements to detect and deter fraud and manipulation.[56] Here, the Exchange provides no evidence to support its assertion of efficient price arbitrage across bitcoin platforms, let alone any evidence that price arbitrage in the bitcoin market is novel or unique so as to warrant the Commission dispensing with the requirement of a surveillance-sharing agreement. Moreover, BZX does not take into account that a market participant with a dominant ownership position would not find it prohibitively expensive to overcome the liquidity supplied by arbitrageurs and could use dominant market share to engage in manipulation.[57]

In addition, the Exchange makes the unsupported claim that bitcoin prices on platforms with fake volume do not influence the real price of bitcoin. The Exchange also asserts that, to the extent that there are bitcoin platforms engaged in or allowing wash trading or other manipulative activities, market participants will generally ignore those platforms. However, without the necessary data, such as lead-lag or other similar analyses, or other evidence, the Commission has no basis on which to conclude that bitcoin platforms are insulated from prices of others that engage in or permit fraud or manipulation.[58]

Additionally, the continuous nature of bitcoin trading does not eliminate manipulation risk, and neither does linkages among markets, as BZX asserts.[59] Even in the presence of continuous trading or linkages among markets, formal (such as those with consolidated quotations or routing requirements) or otherwise (such as in the context of the fragmented, global bitcoin markets), manipulation of asset prices, as a general matter, can occur simply through trading activity that creates a false impression of supply or demand.[60]

BZX also argues that the significant liquidity in the bitcoin spot market and the impact of market orders on the overall price of bitcoin mean that attempting to move the price of bitcoin is costly and has grown more expensive over the past year.[61] According to BZX, in January 2020, for example, the cost to buy or sell $5 million worth of bitcoin averaged roughly 30 basis points (compared to 10 basis points in February 2021) with a market impact of 50 basis points (compared to 30 basis points in February 2021). For a $10 million market order, the cost to buy or sell was roughly 50 basis points (compared to 20 basis points in February 2021) with a market impact of 80 basis points (compared to 50 basis points in February 2021).[62] BZX contends that as the liquidity in the bitcoin spot market increases, it follows that the impact of $5 million and $10 million orders will continue to decrease.[63]

One commenter concurs with BZX. The commenter asserts that the amount of money it would take to actually manipulate the bitcoin spot market would be ''unfathomable'' and so cost-prohibitive that it would be a losing strategy. The commenter also asserts that, given the daily trading volume of bitcoin futures, including those traded on CME, it would be extraordinarily difficult for a single entity to manipulate the market.[64]

However, the data furnished by BZX regarding the cost to move the price of bitcoin, and the market impact of such attempts, are incomplete. BZX does not

has a non-manipulable monetary supply. *See* letter from Erik Aronesty, dated June 17, 2021 (''Aronesty Letter''). The Custodian, in a comment letter, asserts that the growth of the overall bitcoin market and related growth of regulated bitcoin derivatives demonstrate that the depth of the market prevents manipulation of the price of bitcoin in a manner that could affect the share price of an ETP. *See* letter from Gemini Trust Company, LLC, dated October 15, 2021 (''Gemini Letter''), at 2.

Other commenters disagree. These commenters view the bitcoin market to be prone to fraud and manipulation. These commenters described the bitcoin market as: Fraught with manipulation from memes and tweets that can move its price significantly (*see* letter from Eddie, dated March 28, 2021 (''Eddie Letter'')); a haven for money laundering, wash trading, and other criminal and/or collusive activity (*see* letters from: Anonymous, dated June 16, 2021; A. Peterson, dated June 17, 2021 (''Peterson Letter'')); a pyramid scheme that is heavily rigged (*see* Peterson Letter) and from which the only way to profit is to sell to a ''greater fool'' who comes later at a higher price (*see* letter from Mark Pile, dated June 17, 2021 (''Pile Letter'')); fraught with accounting and liquidity irregularities (*see* Pile Letter); leading to prices pumped up by fraudulent tokens (*see* Peterson Letter ) and questionable ''stablecoin'' (*see* Petterson Letter; Pile Letter; letter from Michael Mims, dated June 17, 2021); and, along with other digital assets and the blockchains on which they rely, as having complexity that makes users vulnerable to fraud (*see* letter from Lourdes Ciao, dated June 24, 2021 (''Ciao Letter''), at 1). Finally, some commenters acknowledged that bitcoin prices are susceptible to attempted influence, but no more than other highly volatile stocks, and thus they contend that bitcoin is suitable as an underlying asset for an ETP (*see* letters from: Mike Bofman, dated June 16, 2021 (''Bofman Letter''); Matthew Apodaca, dated July 13, 2021 (''Apodaca Letter'')).

[52] *See* Ellis Letter.

[53] For example, the Amended Registration Statement states that ''[i]f increases in throughput on the Bitcoin network lag behind growth in usage of bitcoin, average fees and settlement times may increase considerably . . . . which could adversely impact the value of the Shares.'' *See* Amended Registration Statement at 20. BZX does not provide data or analysis to address, among other things, whether such risks of increased fees and bitcoin transaction settlement times may affect the arbitrage effectiveness that BZX asserts. *See also infra* note 70 and accompanying text (referencing statements made in the Amended Registration Statement that contradict assertions made by BZX).

[54] *See supra* note 42.

[55] *See* Winklevoss Order, 83 FR 37586; SolidX Order, 82 FR 16256–57; USBT Order, 85 FR 12601.

[56] *See, e.g.,* USBT Order, 85 FR 12601.

[57] *See, e.g.,* Winklevoss Order, 83 FR 37584; USBT Order, 85 FR 12600–01.

[58] *See* USBT Order, 85 FR 12601. *See also infra* notes 114–115 and accompanying text (explaining the lead-lag analysis as central to understanding whether it is reasonably likely that a would-be manipulator of the proposed ETP would have to trade on the CME bitcoin futures market to successfully manipulate the proposed ETP).

[59] *See* Winklevoss Order, 83 FR 37585 n.92 and accompanying text.

[60] *See id.* at 37585.

[61] *See* Notice, 86 FR 14995.

[62] On the other hand, regarding the amounts needed to move the bitcoin spot price, one commenter cites a Bank of America March 2021 research report that provides that $93 million in net inflows increases the bitcoin price by one percent, compared with nearly $1.87 billion for a corresponding increase in the price of gold. *See* Eddie Letter.

[63] *See* Notice, 86 FR 14995.

[64] *See* Ellis Letter.

provide meaningful analysis pertaining to how these figures compare to other markets [65] or why one must conclude, based on the numbers provided, that the bitcoin market is costly to manipulate. Further, BZX's analysis of the market impact of a mere two sample transactions is not sufficient evidence to conclude that the bitcoin market is resistant to manipulation.[66] Even assuming that the Commission agreed with BZX's premise, that it is costly to manipulate the bitcoin market, and it is becoming increasingly so, any such evidence speaks only to establish that there is some resistance to manipulation, not that it establishes *unique* resistance to manipulation to warrant dispensing with the standard surveillance-sharing agreement.[67] The Commission thus concludes that the record does not demonstrate that the nature of bitcoin trading renders the bitcoin market inherently and uniquely resistant to fraud and manipulation.

Moreover, BZX does not sufficiently contest the presence of possible sources of fraud and manipulation in the bitcoin spot market generally that the Commission has raised in previous orders, which have included (1) ''wash'' trading,[68] (2) persons with a dominant position in bitcoin manipulating bitcoin pricing, (3) hacking of the bitcoin network and trading platforms, (4) malicious control of the bitcoin network, (5) trading based on material, non-public information, including the dissemination of false and misleading information, (6) manipulative activity involving the purported ''stablecoin'' Tether (USDT), and (7) fraud and manipulation at bitcoin trading platforms.[69]

In addition, BZX does not address risk factors specific to the bitcoin blockchain and bitcoin platforms, described in the Trust's Amended Registration Statement, that undermine the argument that the bitcoin market is inherently resistant to fraud and manipulation. For example, the Amended Registration Statement acknowledges that ''bitcoin [platforms] on which bitcoin trades are relatively new and, in some cases, unregulated, and, therefore, may be more exposed to fraud and security breaches than established, regulated exchanges for other financial assets or instruments''; that ''[t]he trading for spot bitcoin occurs on multiple trading venues that have various levels and types of regulation, but are not regulated in the same manner as traditional stock and bond exchanges'' and if these spot markets ''do not operate smoothly or face technical, security or regulatory issues, that could impact the ability of Authorized Participants to make markets in the Shares'' which could lead to ''trading in the Shares [to] occur at a material premium or discount against the NAV''; that the bitcoin network ''is at risk of vulnerabilities and bugs that can potentially be exploited by malicious actors''; that the bitcoin blockchain could be vulnerable to a ''51% attack,'' in which a bad actor that controls a majority of the processing power dedicated to mining on the bitcoin network may be able to alter the bitcoin blockchain on which the bitcoin network and bitcoin transactions rely; that the nature of the assets held at bitcoin platforms makes them ''appealing targets for hackers'' and that ''a number of bitcoin platforms have been victims of cybercrimes''; and that bitcoin trading platforms ''have been closed or faced issues due to fraud, failure'' and ''security breaches.'' [70]

BZX also asserts that other means to prevent fraud and manipulation are sufficient to justify dispensing with the requisite surveillance-sharing agreement. First, the Exchange mentions that the Benchmark, which is used to value the Trust's bitcoin, is itself resistant to manipulation based on the Benchmark's methodology.[71] The Exchange states that the Benchmark is calculated by capturing twenty three-minute periods of trade prices and sizes leading up to 4:00 p.m. E.T. from the constituent platforms. An equal-weighted average of the volume-weighted median price of these twenty three-minute periods is then calculated, removing the highest and lowest contributed prices.[72] According to BZX, ''[u]sing twenty consecutive three-minute segments over a sixty-minute period means malicious actors would need to sustain efforts to manipulate the market over an extended period of time, or would need to replicate efforts multiple times across exchanges, potentially triggering review.'' [73] Further, according to BZX, the ''use of a median price reduces the ability of outlier prices to impact the NAV,'' and the ''use of a volume-weighted median (as opposed to a traditional median) serves as an additional protection against attempts to manipulate the NAV by executing a large number of low-dollar trades, because any manipulation attempt would have to involve a majority of global spot bitcoin volume in a three-minute window to have any influence on the NAV.'' [74] BZX also asserts that ''removing the highest and lowest prices further protects against attempts to manipulate the NAV, requiring bad actors to act on multiple [platforms] at once to have any ability to influence the price.'' [75]

The Custodian, in a comment letter, agrees that BZX's choice of the Benchmark, which includes a composite of bitcoin prices from underlying spot bitcoin platforms, including the Custodian's platform, is a further factor in support of the proposed ETP.[76] The Custodian asserts that it and other ''regulated digital asset exchanges'' and custodians have a history of operations in compliance with a regulatory framework developed specifically to address activities in digital assets, including guidance by the New York State Department of Financial Services (''NYSDFS'') regarding the implementation of anti-fraud measures. The Custodian states that it meets this obligation through automated systems and robust internal controls and surveillance, and that the growing sophistication of market surveillance tools and strategies in the bitcoin market as well as the growing proportion of bitcoin activity occurring on ''regulated exchanges'' is a key development to mollify concerns about price manipulation or other manipulative practices in the bitcoin market.[77]

Simultaneously with the Exchange's and the Custodian's assertions regarding the Benchmark, the Exchange also states

[65] While one commenter makes a comparison to the gold market (*see* Eddie Letter and *supra* note 62), this comparison undercuts BZX's argument that the bitcoin market is costly to manipulate by citing to a report that purports to show that it is far less costly to move the price of bitcoin than gold.

[66] Aside from stating that the ''statistics are based on samples of bitcoin liquidity in USD (excluding stablecoins or Euro liquidity) based on executable quotes on Coinbase Pro, Gemini, Bitstamp, Kraken, LMAX Exchange, BinanceUS, and OKCoin during February 2021,'' the Exchange provides no other information pertaining to the methodology used to enable the Commission to evaluate these findings or their significance. *See* Notice, 86 FR 14494–95 nn.60–61.

[67] *See* USBT Order, 85 FR 12601.

[68] *See supra* note 58 and accompanying text.

[69] *See* USBT Order, 85 FR 12600–01 & nn.66–67 (discussing J. Griffin & A. Shams, *Is Bitcoin Really Untethered?* (October 28, 2019), *available at https://ssrn.com/abstract=3195066* and published in 75 J. Finance 1913 (2020)); Winklevoss Order, 83 FR 37585–86.

[70] *See* Amended Registration Statement at 7, 13, 17, 19 and 31. *See also* Winklevoss Order, 83 FR 37585.

[71] *See* Notice, 86 FR 14995.

[72] *See id.* at 14996.

[73] *See id.*

[74] *See id.*

[75] *See id.*

[76] *See* Gemini Letter at 2.

[77] *See id. But see infra* note 148 and accompanying text. The Custodian also states that it is registered with FinCEN as a money service business and maintains money transmitter licenses (or the statutory equivalent) in all states where this is required. *See* Gemini Letter at 3 and *infra* note 89.

that, because the Trust will engage in in-kind creations and redemptions only, the ''manipulability of the Benchmark [is] significantly less important.'' [78] The Exchange elaborates further that, ''because the Trust will not accept cash to buy bitcoin in order to create new shares or . . . be forced to sell bitcoin to pay cash for redeemed shares, the price that the Sponsor uses to value the Trust's bitcoin is not particularly important.'' [79] According to BZX, when authorized participants create Shares with the Trust, they would need to deliver a certain number of bitcoin per share (regardless of the valuation used), and when they redeem with the Trust, they would similarly expect to receive a certain number of bitcoin per share.[80] As such, BZX argues that, even if the price used to value the Trust's bitcoin is manipulated, the ratio of bitcoin per Share does not change, and the Trust will either accept (for creations) or distribute (for redemptions) the same number of bitcoin regardless of the value.[81] This, according to BZX, not only mitigates the risk associated with potential manipulation, but also discourages and disincentivizes manipulation of the Benchmark because there is little financial incentive to do so.[82]

Based on assertions made and the information provided, the Commission can find no basis to conclude that BZX has articulated other means to prevent fraud and manipulation that are sufficient to justify dispensing with the requisite surveillance-sharing agreement. First, the Exchange's assertions that the Benchmark's methodology helps make the Benchmark resistant to manipulation are contradicted by the Amended Registration Statement's own statements. In the Amended Registration Statement, the Sponsor states that the Benchmark is ''based on various inputs which may include price data from various third-party exchanges and markets'' and that these inputs may be subject to ''technological error, manipulative activity, or fraudulent reporting from their initial source.'' [83]

Second, the Custodian asserts that the growing sophistication of market surveillance tools and strategies used by the Benchmark's constituent platforms, as well as the growing proportion of bitcoin activity occurring on ''regulated exchanges,'' ''mollify concerns about price manipulation or other manipulative practices.'' [84] However, the level of regulation on the Benchmark's constituent platforms is not equivalent to the obligations, authority, and oversight of national securities exchanges or futures exchanges and therefore is not an appropriate substitute.[85] National securities exchanges are required to have rules that are ''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.'' [86] Moreover, national securities exchanges must file proposed rules with the Commission regarding certain material aspects of their operations,[87] and the Commission has the authority to disapprove any such rule that is not consistent with the requirements of the Exchange Act.[88] Thus, national securities exchanges are subject to Commission oversight of, among other things, their governance, membership qualifications, trading rules, disciplinary procedures, recordkeeping, and fees.[89]

The Benchmark's constituent platforms, on the other hand, have none of these requirements (none are registered as a national securities exchange).[90] Further, although the Custodian claims that the constituent platforms have market surveillance tools and strategies that are growing in sophistication, the Custodian provides no supporting evidence. Moreover, even assuming that the constituent platforms are as vigilant towards fraud and manipulation as the Custodian describes, neither the Exchange nor the Custodian attempts to establish that only the Benchmark constituent platforms' ability to detect and deter fraud and manipulation would matter, exclusive of other bitcoin spot markets. In other words, neither addresses how fraud and manipulation on other bitcoin spot markets may influence the price of bitcoin.

Third, the Exchange does not explain the significance of the Benchmark's purported resistance to manipulation to the overall analysis of whether the proposal to list and trade the Shares is designed to prevent fraud and manipulation. Even assuming that the Exchange's argument is that, if the Benchmark is resistant to manipulation, the Trust's NAV, and thereby the Shares as well, would be resistant to manipulation, the Exchange has not established in the record a basis for such conclusion. That assumption aside, the Commission notes that the Shares would trade at market-based prices in the secondary market, not at NAV, which then raises the question of the significance of the NAV calculation to the manipulation of the Shares.

[78] *See* Notice, 86 FR 14999.

[79] *See id.*

[80] *See id.* at 15000.

[81] *See id.*

[82] *See id.*

[83] *See* Amended Registration Statement at 23. The Amended Registration Statement further states that ''[b]itcoin [platforms] on which bitcoin trades . . . may be more exposed to fraud and security breaches than established, regulated exchanges for other financial assets or instruments, which could have a negative impact on the performance of the Trust.'' *See id.* at 7 and 19.

[84] *See* Gemini Letter at 2.

[85] *See also* USBT Order, 85 FR 12603–05.

[86] *See* 15 U.S.C. 78f(b)(5)

[87] 17 CFR 240.19b-4(a)(6)(i).

[88] Section 6 of the Exchange Act, 15 U.S.C. 78f, requires national securities exchanges to register with the Commission and requires an exchange's registration to be approved by the Commission, and Section 19(b) of the Exchange Act, 15 U.S.C. 78s(b), requires national securities exchanges to file proposed rules changes with the Commission and provides the Commission with the authority to disapprove proposed rule changes that are not consistent with the Exchange Act. Designated contract markets (''DCMs'') (commonly called ''futures markets'') registered with and regulated by the Commodity Futures Trading Commission (''CFTC'') must comply with, among other things, a similarly comprehensive range of regulatory principles and must file rule changes with the CFTC. *See, e.g.,* Designated Contract Markets (DCMs), CFTC, *available at http://www.cftc.gov/IndustryOversight/TradingOrganizations/DCMs/index.htm.*

[89] *See* Winklevoss Order, 83 FR 37597. The Commission notes that the NYSDFS has issued ''guidance'' to supervised virtual currency business entities, stating that these entities must ''implement measures designed to effectively detect, prevent, and respond to fraud, attempted fraud, and similar wrongdoing.'' *See* Maria T. Vullo, Superintendent of Financial Services, NYSDFS, *Guidance on Prevention of Market Manipulation and Other Wrongful Activity* (Feb. 7, 2018), *available at https://www.dfs.ny.gov/docs/legal/industry/il180207.pdf.* The NYSDFS recognizes that its ''guidance is not intended to limit the scope or applicability of any law or regulation'' (*id.*), which would include the Exchange Act. Nothing in the record evidences whether the Benchmark's constituent platforms have complied with this NYSDFS guidance.

Further, as stated previously, there are substantial differences between the NYSDFS and FinCEN versus the Commission's regulation. AML and KYC policies and procedures, for example, have been referenced in other bitcoin-based ETP proposals as a purportedly alternative means by which such ETPs would be uniquely resistant to manipulation. The Commission has previously concluded that such AML and KYC policies and procedures do not serve as a substitute for, and are not otherwise dispositive in the analysis regarding the importance of, having a surveillance sharing agreement with a regulated market of significant size relating to bitcoin. For example, AML and KYC policies and procedures do not substitute for the sharing of information about market trading activity or clearing activity and do not substitute for regulation of a national securities exchange. *See* USBT Order, 85 FR 12603 n.101.

[90] *See* 15 U.S.C. 78e, 78f.

Fourth, the Exchange's arguments are contradictory. While arguing that the Benchmark is resistant to manipulation, the Exchange simultaneously downplays the importance of the Benchmark in light of the Trust's in-kind creation and redemption mechanism.[91] The Exchange points out that the Trust will create and redeem Shares in-kind, not in cash, which renders the NAV calculation, and thereby the ability to manipulate NAV, ''significantly less important.'' [92] In BZX's own words, the Trust will not accept cash to buy bitcoin in order to create shares or sell bitcoin to pay cash for redeemed shares, so the price that the Sponsor uses to value the Trust's bitcoin ''is not particularly important.'' [93] If the Benchmark that the Trust uses to value the Trust's bitcoin ''is not particularly important,'' it follows that the Benchmark's resistance to manipulation is not material to the Shares' susceptibility to fraud and manipulation. As the Exchange does not address or provide any analysis with respect to these issues, the Commission cannot conclude that the Benchmark aids in the determination that the proposal to list and trade the Shares is designed to prevent fraudulent and manipulative acts and practices.[94]

Finally, the Commission finds that BZX has not demonstrated that in-kind creations and redemptions provide the Shares with a unique resistance to manipulation. The Commission has previously addressed similar assertions.[95] As the Commission stated before, in-kind creations and redemptions are a common feature of ETPs, and the Commission has not previously relied on the in-kind creation and redemption mechanism as a basis for excusing exchanges that list ETPs from entering into surveillance-sharing agreements with significant, regulated markets related to the portfolio's assets.[96] Accordingly, the Commission is not persuaded here that the Trust's in-kind creations and redemptions afford it a unique resistance to manipulation.[97]

(2) Assertions That BZX Has Entered Into a Comprehensive Surveillance-Sharing Agreement With a Regulated Market of Significant Size

As BZX has not demonstrated that other means besides surveillance-sharing agreements will be sufficient to prevent fraudulent and manipulative acts and practices, the Commission next examines whether the record supports the conclusion that BZX has entered into a comprehensive surveillance-sharing agreement with a regulated market of significant size relating to the underlying assets. In this context, the term ''market of significant size'' includes a market (or group of markets) as to which (i) there is a reasonable likelihood that a person attempting to manipulate the ETP would also have to trade on that market to successfully manipulate the ETP, so that a surveillance-sharing agreement would assist in detecting and deterring misconduct, and (ii) it is unlikely that trading in the ETP would be the predominant influence on prices in that market.[98]

As the Commission has stated in the past, it considers two markets that are members of the ISG to have a comprehensive surveillance-sharing agreement with one another, even if they do not have a separate bilateral surveillance-sharing agreement.[99] Accordingly, based on the common membership of BZX and CME in the ISG,[100] BZX has the equivalent of a comprehensive surveillance-sharing agreement with CME. However, while the Commission recognizes that the CFTC regulates the CME futures market,[101] including the CME bitcoin futures market, and thus such market is ''regulated,'' in the context of the proposed ETP, the record does not, as explained further below, establish that the CME bitcoin futures market is a ''market of significant size'' as that term is used in the context of the applicable standard here.[102]

(i) Whether There Is a Reasonable Likelihood That a Person Attempting To Manipulate the ETP Would Also Have To Trade on the CME Bitcoin Futures Market to Successfully Manipulate the ETP

The first prong in establishing whether the CME bitcoin futures market constitutes a ''market of significant size'' is the determination that there is a reasonable likelihood that a person attempting to manipulate the ETP would have to trade on the CME bitcoin futures market to successfully manipulate the ETP.

BZX notes that CME began to offer trading in bitcoin futures in 2017.[103] According to BZX, nearly every measurable metric related to CME bitcoin futures contracts, which trade and settle like other cash-settled commodity futures contracts, has ''trended consistently up since launch and/or accelerated upward in the past year.'' [104] For example, according to BZX, there was approximately $28 billion in trading in CME bitcoin futures in December 2020 compared to $737 million, $1.4 billion, and $3.9 billion in total trading in December 2017, December 2018, and December 2019, respectively.[105] Additionally, CME

[91] *See supra* notes 78–82 and accompanying text.

[92] *See* Notice, 86 FR 14995 and 14999 (''While the Sponsor believes that the Benchmark which it uses to value the Trust's bitcoin is itself resistant to manipulation based on the methodology further described below, the fact that creations and redemptions are only available in-kind makes the manipulability of the Benchmark significantly less important.'').

[93] *See id.* (concluding that ''because the Trust will not accept cash to buy bitcoin in order to create new shares or, barring a forced redemption of the Trust or under other extraordinary circumstances, be forced to sell bitcoin to pay cash for redeemed shares, the price that the Sponsor uses to value the Trust's bitcoin is not particularly important.'').

[94] In addition, with respect to the valuation of bitcoin according to a benchmark or a reference price, the Commission has previously considered and rejected similar arguments. *See* SolidX Order, 82 FR 16258; Winklevoss Order, 83 FR 37589–90. Among other things, the Exchange fails to explain why prices and volumes of bitcoin platforms that are not constituents of the Benchmark do not affect the prices of the constituent platforms. Likewise, the Exchange also fails to establish how the Benchmark's methodology eliminates fraudulent or manipulative activity that is not transient. *See* USBT Order, 85 FR 12607.

[95] *See* Winklevoss Order, 83 FR 37589–90; USBT Order, 85 FR 12607–08.

[96] *See, e.g.,* iShares COMEX Gold Trust, Securities Exchange Act Release No. 51058 (Jan. 19, 2005), 70 FR 3749, 3751–55 (Jan. 26, 2005) (SR–Amex–2004–38); iShares Silver Trust, Securities Exchange Act Release No. 53521 (Mar. 20, 2006), 71 FR 14969, 14974 (Mar. 24, 2006) (SR–Amex–2005–072).

[97] Putting aside the Exchange's various assertions about the nature of bitcoin and the bitcoin market, the Benchmark, and the Shares, the Exchange also does not address concerns the Commission has previously identified, including the susceptibility of bitcoin markets to potential trading on material, non-public information (such as plans of market participants to significantly increase or decrease their holdings in bitcoin; new sources of demand for bitcoin; the decision of a bitcoin-based investment vehicle on how to respond to a ''fork'' in the bitcoin blockchain, which would create two different, non-interchangeable types of bitcoin), or to the dissemination of false or misleading information. *See* Winklevoss Order, 83 FR 37585. *See also* USBT Order, 85 FR 12600–01.

[98] *See* Winklevoss Order, 83 FR 37594. This definition is illustrative and not exclusive. There could be other types of ''significant markets'' and ''markets of significant size,'' but this definition is an example that provides guidance to market participants. *See id.*

[99] *See id.* at 37580 n.19.

[100] *See* Notice, 86 FR 14994 n.56 and accompanying text.

[101] While the Commission recognizes that the CFTC regulates the CME, the CFTC is not responsible for direct, comprehensive regulation of the underlying bitcoin spot market. *See* Winklevoss Order, 83 FR 37587, 37599.

[102] As described above (*see supra* notes 85–90 and accompanying text), in the context of the proposed ETP, the Benchmark's constituent platforms are not ''regulated.'' They are not registered as ''exchanges'' and lack the obligations, authority, and oversight of national securities exchanges.

[103] According to BZX, each contract represents five bitcoin and is based on the CME CF Bitcoin Reference Rate. *See* Notice, 86 FR 14991.

[104] *See id.*

[105] *See id.*

bitcoin futures traded over $1.2 billion per day in December 2020 and represented $1.6 billion in open interest compared to $115 million in December 2019.[106] Similarly, BZX contends that the number of large open interest holders [107] has continued to increase, even as the price of bitcoin has risen, as have the number of unique accounts trading CME bitcoin futures.[108]

BZX argues that the significant growth in CME bitcoin futures across each of trading volumes, open interest, large open interest holders, and total market participants since the USBT Order was issued is reflective of that market's growing influence on the spot price. BZX asserts that where CME bitcoin futures lead the price in the spot market such that a potential manipulator of the bitcoin spot market (beyond just the constituents of the Benchmark) would have to participate in the CME bitcoin futures market, it follows that a potential manipulator of the Shares would similarly have to transact in the CME bitcoin futures market.[109]

BZX further states that academic research corroborates the overall trend outlined above and supports the thesis that CME bitcoin futures pricing leads the spot market. BZX asserts that academic research demonstrates that the CME bitcoin futures market was already leading the spot price in 2018 and 2019.[110] BZX concludes that a person attempting to manipulate the Shares would also have to trade on that market to manipulate the ETP.[111]

The Commission disagrees. The record does not demonstrate that there is a reasonable likelihood that a person attempting to manipulate the proposed ETP would have to trade on the CME bitcoin futures market to successfully manipulate it. Specifically, BZX's assertions about the general upward trends from 2018 to February 2021 in trading volume and open interest of, and in the number of large open interest holders and number of unique accounts trading in, CME bitcoin futures do not establish that the CME bitcoin futures market is of significant size. As the Commission has previously articulated, the interpretation of the term ''market of significant size'' or ''significant market'' depends on the interrelationship between the market with which the listing exchange has a surveillance-sharing agreement and the proposed ETP.[112] BZX's recitation of data reflecting the size of the CME bitcoin futures market, alone, either currently or in relation to previous years, is not sufficient to establish an interrelationship between the CME bitcoin futures market and the proposed ETP.[113]

Further, the evidence in the record also does not support a conclusion that the CME bitcoin futures market leads the bitcoin spot market in such a manner that the CME bitcoin futures market is a ''market of significant size.'' As the Commission has previously explained, establishing a lead-lag relationship between the bitcoin futures market and the spot market is ''central to understanding whether it is reasonably likely that a would-be manipulator of the ETP would need to trade on the bitcoin futures market to successfully manipulate prices on those spot platforms that feed into the proposed ETP's pricing mechanism.'' [114] The Commission has previously stated that, in particular, if the spot market leads the futures market, this would indicate that it would not be necessary to trade on the futures market to manipulate the proposed ETP, because the futures price would move to meet the spot price.[115]

While BZX states that CME bitcoin futures pricing leads the spot market,[116] it relies on the findings of a price discovery analysis in one section of a single academic paper to support the overall thesis.[117] However, the findings of that paper's Granger causality analysis, which is widely used to formally test for lead-lag relationships, are concededly mixed.[118] In addition, the Commission considered an unpublished version of the paper in the USBT Order, as well as a comment letter submitted by the authors on that record.[119] In the USBT Order, as part of the Commission's conclusion that ''mixed results'' in academic studies failed to demonstrate that the CME bitcoin futures market constitutes a market of significant size, the Commission noted the paper's inconclusive evidence that CME bitcoin futures prices lead spot prices—in particular that the months at the end of the paper's sample period showed that the spot market was the leading market—and stated that the record did not include evidence to explain why this would not indicate a shift towards prices in the spot market leading the futures market that would be expected to persist into the future.[120] The Commission also stated that the paper's use of daily price data, as opposed to intraday prices, may not be able to distinguish which market incorporates new information faster.[121] BZX has not addressed either issue.

Moreover, BZX does not provide results of its own analysis and does not present any other data supporting its conclusion. BZX's unsupported representations constitute an insufficient basis for approving a proposed rule change in circumstances where, as here, the Exchange's assertion would form such an integral role in the Commission's analysis and the assertion is subject to several challenges.[122] In this context, BZX's reliance on a single paper, whose own lead-lag results are inconclusive, is especially lacking because the academic literature on the lead-lag relationship and price discovery between bitcoin spot and futures markets is unsettled.[123] In the

[106] *See id.*

[107] BZX represents that a large open interest holder in CME bitcoin futures is an entity that holds at least 25 contracts, which is the equivalent of 125 bitcoin. According to BZX, at a price of approximately $30,000 per bitcoin on December 31, 2020, more than 80 firms had outstanding positions of greater than $3.8 million in CME bitcoin futures. *See id.* at 14992 n.50.

[108] *See id.* at 14992.

[109] *See id.* at 14994.

[110] *See id.* at 14994 and 14993 n.51 (citing Y. Hu, Y. Hou & L. Oxley, *What role do futures markets play in Bitcoin pricing? Causality, cointegration and price discovery from a time-varying perspective,* 72 Int'l Rev. of Fin. Analysis 101569 (2020) (*available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7481826/*) (''Hu, Hou & Oxley'').

[111] *See id.* at 14994.

[112] *See* USBT Order, 85 FR 12611.

[113] *See id.* at 12612.

[114] *See id.*

[115] *See id.*

[116] *See* Notice, 86 FR 14993.

[117] *See supra* note 110 and accompanying text. BZX references the following conclusion from the ''time-varying price discovery'' section of Hu, Hou & Oxley: ''There exist no episodes where the Bitcoin spot markets dominates the price discovery processes with regard to Bitcoin futures. This points to a conclusion that the price formation originates solely in the Bitcoin futures market. We can, therefore, conclude that the Bitcoin futures markets dominate the dynamic price discovery process based upon time-varying information share measures. Overall, price discovery seems to occur in the Bitcoin futures markets rather than the underlying spot market based upon a time-varying perspective . . .'' *See* Notice, 86 FR 14993 n.51.

[118] The paper finds that the CME bitcoin futures market dominates the spot markets in terms of Granger causality, but that the causal relationship is bi-directional, and a Granger causality episode from March 2019 to June/July 2019 runs from bitcoin spot prices to CME bitcoin futures prices. The paper concludes: ''[T]he Granger causality episodes are not constant throughout the whole sample period. Via our causality detection methods, market participants can identify when markets are being led by futures prices and when they might not be.'' *See* Hu, Hou & Oxley, *supra* note 110.

[119] *See* USBT Order, 85 FR 12609.

[120] *See id.* at 12613 n.244.

[121] *See id.*

[122] *See Susquehanna,* 866 F.3d at 447.

[123] *See, e.g.,* D. Baur & T. Dimpfl, *Price discovery in bitcoin spot or futures?,* 39 J. Futures Mkts. 803 (2019) (finding that the bitcoin spot market leads price discovery); O. Entrop, B. Frijns & M. Seruset, *The determinants of price discovery on bitcoin markets,* 40 J. Futures Mkts. 816 (2020) (finding that price discovery measures vary significantly over time without one market being clearly dominant

Continued

USBT Order, the Commission responded to multiple academic papers that were cited and concluded that, in light of the mixed results found, the exchange there had not demonstrated that it is reasonably likely that a would-be manipulator of the proposed ETP would transact on the CME bitcoin futures market.[124] Likewise, here, given the body of academic literature to indicate to the contrary, the Commission concludes that the information that BZX provides is not a sufficient basis to support a determination that it is reasonably likely that a would-be manipulator of the proposed ETP would have to trade on the CME bitcoin futures market.[125]

The Commission accordingly concludes that the information provided in the record does not establish a reasonable likelihood that a would-be manipulator of the proposed ETP would have to trade on the CME bitcoin futures market to successfully manipulate the proposed ETP. Therefore, the information in the record also does not establish that the CME bitcoin futures market is a ''market of significant size'' with respect to the proposed ETP.

(ii) Whether It Is Unlikely That Trading in the Proposed ETP Would Be the Predominant Influence on Prices in the CME Bitcoin Futures Market

The second prong in establishing whether the CME bitcoin futures market constitutes a ''market of significant size'' is the determination that it is unlikely that trading in the proposed ETP would be the predominant influence on prices in the CME bitcoin futures market.[126]

BZX asserts that trading in the Shares would not be the predominant force on prices in the CME bitcoin futures market (or spot market) because of the significant volume in the CME bitcoin futures market, the size of bitcoin's market capitalization, which is approximately $1 trillion, and the significant liquidity available in the spot market.[127] BZX provides that, according to February 2021 data, the cost to buy or sell $5 million worth of bitcoin averages roughly 10 basis points with a market impact of 30 basis points.[128] For a $10 million market order, the cost to buy or sell is roughly 20 basis points with a market impact of 50 basis points. Stated another way, BZX states that a market participant could enter a market buy or sell order for $10 million of bitcoin and only move the market 0.5 percent.[129] BZX further asserts that more strategic purchases or sales (such as using limit orders and executing through OTC bitcoin trade desks) would likely have less obvious impact on the market, which is consistent with MicroStrategy, Tesla, and Square being able to collectively purchase billions of dollars in bitcoin.[130] Thus, BZX concludes that the combination of CME bitcoin futures leading price discovery, the overall size of the bitcoin market, and the ability for market participants (including authorized participants creating and redeeming in-kind with the Trust) to buy or sell large amounts of bitcoin without significant market impact, will help prevent the Shares from becoming the predominant force on pricing in either the bitcoin spot or the CME bitcoin futures market.[131]

The Commission does not agree. The record does not demonstrate that it is unlikely that trading in the proposed ETP would be the predominant influence on prices in the CME bitcoin futures market. As the Commission has already addressed and rejected one of the bases of BZX's assertion—that CME bitcoin futures leads price discovery[132]—it will only address below the other two bases—the overall size of, and the impact of buys and sells on, the bitcoin market.

BZX's assertions about the potential effect of trading in the Shares on the CME bitcoin futures market and bitcoin spot market are general and conclusory, repeating the aforementioned trade volume of the CME bitcoin futures market and the size and liquidity of the bitcoin spot market, as well as the market impact of a large transaction, without any analysis or evidence to support these assertions. For example, there is no limit on the amount of mined bitcoin that the Trust may hold. Yet BZX does not provide any information on the expected growth in the size of the Trust and the resultant increase in the amount of bitcoin held by the Trust over time, or on the overall expected number, size, and frequency of creations and redemptions—or how any of the foregoing could (if at all) influence prices in the CME bitcoin futures market. Moreover, in the Trust's Amended Registration Statement, the Sponsor acknowledges that the Trust may acquire large size positions in bitcoin, which would increase the risk of illiquidity in the underlying bitcoin. Specifically, the Sponsor, in the Amended Registration Statement, states that the Trust may acquire large size positions in bitcoin, which will increase the risk of illiquidity by both making the positions more difficult to liquidate and increasing the losses incurred while trying to do so, or by making it more difficult for authorized participants to acquire or liquidate bitcoin as part of the creation and/or redemption of Shares of the Trust.[133] Although the Trust's Amended Registration Statement concedes that the Trust could negatively affect the liquidity of bitcoin, BZX does not address this in the proposal or discuss how impacting the liquidity of bitcoin can be consistent with the assertion that the Shares are unlikely to be the predominant influence on the

over the other); J. Hung, H. Liu & J. Yang, *Trading activity and price discovery in Bitcoin futures markets,* 62 J. Empirical Finance 107 (2021) (finding that the bitcoin spot market dominates price discovery); B. Kapar & J. Olmo, *An analysis of price discovery between Bitcoin futures and spot markets,* 174 Econ. Letters 62 (2019) (finding that bitcoin futures dominate price discovery); E. Akyildirim, S. Corbet, P. Katsiampa, N. Kellard & A. Sensoy, *The development of Bitcoin futures: Exploring the interactions between cryptocurrency derivatives,* 34 Fin. Res. Letters 101234 (2020) (finding that bitcoin futures dominate price discovery); A. Fassas, S. Papadamou, & A. Koulis, *Price discovery in bitcoin futures,* 52 Res. Int'l Bus. Fin. 101116 (2020) (finding that bitcoin futures play a more important role in price discovery); S. Aleti & B. Mizrach, *Bitcoin spot and futures market microstructure,* 41 J. Futures Mkts. 194 (2021) (finding that relatively more price discovery occurs on CME as compared to four spot exchanges); J. Wu, K. Xu, X. Zheng & J. Chen, *Fractional cointegration in bitcoin spot and futures markets,* 41 J. Futures Mkts. 1478 (2021) (finding that CME bitcoin futures dominate price discovery). *See also* C. Alexander & D. Heck, *Price discovery in Bitcoin: The impact of unregulated markets,* 50 J. Financial Stability 100776 (2020) (finding that, in a multi-dimensional setting, including the main price leaders within futures, perpetuals, and spot markets, CME bitcoin futures have a very minor effect on price discovery; and that faster speed of adjustment and information absorption occurs on the unregulated spot and derivatives platforms than on CME bitcoin futures) (''Alexander & Heck''). One commenter states they have updated the Alexander & Heck study using data from June 1, 2020 to April 30, 2021, and they found that CME bitcoin futures now have a far more pronounced price leadership role, but also that, similar to Alexander & Heck's findings, Huobi and OKEx futures are the leading instruments in bitcoin's price discovery. *See* letter from Vetle Andreas Gusgaard Lunde, dated July 2, 2021, and weblink cited therein: *https://www.research.arcane.no/blog/the-regulated-tail-that-wags-the-honey-badger.*

[124] *See* USBT Order, 85 FR 12613 nn.239–244 and accompanying text.

[125] In addition, the Exchange fails to address the lead-lag relationship (if any) between prices on other bitcoin futures markets and the CME bitcoin futures market, the bitcoin spot market, and/or the particular Benchmark constituent platforms, or where price formation occurs when the entirety of bitcoin futures markets, not just CME, is considered.

[126] *See* Winklevoss Order, 83 FR 37594; USBT Order, 85 FR 12596–97.

[127] *See* Notice, 86 FR 14999.

[128] *See id.* According to BZX, these statistics are based on samples of bitcoin liquidity in U.S. dollars (excluding stablecoins or Euro liquidity) based on executable quotes on Coinbase Pro, Gemini, Bitstamp, Kraken, LMAX Exchange, BinanceUS, and OKCoin during February 2021. *See id.* at 14999 n.80.

[129] *See id.* at 14999.

[130] *See id.*

[131] *See id.*

[132] *See supra* notes 123–125 and accompanying text.

[133] *See* Amended Registration Statement at 26.

prices of the CME bitcoin futures market. Thus, the Commission cannot conclude, based on BZX's statements alone and absent any evidence or analysis in support of BZX's assertions, that it is unlikely that trading in the ETP would be the predominant influence on prices in the CME bitcoin futures market.

The Commission also is not persuaded by BZX's assertions about the minimal effect a large market order to buy or sell bitcoin would have on the bitcoin market.[134] While BZX concludes by way of a $10 million market order example that buying or selling large amounts of bitcoin would have insignificant market impact, the conclusion does not analyze the extent of any impact on the CME bitcoin futures market. Even assuming that BZX is suggesting that a single $10 million order in bitcoin would have immaterial impact on the prices in the CME bitcoin futures market, this prong of the ''market of significant size'' determination concerns the influence on prices from trading *in* the proposed ETP, which is broader than just trading *by* the proposed ETP. While authorized participants of the Trust might only transact in the bitcoin spot market as part of their creation or redemption of Shares, the Shares themselves would be traded in the secondary market on BZX. The record does not discuss the expected number or trading volume of the Shares, or establish the potential effect of the Shares' trade prices on CME bitcoin futures prices. For example, BZX does not provide any data or analysis about the potential effect the quotations or trade prices of the Shares might have on market-maker quotations in CME bitcoin futures contracts and whether those effects would constitute a predominant influence on the prices of those futures contracts.

Thus, because BZX has not provided sufficient information to establish both prongs of the ''market of significant size'' determination, the Commission cannot conclude that the CME bitcoin futures market is a ''market of significant size'' such that BZX would be able to rely on a surveillance-sharing agreement with the CME to provide sufficient protection against fraudulent and manipulative acts and practices.

The requirements of Section 6(b)(5) of the Exchange Act apply to the rules of national securities exchanges. Accordingly, the relevant obligation for a comprehensive surveillance-sharing agreement with a regulated market of significant size, or other means to prevent fraudulent and manipulative acts and practices that are sufficient to justify dispensing with the requisite surveillance-sharing agreement, resides with the listing exchange. Because there is insufficient evidence in the record demonstrating that BZX has satisfied this obligation, the Commission cannot approve the proposed ETP for listing and trading on BZX.

*C. Whether BZX has met its Burden To Demonstrate That the Proposal Is Designed To Protect Investors and the Public Interest*

BZX contends that, if approved, the proposed ETP would protect investors and the public interest. However, the Commission must consider these potential benefits in the broader context of whether the proposal meets each of the applicable requirements of the Exchange Act.[135] Because BZX has not demonstrated that its proposed rule change is designed to prevent fraudulent and manipulative acts and practices, the Commission must disapprove the proposal.

BZX asserts that, with the growth of U.S. investor exposure to bitcoin through OTC bitcoin funds, so too has grown the potential risk to U.S. investors.[136] Specifically, BZX argues that premium volatility, high fees, insufficient disclosures, and technical hurdles are putting U.S. investor money at risk on a daily basis and that such risk could potentially be eliminated through access to a bitcoin ETP.[137] As such, the Exchange believes that approving this proposal (and comparable proposals submitted hereafter) would give U.S. investors access to bitcoin in a regulated and transparent exchange-traded vehicle that would act to limit risk to U.S. investors by: (i) Reducing premium volatility; (ii) reducing management fees through meaningful competition; (iii) providing an alternative to custodying spot bitcoin; and (iv) reducing risks associated with investing in operating companies that are imperfect proxies for bitcoin exposure.[138]

According to BZX, OTC bitcoin funds are generally designed to provide exposure to bitcoin in a manner similar to the Shares. However, unlike the Shares, BZX states that ''OTC bitcoin funds are unable to freely offer creation and redemption in a way that incentivizes market participants to keep their shares trading in line with their NAV and, as such, frequently trade at a price that is out-of-line with the value of their assets held.''[139] BZX represents that, historically, OTC bitcoin funds have traded at a significant premium to NAV.[140] Although the Exchange concedes that trading at a premium (or potentially a discount) is not unique to OTC bitcoin funds and not inherently problematic, BZX believes that it raises certain investor protections issues. First, according to BZX, investors are buying shares of a fund for a price in excess of the per-share value of the fund's underlying assets; the price of bitcoin could stay exactly the same from market close on one day to market open the next, yet the value of the shares held by the investor could decrease only because of the fluctuation of the premium.[141] Second, according to BZX, only accredited investors, generally, are able to create new shares with the OTC bitcoin fund and can purchase the shares at NAV. While they are forced to hold the shares for at least six months before selling, in reality they can immediately hedge any exposure to the price of bitcoin and simply wait six months to sell the shares to a retail investor and collect the premium.[142]

Several commenters also express support for the approval of bitcoin ETPs because they believe such ETPs would have lower premium/discount

[134] *See* Notice, 86 FR 14994–95 (''For a $10 million market order, the cost to buy or sell is roughly 20 basis points with a market impact of 50 basis points. Stated another way, a market participant could enter a market buy or sell order for $10 million of bitcoin and only move the market 0.5%.'').

[135] *See* Winklevoss Order, 83 FR 37601. *See also* GraniteShares Order, 83 FR 43931; ProShares Order, 83 FR 43941; USBT Order, 85 FR 12615.

[136] *See* Notice, 86 FR 14990.

[137] *See id.* BZX states that while it understands the Commission's previous focus on potential manipulation of a bitcoin ETP in prior disapproval orders, it now believes that ''such concerns have been sufficiently mitigated and that the growing and quantifiable investor protection concerns should be the central consideration as the Commission reviews this proposal.'' *See id.*

[138] *See id.*

[139] *See id.* BZX also states that, unlike the Shares, because OTC bitcoin funds are not listed on an exchange, they are not subject to the same transparency and regulatory oversight by a listing exchange. BZX further asserts that the existence of a surveillance-sharing agreement between BZX and the CME bitcoin futures market would result in increased investor protections for the Shares compared to OTC bitcoin funds. *See id.* at 14990 n.38.

[140] *See id.* at 14990. BZX further represents that the inability to trade in line with NAV may at some point result in OTC bitcoin funds trading at a discount to their NAV. According to BZX, while that has not historically been the case, trading at a discount would give rise to nearly identical potential issues related to trading at a premium. *See id.* at 14990 n.39.

[141] *See id.* at 14990.

[142] *See id.*

volatility[143] and lower management fees[144] than an OTC bitcoin fund.

Another commenter argues that a bitcoin ETP has the potential to reduce volatility in the price of bitcoin itself, which the commenter believes would generate positive externalities for existing investors and ultimately for financial stability. The commenter asserts, with no supporting evidence, that marginal demand for a bitcoin ETP is likely to come from relatively more conservative investors—for example, retail traders unwilling to trade on unregulated markets, as well as institutional traders who lack a ''mandate'' or the risk tolerance to do so. The commenter states that a shift in the marginal investor's risk aversion, as well as increased attention from sophisticated institutions, would lead to a bitcoin price that is less susceptible to wild swings that are often driven by social media.[145]

BZX also asserts that exposure to bitcoin through an ETP also presents advantages for retail investors compared to buying spot bitcoin directly.[146] BZX asserts that, without the advantages of an ETP, an individual retail investor holding bitcoin through a cryptocurrency trading platform lacks protections.[147] BZX explains that, typically, retail platforms hold most, if not all, retail investors' bitcoin in ''hot'' (internet-connected) storage and do not make any commitments to indemnify retail investors or to observe any particular cybersecurity standard.[148] Meanwhile, a retail investor holding spot bitcoin directly in a self-hosted wallet may suffer from inexperience in private key management (*e.g.,* insufficient password protection, lost key, etc.), which could cause them to lose some or all of their bitcoin holdings.[149] BZX represents that the Custodian would, by contrast, use ''cold'' (offline) storage to hold private keys, employ a certain degree of cybersecurity measures and operational best practices, be highly experienced in bitcoin custody, and be accountable for failures.[150] Thus, with respect to custody of the Trust's bitcoin assets, BZX concludes that, compared to owning spot bitcoin directly, the Trust presents advantages from an investment protection standpoint for retail investors.[151]

The Custodian, in a comment letter, echoes some of the descriptions of the custodial arrangement.[152] The Custodian also specifies that it employs a multi-signature system which requires a quorum of unique private key signatures before transactions can be effectuated on the bitcoin blockchain and that this approach allows for constant monitoring and auditability of the Trust's holdings.[153] Also, according to the Custodian, it maintains digital asset insurance, is regularly audited by major financial and audit firms, and is subject to independent third-party verification that the Custodian's operations and security compliance structures meet the most robust of industry standards.[154]

BZX further asserts that a number of operating companies engaged in unrelated businesses have announced investments as large as $1.5 billion in bitcoin.[155] Without access to bitcoin ETPs, BZX argues that retail investors seeking investment exposure to bitcoin may purchase shares in these companies in order to gain the exposure to bitcoin that they seek.[156] BZX contends that such operating companies, however, are imperfect bitcoin proxies and provide investors with partial bitcoin exposure paired with additional risks associated with whichever operating company they decide to purchase. BZX concludes that investors seeking bitcoin exposure through publicly traded companies are gaining only partial exposure to bitcoin and are not fully benefitting from the risk disclosures and associated investor protections that come from the securities registration process.[157]

BZX also states that investors in many other countries, including Canada, are able to use more traditional exchange listed and traded products to gain exposure to bitcoin, disadvantaging U.S. investors and leaving them with more risky means of getting bitcoin exposure.[158]

In essence, BZX asserts that the risky nature of direct investment in the underlying bitcoin and the unregulated markets on which bitcoin and OTC bitcoin funds trade compel approval of the proposed rule change. BZX, however, offers no limiting principle to this argument, under which, by logical extension, the Commission would be required to approve the listing and trading of any ETP that arguably presents marginally less risk to investors than a direct investment in the underlying asset or in an OTC-traded product.

The Commission disagrees with this reading of the Exchange Act. Pursuant to Section 19(b)(2) of the Exchange Act, the Commission must approve a proposed rule change filed by a national securities exchange if it finds that the proposed rule change is consistent with the applicable requirements of the Exchange Act—including the requirement under Section 6(b)(5) that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices—and it must disapprove the filing if it does not make such a finding.[159] Thus, even if a proposed rule change purports to protect investors from a particular type of investment

[143] *See* Ellis Letter; Apodaca Letter; letters from: Anonymous, dated June 16, 2021 (''Anonymous 6 Letter''); Anonymous, dated June 17, 2021 (''Anonymous 9 Letter''); Brian Havermann, dated July 6, 2021 (''Havermann Letter'').

[144] *See* Anonymous 6 Letter; Anonymous 9 Letter; Havermann Letter; Apodaca Letter; letter from Chris Kim, dated June 17, 2021 (''Kim Letter'').

[145] *See* letter from Marius Zoican, Assistant Professor of Finance, University of Toronto Mississauga, Rotman School of Management, dated June 17, 2021 (''Zoican Letter''). Another commenter puts forward a different reason why an approval of a bitcoin ETP could reduce bitcoin price volatility. This other commenter asserts that bitcoin ETPs (and other crypto ETPs) would allow non-institutional investors to more easily take ''short'' positions on crypto assets. The commenter believes some of the price volatility is caused by asymmetric buy/sell-side access in crypto markets that has added unnecessary tailwind to a standard asset bubble. *See* letter from Christian Lewis, dated June 16, 2021.

[146] *See* Notice, 86 FR 14991.

[147] *See id.*

[148] *See id.*

[149] *See id.*

[150] *See id.*

[151] *See id.* Likewise, several commenters cite risks and difficulties associated with the self-custody of bitcoin as part of the basis for their support for the proposed ETP. *See* Ellis Letter; Havermann Letter; Apodaca Letter; letters from: Michael Anderson, dated June 16, 2021; Joshua Park, dated June 16, 2021; John, dated June 17, 2021; Taylor Ailshie, dated June 17, 2021 (''Ailshie Letter''); Sebastian Aroca, dated July 6, 2021 (''Aroca Letter''); Michael Althaus, dated June 24, 2021 and June 28, 2021.

[152] *See* Gemini Letter at 3–4.

[153] *See id.* at 3.

[154] *See id.* at 3–4.

[155] *See* Notice, 86 FR 14991.

[156] *See id.* One commenter disagrees with the contention that investors would pay a premium to gain exposure to bitcoin by investing in companies that have decided to invest in bitcoin. *See* Eddie Letter.

[157] *See* Notice, 86 FR 14991. The Custodian, in its comment letter, agrees that the proposed ETP would offer greater customer protection and transparency than existing alternatives for retail customers to gain proxy exposure to bitcoin. *See* Gemini Letter at 2.

[158] *See* Notice, 86 FR 14990. BZX represents that the Purpose Bitcoin ETF, a retail bitcoin-based ETP launched in Canada, reportedly reached $421.8 million in assets under management in two days, demonstrating the demand for a North American market listed bitcoin ETP. BZX contends that the Purpose Bitcoin ETF also offers a class of units that is U.S. dollar denominated, which could appeal to U.S. investors. BZX also argues that without an approved bitcoin ETP in the U.S. as a viable alternative, U.S. investors could seek to purchase these shares in order to get access to bitcoin exposure. BZX believes that, given the separate regulatory regime and the potential difficulties associated with any international litigation, such an arrangement would create more risk exposure for U.S. investors than they would otherwise have with a U.S. exchange-listed ETP. *See id.* at 14990 n.36.

[159] *See* Exchange Act Section 19(b)(2)(C), 15 U.S.C. 78s(b)(2)(C).

risk—such as the susceptibility of an asset to loss or theft—the proposed rule change may still fail to meet the requirements under the Exchange Act.[160]

Here, even if it were true that, compared to trading in unregulated bitcoin spot markets, trading a bitcoin-based ETP on a national securities exchange provides some additional protection to investors, the Commission must consider this potential benefit in the broader context of whether the proposal meets each of the applicable requirements of the Exchange Act.[161] As explained above, for bitcoin-based ETPs, the Commission has consistently required that the listing exchange have a comprehensive surveillance-sharing agreement with a regulated market of significant size related to bitcoin, or demonstrate that other means to prevent fraudulent and manipulative acts and practices are sufficient to justify dispensing with the requisite surveillance-sharing agreement. The listing exchange has not met that requirement here. Therefore the Commission is unable to find that the proposed rule change is consistent with the statutory standard.

Pursuant to Section 19(b)(2) of the Exchange Act, the Commission must disapprove a proposed rule change filed by a national securities exchange if it does not find that the proposed rule change is consistent with the applicable requirements of the Exchange Act—including the requirement under Section 6(b)(5) that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices.[162]

For the reasons discussed above, BZX has not met its burden of demonstrating that the proposal is consistent with Exchange Act Section 6(b)(5),[163] and, accordingly, the Commission must disapprove the proposal.[164]

*D. Other Comments*

Comment letters also address the general nature and uses of bitcoin;[165] the state of development of bitcoin as a digital asset;[166] the state of regulation of bitcoin markets;[167] the inherent value of, and risks of investing in, bitcoin;[168] the desire (or not) of investors to gain access to bitcoin through an ETP;[169] the potential impact of Commission approval of the proposed ETP on the price of bitcoin and on bitcoin markets;[170] the potential impact of Commission approval of bitcoin ETPs on the economy, jobs, U.S. monetary policy, U.S. innovation, and/or U.S. geopolitical position;[171] the tax and/or retirement investment benefits or risks of a bitcoin ETP;[172] and the bitcoin network's effect on the environment.[173] Ultimately, however, additional discussion of these topics is unnecessary, as they do not bear on the basis for the Commission's decision to disapprove the proposal.

*E. The Exchange's Untimely Amendments to the Proposal*

The deadline for rebuttal comments in response to the Order Instituting Proceedings was July 28, 2021.[174] On September 30, 2021, the Exchange filed Amendment No. 1 to the proposed rule change and withdrew it on October 1, 2021. On October 1, 2021, the Exchange filed Amendment No. 2 with the Commission to amend and replace in its entirety Amendment No. 1 to the proposal as submitted on September 30, 2021, and as originally submitted on March 1, 2021. Subsequently, on November 4, 2021, the Exchange filed Amendment No. 3 with the Commission to amend and replace in its entirety Amendment No. 2 to the proposal as submitted on October 1, 2021, and as originally submitted on March 1, 2021. Because these amendments were filed months after the deadline for comments on the proposed rule change, the Commission deems Amendments No. 1, 2, and 3 to have been untimely filed.

Even if these amendments had been timely filed, the Commission would still conclude that the Exchange has not met its burden to demonstrate that its proposal is consistent with Exchange Act Section 6(b)(5). The primary change that the Exchange makes in the amendments is to argue that it would be inconsistent for the Commission to allow the launch of exchange-traded funds registered under the Investment Company Act of 1940 (''1940 Act'') that provide exposure to bitcoin through CME bitcoin futures (''Bitcoin Futures ETFs'') while disapproving this proposal.

In the amendments, the Exchange asserts that, if the Commission does not deem the CME bitcoin futures market a regulated market of significant size, permitting Bitcoin Futures ETFs to list and trade would be inconsistent with the requirement under the Exchange Act—namely, the requirement that the listing and trading of the Bitcoin Futures ETFs be designed to prevent fraudulent and manipulative acts and practices as articulated in the

[160] *See* SolidX Order, 82 FR 16259.

[161] *See supra* note 135.

[162] *See* 15 U.S.C. 78s(b)(2)(C).

[163] 15 U.S.C. 78f(b)(5).

[164] In disapproving the proposed rule change the Commission has considered its impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f). Three commenters argue that, for competitive reasons, the Commission should approve several bitcoin-based ETPs together. *See* Zoican Letter; letters from: Jared Henry, dated March 18, 2021 (''Henry Letter''); Ge De, dated July 4, 2021 (''Ge De Letter''). The Zoican Letter states that network externalities are particularly strong for exchange-traded funds with identical underlying portfolios, conferring large advantages to the first mover by enabling it to command higher management fees than subsequent entrants. According to this commenter, this effect leads to segmentation of investors, with short-horizon traders preferring liquid products and long-horizon investors focusing on cheaper products. This commenter believes that allowing for several products to be launched simultaneously would help investors coordinate on the product with the lowest fees, stimulating both liquidity and competition on management fees between issuers.

Another commenter argues, for efficiency reasons, against approving a bitcoin ETP. This commenter asserts that the adoption of multiple digital assets would force merchants to deal with ''complexity [that] doesn't foster [the] modularity which is needed to gain economic efficiency.'' *See* Ciao Letter at 1.

For the reasons discussed throughout, however, *see supra* note 38, the Commission is disapproving the proposed rule change because it does not find that the proposed rule change is consistent with the Exchange Act. *See also* USBT Order, 85 FR 12615.

[165] *See, e.g.,* Eddie Letter; Anonymous 6 Letter; Pile Letter; Ciao Letter; Ge De Letter; letters from: Anonymous, dated March 27, 2021 (''Anonymous 1 Letter''); Sam Ahn, dated April 8, 2021; Darrin Donithorne, dated April 10, 2021 (''Donithorne Letter''); JC, dated May 16, 2021 (''JC Letter''); Lourdes Ciao, dated June 2, 2021; Anonymous, dated June 10, 2021; Roger Lowenstein, dated June 28, 2021 (''Lowenstein Letter'').

[166] *See, e.g.,* Ellis Letter; Gemini Letter at 1–2; letters from: Courtney, dated April 1, 2021; Nicolas Casal, dated June 9, 2021; James Cook, dated June 17, 2021 (''Cook Letter''); Jason Green, dated June 17, 2021 (''Green Letter'').

[167] *See, e.g.,* Bofman Letter; Aronesty Letter; Pile Letter.

[168] *See, e.g.,* Bofman Letter; Rye Letter; Lowenstein Letter; Havermann Letter; Apodaca Letter; letters from: Bradley M. Kuhn, dated April 15, 2021 (''Kuhn Letter''); Anonymous, dated May 7, 2021 (''Anonymous 2 Letter''); James Monroe, dated June 7, 2021; Ken Morgan, dated June 17, 2021; Sam Ahn, dated July 14, 2021.

[169] *See, e.g.,* Henry Letter; Anonymous 1 Letter; Kuhn Letter; Bofman Letter; Cook Letter; Ailshie Letter; Gemini Letter at 1–2; letters from: Michael Ort, dated April 10, 2021; Chez, dated June 16, 2021; Anonymous, dated June 16, 2021 (''Anonymous 8 Letter''); Bill Meyers, dated June 16, 2021; Jarron Jackson, dated June 16, 2021; Jacob, dated June 16, 2021 (''Jacob Letter''); Charles E. Haluska, dated June 17, 2021; Travis, dated June 17, 2021; Scott Davis, dated June 23, 2021; Ryan I, dated June 27, 2021.

[170] *See, e.g.,* Green Letter; Ailshie Letter; Aronesty Letter; letter from Steve Condrill, dated July 4, 2021.

[171] *See, e.g.,* Donithorne Letter; Anonymous 2 Letter; Bofman Letter; Anonymous 8 Letter; Jacob Letter; Kim Letter; Ciao Letter; Aroca Letter; Apodaca Letter; letters from: Chris McMurphy, dated April 2, 2021 (''McMurphy Letter''); Praveen Javali, dated April 9, 2021; Khaled Khan, dated April 20, 2021; Ramesh Patel, dated June 16, 2021; Anonymous, dated June 21, 2021.

[172] *See, e.g.,* Kuhn Letter; JC Letter; Rose Letter; Ciao Letter; Lowenstein Letter; Havermann Letter; Apodaca Letter.

[173] *See, e.g.,* Eddie Letter; Donithorne Letter; McMurphy Letter; Ge De Letter; letter from Anonymous, dated June 10, 2021.

[174] *See supra* note 7.

Winklevoss Order and other disapproval orders. The Exchange states that, while one may argue that the 1940 Act provides certain investor protections, those protections relate primarily to the composition of board of directors, limitations on leverage, and transactions with affiliates, among others, and thus do not confer additional protections to investors in relation to the underlying CME bitcoin futures market to justify different regulatory outcomes for Bitcoin Futures ETFs and non-1940 Act-regulated ETPs that hold spot bitcoin. The Exchange also adds that the largest Bitcoin Futures ETF has contracts representing about 37 percent of open interest in CME bitcoin futures, which, according to the Exchange, ''seems to directly contradict'' the ''predominant influence'' prong in establishing whether the CME bitcoin futures market constitutes a market of significant size.

The Commission disagrees with the premise of the Exchange's argument. The proposed rule change does not relate to a product regulated under the 1940 Act, nor does it relate to the same underlying holdings as the Bitcoin Futures ETFs. The Commission considers the proposed rule change on its own merits and under the standards applicable to it. Namely, with respect to this proposed rule change, the Commission must apply the standards as provided by Section 6(b)(5) of the Exchange Act, which it has applied in connection with its orders considering previous proposals to list bitcoin-based commodity trusts and bitcoin-based trust issued receipts.[175] Accordingly, even if the Exchange's Amendments No. 1, 2, and 3 had been timely filed, there is no additional information in such amendments that would enable the Commission to approve the proposed rule change as amended.

## IV. Conclusion

For the reasons set forth above, the Commission does not find, pursuant to Section 19(b)(2) of the Exchange Act, that the proposed rule change is consistent with the requirements of the Exchange Act and the rules and regulations thereunder applicable to a national securities exchange, and in particular, with Section 6(b)(5) of the Exchange Act.

*It is therefore ordered,* pursuant to Section 19(b)(2) of the Exchange Act, that proposed rule change SR–CboeBZX–2021–019 be, and hereby is, disapproved.

[175] *See supra note* 11.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[176]

**J. Matthew DeLesDernier,**

*Assistant Secretary.*

[FR Doc. 2021–25129 Filed 11–17–21; 8:45 am]

**BILLING CODE 8011–01–P**

[176] 17 CFR 200.30–3(a)(12).

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## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–93560; File No. SR–IEX–2021–15]**

## Self-Regulatory Organizations; Investors Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Make Juneteenth National Independence Day a Holiday of the Exchange

November 12, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 9, 2021, the Investors Exchange LLC (''IEX'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

### I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

Pursuant to the provisions of Section 19(b)(1) under the Act,[3] and Rule 19b–4 thereunder,[4] IEX is filing with the Commission a proposed rule change to amend IEX Rule 11.110 (Hours of Trading and Trading Days) to make Juneteenth National Independence Day a holiday of the Exchange. Juneteenth National Independence Day was designated a legal public holiday in June 2021. The Exchange has designated this rule change as ''non-controversial'' under Section 19(b)(3)(A) of the Act[5] and provided the Commission with the notice required by Rule 19b–4(f)(6) thereunder.[6]

The text of the proposed rule change is available at the Exchange's website at *www.iextrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(1).

[4] 17 CFR 240.19b–4.

[5] 15 U.S.C. 78s(b)(3)(A).

[6] 17 CFR 240.19b–4.

### 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 statement may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

*A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

1. Purpose

The Exchange proposes to amend IEX Rule 11.110 (Hours of Trading and Trading Days) to make Juneteenth National Independence Day a holiday of the Exchange. This rule filing is based on a proposal recently submitted by the New York Stock Exchange LLC (''NYSE'') and its affiliated exchanges.[7] On June 17, 2021, Juneteenth National Independence Day was designated a legal public holiday.[8] Consistent with industry sentiment,[9] the approach recommended by the Securities Industry and Financial Markets Association (''SIFMA''),[10] and IEX's own determination that IEX's rules should recognize this important date in American history, the Exchange proposes to add ''Juneteenth National Independence Day'' to the existing list of holidays in paragraph (b) of IEX Rule 11.110. As a result, the Exchange will not be open for business on Juneteenth National Independence Day, which falls on June 19 of each year. In accordance with paragraph (b) of IEX Rule 11.110, when the holiday falls on a Saturday, the Exchange will not be open for business on the preceding Friday, and when it falls on a Sunday, the Exchange will not be open for business on the

[7] *See* Securities Exchange Act Release No. 93183 (September 30, 2021), 86 FR 55068 (October 5, 2021) (SR–NYSE–2021–56) (amending NYSE Rule 7.2 to include Juneteenth as an exchange holiday).

[8] Public Law 117–17.

[9] *See, e.g.,* Bank of America Makes Juneteenth a Holiday, Joining JPMorgan, Wells Fargo.

[10] SIFMA recommends a full market close in observance of Juneteenth National Independence Day. *See* SIFMA Revises 2022 Fixed Income Market Close Recommendations in the U.S. to Include Full Close for Juneteenth National Independence Day.

following Monday, unless otherwise indicated by the Exchange.[11]

Accordingly, as proposed paragraph (b) of IEX Rule 11.110 would be revised to read as follows (proposed additions *underlined*):

The Exchange will be open for the transaction of business on business days. The Exchange will not be open for business on the following holidays: New Year's Day, Dr. Martin Luther King Jr. Day, Presidents Day, Good Friday, Memorial Day, *Juneteenth National Independence Day,* Independence Day, Labor Day, Thanksgiving Day, and Christmas. When any holiday observed by the Exchange falls on a Saturday, the Exchange will not be open for business on the preceding Friday. When any holiday observed by the Exchange falls on a Sunday, the Exchange will not be open for business on the following Monday, unless otherwise indicated by the Exchange.

The Exchange also notes that several other national securities exchanges have added Juneteenth National Independence Day as an exchange holiday as well.[12]

2. Statutory Basis

IEX believes that the proposed rule change is consistent with the provisions of Section 6(b)[13] of the Act in general, and furthers the objectives of Section 6(b)(5) of the Act[14] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

Specifically, the Exchange believes that the proposed change would remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, protect investors and the public interest because the proposed amended rule would clearly state that the Exchange will not be open for business on Juneteenth National Independence Day, which is a federal holiday, and would address what day would be taken off if June 19 fell on a Saturday or Sunday. The change would thereby promote clarity and transparency in the Exchange rules by updating the list of holidays of the Exchange.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

IEX does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed correction does not impact competition in any respect since it is designed to simply amend the Exchange rule regarding holidays.

*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[15] and Rule 19b–4(f)(6)(iii) thereunder.[16]

A proposed rule change filed under Rule 19b–4(f)(6)[17] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[18] the Commission may 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 prior to 30 days after the date of the filing. The Exchange states that waiver of the operative delay would be consistent with the protection of investors and the public interest because the proposed rule change, as described above, would state that the Exchange will not be open for business on Juneteenth National Independence Day, which is a federal holiday, and would address what day would be taken off if June 19 fell on a Saturday or Sunday. The Exchange further states that the proposed change does not raise any new or novel issues. 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. Accordingly, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.[19]

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 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–IEX–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–IEX–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

[11] The Exchange might otherwise indicate if unusual business conditions exist such as the ending of a monthly or yearly accounting period.

[12] *See* BOX Exchange LLC Rule 7020(e); Miami International Securities Exchange LLC Rule 501; MIAX Emerald, LLC Rule 501; MIAX Pearl, LLC Rule 501; NYSE Rule 7.2; NYSE American LLC Rule 7.2E; NYSE Arca, Inc. Rules 7.2–E and 7.2–O; NYSE Chicago, Inc. Rule 7.2 and NYSE National Rule 7.2.

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(5).

[15] 15 U.S.C. 78s(b)(3)(A).

[16] 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.

[17] 17 CFR 240.19b–4(f)(6).

[18] 17 CFR 240.19b–4(f)(6)(iii).

[19] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

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–IEX–2021–15, and should be submitted on or before December 9, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

**J. Matthew DeLesDernier,**

*Assistant Secretary.*

[FR Doc. 2021–25128 Filed 11–17–21; 8:45 am]

**BILLING CODE 8011–01–P**

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–93562; File No. SR–BOX–2021–26]**

## Self-Regulatory Organizations; BOX Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fee Schedule on the BOX Options Market LLC Facility

November 12, 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 October 28, 2021, BOX Exchange LLC (''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange filed the proposed rule change pursuant to Section 19(b)(3)(A)(ii) of the Act,[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposal effective upon filing with the Commission. 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 is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to amend the Fee Schedule on the BOX Options Market LLC (''BOX'') options facility. While changes to the fee schedule pursuant to this proposal will be effective upon filing, the changes will become operative on November 1, 2021. 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://boxexchange.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 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 Section II.A. (QOO Order Fees) and Section II.C. (QOO Order Rebate) of the BOX Fee Schedule. Specifically, the Exchange proposes to amend Section II.A. (QOO Order Fees) to remove the QOO Order fee cap of $75,000 per month per Broker Dealer and Section II.C. (QOO Order Rebate) to remove the QOO Order rebate cap of $30,000 per month per Broker Dealer.

Currently, QOO Order fees for Broker Dealers on BOX are capped at $75,000 per month per Broker Dealer. The Exchange proposes to eliminate this monthly QOO Order fee cap for Broker Dealers. The fee cap was intended to incentivize Broker Dealers to submit floor transactions on the Exchange by capping manual transaction fees. The Exchange no longer believes such fee cap is necessary because, as discussed herein, the fee cap was initially established to incentivize Broker Dealers to bring increased liquidity and order flow to the new BOX Trading Floor, however the BOX Trading Floor is now well established and does not need this incentive to encourage order flow to the Trading Floor.

The Exchange also applies a QOO Order rebate cap of $30,000 per month per Broker Dealer. Currently, Floor Brokers are eligible to receive a $0.075 per contract rebate for all Broker Dealer and Market Maker QOO Orders presented on the BOX Trading Floor.[5] The rebate is not applied to Public Customer executions, executions subject to the Strategy QOO Order Fee Cap, or Broker Dealer executions where the Broker Dealer is facilitating a Public Customer. The Exchange proposes to remove the monthly rebate cap for Broker Dealer executions.[6] The Exchange notes that it is not making any other changes to the QOO Order fees or the QOO Order Rebate. The QOO Order fees and QOO Order rebate will be assessed and applied in the same manner as they are today.

2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirements of Section 6(b) of the Act, in general, and Section 6(b)(4) and 6(b)(5) of the Act,[7] in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among BOX Participants and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange believes that the proposed elimination of the QOO Order fee cap of $75,000 per month per Broker Dealer and the QOO Order rebate cap of $30,000 per month per Broker Dealer is reasonable, equitable, and not unfairly discriminatory. As discussed above, the Exchange established the QOO Order fee cap and rebate cap in an effort to incentivize market participants to send order flow to the BOX Trading Floor. The Exchange believes such incentive is no longer necessary because the Exchange has a well-established trading floor and no longer needs this incentive to encourage increased order flow to the BOX Trading Floor.

[20] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] Floor Brokers are also eligible to receive a $0.05 per contract rebate for all Professional Customer QOO Orders presented on the BOX Trading Floor.

[6] The Exchange notes that BOX has removed the QOO Order rebate cap in the past. *See* Securities Exchange Act Release No. 87704 (December 10, 2019), 84 FR 68499 (December 16, 2019) (SR–BOX–2019–35).

[7] 15 U.S.C. 78f(b)(4) and (5).

QOO Order Fee Cap

The Exchange established the QOO Order fee cap of $75,000 per month per Broker Dealer in 2017 when the Exchange introduced fees for Manual Transactions after the approval of the BOX Trading Floor.[8] The Exchange established the QOO Order fee cap for Broker Dealers to incentivize Broker Dealers to bring increased liquidity and order flow to the new BOX Trading Floor.

The Exchange believes that removing the $75,000 monthly cap on QOO Order Fees for Broker Dealers is reasonable and appropriate because, as discussed above, these fee caps were introduced to provide incentives for Broker Dealers to bring increased liquidity and order flow to the BOX Trading Floor. The Exchange no longer believes such incentive is necessary. As such, the Exchange believes the removal of the QOO Order fee cap is reasonable.

The Exchange believes the removal of the QOO Order fee cap is not unfairly discriminatory because Public Customer, Market Maker, and Professional Customer order fees are not subject to the fee cap. Additionally, the QOO Order Fees will continue to be applied in the same manner as they are today. Further, the Exchange believes that the removal of the monthly QOO Order fee cap for Broker Dealer executions is equitable and not unfairly discriminatory because the proposal applies to all similarly situated market participants.

QOO Order Rebate Cap

BOX established the QOO Order Rebate program and the monthly rebate cap in August 2017. As discussed in BOX's 2017 proposal to establish the QOO Order Rebate program and rebate cap, the rebate was created to incentivize order flow to the BOX Trading Floor. Unlike competing exchanges, the Exchange does not offer a front-end order entry on the BOX Trading Floor. With this, Participants have two possible means of bringing orders to the Exchange's Trading Floor for possible execution: (1) They can invest in the technology, systems and personnel to participate on the Trading Floor and deliver the order to the Exchange matching engines for validation and execution; or (2) they can utilize the services of another Participant acting as a Floor Broker. The QOO Order Rebate program was established to attract order flow by rewarding Floor Brokers with rebates for directing qualifying orders to the BOX Trading Floor.

The Exchange believes that removing the rebate cap is reasonable and appropriate as it will continue to allow Floor Brokers to price their services at a level that would enable them to attract increased QOO order flow from market participants who might otherwise utilize the front-end order entry mechanism offered by the Exchange's competitors, instead of incurring the cost in time and resources to install and develop their own internal systems to deliver QOO orders directly to the Exchange system. As such, the Exchange believes it is beneficial from a competitive standpoint to continue to offer the rebate to the executing Floor Broker on a QOO order without capping the dollar amount allowed for the rebate. Further, the Exchange believes removing the rebate cap will encourage Floor Brokers to bring additional QOO order flow to the Exchange because Floor Brokers will be further incentivized by the removal of the QOO Order rebate cap for these specific QOO orders. Lastly, the Exchange believes the proposed change is reasonable and appropriate, as the Exchange is allowing eligible Floor Brokers greater opportunities to price their services related to the execution of qualifying QOO transactions more competitively.

In addition, the Exchange believes that removing the QOO Order rebate cap is reasonable as a competing exchange with a similar rebate program offered to Floor Brokers currently has a rebate cap twelve times higher than the QOO Order rebate cap on BOX.[9]

The Exchange believes that the removal of the monthly rebate cap is equitable and not unfairly discriminatory because the proposal allows all similarly situated Floor Brokers to benefit from the removal of the QOO Order rebate cap. Furthermore, the Exchange believes that all market participants would benefit from additional trading opportunities generated from increased order flow due to the removal of the QOO Order rebate cap.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The 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. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges. Because competitors are free to modify their own fees in response, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is limited. For the reasons discussed above, the Exchange believes that the proposed changes do not impose an undue burden on competition. The Exchange does not believe that removing the monthly fee cap of $75,000 per Broker Dealer and the monthly rebate cap of $30,000 per month per Broker Dealer will burden competition because the Exchange capped the Manual Transaction Fees for QOO Orders and introduced the QOO Order monthly rebate cap in an effort to incentivize market participants, but such incentives are no longer necessary because the Exchange has a well-established trading floor and no longer needs these incentives to encourage increased order flow to the BOX Trading Floor.

With respect to the QOO Order rebate cap, one of the Exchange's competitors offers a QCC credit cap that is twelve times higher than the Exchange's QOO Order rebate cap.[10] In addition, as mentioned above, the Floor Broker Credit for QCC Transactions on NYSE Arca is similar to the QOO Order Rebate on BOX in that it is applied to both sides of the paired order and is directed to the Floor Broker and not to the Participant who is assessed the QOO Order fee. Moreover, similar to the BOX QOO Rebate, the NYSE Arca QCC credit is only applied when the Floor Broker executes the QCC Order manually on the NYSE Arca trading floor.

[8] *See* Securities Exchange Act Release No. 81292 (August 2, 2017), 82 FR 37144 (August 8, 2017) (SR–BOX–2016–48). *See also* Securities Exchange Act Release No. 81504 (August 30, 2017), 82 FR 42195 (September 6, 2017) (SR–BOX–2017–28).

[9] *See* NYSE Arca Options Fees and Charges, Qualified Contingent Cross (''QCC'') Transactions Fees and Credits, Footnote 13 (stating the ''maximum Floor Broker credit paid shall not exceed $375,000 per month per Floor Broker firm.''). Similar to the Floor Broker Credit for Executed QCC Transactions on NYSE Arca, the QOO Order Rebate on BOX is applied to both sides of the paired order and is directed to the Floor Broker, and not to the Participant who is assessed the QOO Order fee. Finally, similar to the BOX QOO Rebate, the NYSE Arca QCC credit is only applied when the Floor Broker executes the QCC Order manually on the NYSE Arca trading floor.

[10] *Id. See also* NASDQ PHLX (''Phlx'') Pricing Schedule, Section 4 (stating the ''maximum QCC Rebate to be paid in a given month will not exceed $550,000.''). The Exchange notes Phlx's QCC Rebate cap is over eighteen times higher than the current QOO Order rebate cap on BOX.

Further, the Exchange does not believe that removing the QOO Order rebate cap will impose an undue burden on intra-market competition because all Floor Brokers will remain eligible to transact QOO Orders and receive the same rebate. Further, the Exchange believes that the removal of the rebate cap will promote competition by allowing Floor Brokers to competitively price their services and for the Exchange to remain competitive with other exchanges. As noted above, the Exchange previously removed the monthly rebate cap in 2019.

Finally, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and credits to remain competitive with other exchanges. 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 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 Exchange Act [11] and Rule 19b–4(f)(2) thereunder,[12] because it establishes or changes a due, or fee.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend the rule change if it appears to the Commission that the action is necessary or appropriate in the public interest, for the protection of investors, or would otherwise further 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.

[11] 15 U.S.C. 78s(b)(3)(A)(ii).

[12] 17 CFR 240.19b–4(f)(2).

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–2021–26 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–BOX–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 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–2021–26, and should be submitted on or before December 9, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

**J. Matthew DeLesDernier,**

*Assistant Secretary.*

[FR Doc. 2021–25126 Filed 11–17–21; 8:45 am]

**BILLING CODE 8011–01–P**

[13] 17 CFR 200.30–3(a)(12).

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–93565; File No. SR–NYSECHX–2021–17]**

## Self-Regulatory Organizations; NYSE Chicago, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Fee Schedule of NYSE Chicago, Inc. Regarding Colocation Services

November 12, 2021.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act''),[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on November 3, 2021, the NYSE Chicago, Inc. (''NYSE Chicago'' 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 the Fee Schedule of NYSE Chicago, Inc. (''Fee Schedule'') regarding colocation services and fees to provide Users with wireless connectivity to CME Group market data. 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

*A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

1. Purpose

The Exchange proposes to amend the Fee Schedule regarding colocation services and fees to provide Users [4] with wireless connectivity to CME Group market data.[5]

The Exchange currently provides Users with wireless connections to eight market data feeds or combinations of feeds from third party markets (the ''Existing Third Party Data''),[6] and wired connections to 43 market data feeds.[7] The Exchange now proposes to add to its Fee Schedule wireless connections to CME Group, Inc. (''CME Group'') market data (such data, ''CME Group Data'' and, together with the Existing Third Party Data, the ''Third Party Data''). Users would be offered the proposed wireless connection to the CME Group Data through connections into the colocation center in the Mahwah, New Jersey data center (''Data Center'').[8]

The Exchange expects that the proposed rule change would become operative no later than March 31, 2022. The Exchange will announce the date that the wireless connection to the CME Group Data will be available through a customer notice.

To receive CME Group Data, the User would enter into an agreement with a non-Exchange affiliated party for permission to receive the data, if required. The User would pay this third party any fees for the data content.

For each wireless connection to CME Group Data, a User would be charged a $5,000 non-recurring initial charge and a monthly recurring charge of $6,000. The Exchange proposes to revise its Fee Schedule to reflect fees related to the wireless connection to CME Group Data.

The CME Group Data would not include all possible CME Group data feeds. There is limited bandwidth available on the wireless network to co-location, and there are currently dozens of CME Group data feeds. To provide connectivity to all of them would use a large amount of bandwidth.

Accordingly, rather than provide connectivity to all possible symbols included in the CME Group data feeds, the wireless connection would only provide connectivity to a selection of CME Group market data for which IDS determines there is User demand. IDS similarly provides connectivity to a selection of data, rather than entire feeds, over a wireless connection to the Markham, Canada third party data center.[9] The User would then determine the symbols for which it would receive data, which could include data regarding some or all of the symbols for which IDS provides connectivity.[10] The Exchange would not have visibility into which portion of the CME Group Data a given User receives.

As with the Existing Third Party Data, if a User purchased two wireless connections, it would pay two non-recurring initial charges. Each wireless connection would include the use of one port for connectivity to CME Group Data. A User would not pay a fee for the use of such port. If a User also connects to Existing Third Party Data, it would not be able to use the same port that it uses for connectivity to CME Group Data to connect to such Existing Third Party Data. Accordingly, a User that connects to both CME Group Data and Existing Third Party Data would have at least two ports, and would not be separately charged for two ports.[11]

Application and Impact of the Proposed Changes

The proposed changes would not apply differently to distinct types or sizes of market participants. Rather, they would apply to all Users equally.

As is currently the case, the purchase of any co-location service, including connectivity to Third Party Data, is completely voluntary and the Fee Schedule is applied uniformly to all Users.

Competitive Environment

Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data using other methods: From another User, a third party wireless connection, or through an IDS or third party fiber connection.

Based on the information available to it, the Exchange believes that at least one market participant provides wireless connectivity to CME Group market data in the Data Center. The Exchange believes that the wireless connection offered by this third party entity provides connectivity at the same or similar speed as the proposed connection to CME Group Data, and at the same or similar cost.[12] The proposed connection to CME Group Data and the existing third party wireless connection to CME Group Data would follow the same route within the Data Center: They would both enter through a meet-me-room, connect to equipment in co-location, and then connect to any Users that are customers. Because of this, the Exchange does not believe that IDS has an advantage over the third party in providing the connectivity. The proposed wireless connection would lead to a pole, from where a fiber connection would lead into the Data Center. The pole is owned by a third party and is not on the grounds of the Data Center.

IDS already offers fiber connections to CME Group market data to Users.[13] The Exchange also believes that at least two third party market participants offer such fiber connections to CME Group market data. In addition to these options, a User may create a proprietary wireless connection or connect through another User in order to connect to CME

[4] 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. 87408 (October 28, 2019), 84 FR 58778 (November 1, 2019) (SR–NYSECHX–2019–27). 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–NYSE–2021–67, SR–NYSEAMER–2021–43, SR–NYSEArca–2021–97, and SR–NYSENAT–2021–23.

[5] The Exchange initially filed rule changes relating to its co-location services with the Securities and Exchange Commission (''Commission'') in 2019. *See* 84 FR 58778, *supra* note 4.

[6] *See id.,* at 58784–58785.

[7] *See id.,* at 58787–58788.

[8] Through its ICE Data Services (''IDS'') business, Intercontinental Exchange, Inc. (''ICE'') operates the Data Center in Mahwah, New Jersey. The Exchange and the Affiliate SROs are indirect subsidiaries of ICE. The proposed service would be provided by IDS pursuant to an agreement with a non-ICE entity. IDS does not own the wireless network that would be used to provide the service.

[9] *See* Securities Exchange Act Release No. 88240 (February 19, 2020), 85 FR 10795 (February 25, 2020) (SR–NYSECHX–2020–05). *See also* Securities Exchange Act Release No. 90209 (October 15, 2020), 85 FR 67044 (October 21, 2020) (SR–NYSE–2020–05, SR–NYSEAMER–2020–05, SR–NYSEArca–2020–08, SR–NYSECHX–2020–02, SR–NYSENAT–2020–03, SR–NYSE–2020–11, SR–NYSEAMER–2020–10, SR–NYSEArca–2020–15, SR–NYSECHX–2020–05, SR–NYSENAT–2020–08).

[10] The Exchange understands that the third parties that provide wireless connectivity to CME Group market data to the Data Center and other data centers in New Jersey follow a substantially similar model, offering connectivity to a selection of market data rather than entire feeds.

[11] If a User purchased a wireless connection to CME Group Data, that connection would include the use of one port for connectivity to CME Group Data. If the same User connected to Existing Third Party Data, it would receive the use of one port for connectivity to the Existing Third Party Data. It would not be separately charged for such ports. A User may purchase additional ports. *See* 84 FR 58778, *supra* note 4, at 58782.

[12] Because the third party is not a regulated entity, it is not obligated to make its latency figures or fees publicly available or the same for all entities.

[13] *See id.,* at 58788.

Group market data. The Exchange believes that at least two market participants already provide wireless connectivity to CME Group market data to other data centers in New Jersey.

Wireless connections involve beaming signals through the air between antennas that are within line of sight of one another. Because the signals travel a straight, unimpeded line, and because light waves travel faster through air than through glass (fiber optics), wireless messages have lower latency than messages travelling through fiber optics. At the same time, as a general rule wireless networks have less uptime than fiber networks. Wireless networks are directly and immediately affected by adverse weather conditions, which can cause message loss and outage periods. Wireless networks cannot be configured with redundancy in the same way that fiber networks can. As a result, an equipment or weather issue at any one location on the network will cause the entire network to have an outage. In addition, maintenance can take longer than it would with a fiber based network, as the relevant tower may be in a hard to reach location, or weather conditions may present safety issues, delaying technicians servicing equipment. Even under normal conditions, a wireless network will have a higher error rate than a fiber network of the same length.

The latency of a wireless network depends on several factors. Variables include the wireless equipment utilized; the route of, and number of towers or buildings in, the network; their proximity to the data centers on either end; and the fiber equipment used at either end of the connection. Moreover, latency is not the only consideration that a customer may have in selecting a wireless network to connect to CME Group market data. Other considerations may include the amount of network uptime; the equipment that the network uses; the cost of the connection; and the applicable contractual provisions. Indeed, fiber network connections may be more attractive to some market participants as they are more reliable and less susceptible to weather conditions.

The Exchange operates in a highly competitive market in which exchanges and other vendors (*e.g.,* Hosting Users) offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [14]

The proposed change is not otherwise intended to address any other issues relating to co-location services and/or related fees, and the Exchange is not aware of any problems that Users 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,[15] in general, and furthers the objectives of Section 6(b)(5) of the Act,[16] 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,[17] 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 Proposed Change Is Reasonable

The Exchange believes that the proposed rule change is reasonable.

The wireless connection would provide Users with an alternative means of connectivity to CME Group Data. The proposed change would provide Users with an additional choice with respect to the form and optimal latency of the connectivity they use to receive CME Group market data, allowing a User to select the connectivity that better suits its needs, helping it tailor its colocation operations to the requirements of its business operations. Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data using other methods: From another User, a third party wireless connection, or through an IDS or third party fiber connection.

Based on the information available to it, the Exchange believes that at least one market participant provides wireless connectivity to CME Group market data in the Data Center. The Exchange believes that the wireless connection offered by this third party entity provides connectivity at the same or similar speed as the proposed connection to CME Group Data, and at the same or similar cost. The proposed connection to CME Group Data and the existing third party wireless connection to CME Group Data would follow the same route within the Data Center: They would both enter through a meet-me-room, connect to equipment in co-location, and then connect to any Users that are customers. Because of this, the Exchange does not believe that IDS has an advantage over the third party in providing the connectivity. The proposed wireless connection would lead to a pole, from where a fiber connection would lead into the Data Center. The pole is owned by a third party and is not on the grounds of the Data Center.

IDS already offers fiber connections to CME Group market data to Users.[18] The Exchange also believes that at least two third party market participants offer such fiber connections to CME Group. In addition to these options, a User may create a proprietary wireless connection or connect through another User in order to connect to CME Group market data. The Exchange believes that at least two market participants already provide wireless connectivity to CME Group market data to other data centers in New Jersey.

Market participants' considerations in determining what connectivity to purchase may include latency; the amount of network uptime; the equipment that the network uses; the cost of the connection; and the applicable contractual provisions. Indeed, fiber network connections may be more attractive to some market participants as they are more reliable and less susceptible to weather conditions.

The Exchange believes that it is reasonable to not transport information for all of the symbols included in CME Group data feeds to the Data Center, but

[14] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[15] 15 U.S.C. 78f(b).

[16] 15 U.S.C. 78f(b)(5).

[17] 15 U.S.C. 78f(b)(4).

[18] *See* 84 FR 58778, *supra* note 4, at 58788.

rather to transport a subset of that data. There is limited bandwidth available on the wireless network to co-location, and there are a number of CME Group data feeds. Limiting the feeds to the selection of CME Group market data regarding securities for which IDS determines there is demand would allow Users to receive the relevant CME Group Data over a wireless network, which could include data regarding some or all of the symbols for which IDS provides connectivity. The User would then determine those symbols for which it will receive data.

The Exchange believes that it is reasonable that a User that has already purchased wireless connections to other Third Party Data would be charged a non-recurring charge when it purchases a wireless connection to the CME Group Data, because it would allow the Exchange to defray or cover certain costs it incurs in installing the wireless connection to the CME Group Data, which costs it incurs irrespective of whether the User has existing wireless connections to Third Party Data, while providing the User the benefit of the installation, which would allow it to receive CME Group Data within co-location and with a lower latency over the fiber optics option. To do the initial installation, the Exchange must provide the personnel required for initial installation and testing. The costs associated with installing wireless connections are incrementally higher than those associated with installing fiber optics-based solutions.

The Exchange believes that it is reasonable that a User that connects to both CME Group Data and Existing Third Party Data may not use the same port for connectivity to both, and so would have at least two ports, because the proposed wireless connection would include the use of one port for connectivity to CME Group Data and connectivity to the Existing Third Party Data includes the use of one port for connectivity to Existing Third Party Data. A User would not pay a separate fee for using such ports.

The Exchange believes the proposed pricing for the wireless connection to CME Group Data is reasonable because it would allow the Exchange to defray or cover the costs associated with offering Users a wireless connection to CME Group Data while providing Users the benefit of receiving CME Group Data within co-location and with a lower latency over the fiber optics option. The wireless connection for CME Group Data would allow Users to select the CME Group Data connectivity option that better suits their needs.

The Exchange believes that the proposed pricing is reasonable because the Exchange proposes to offer the wireless connection to CME Group Data described herein as a convenience to Users, but in order to do so must provide, maintain and operate the Data Center facility hardware and technology infrastructure. The Exchange must handle the installation, administration, monitoring, support and maintenance of such services, including by responding to any production issues. Since the inception of co-location, the Exchange has made numerous improvements to the network hardware and technology infrastructure and has established additional administrative controls. The Exchange has expanded the network infrastructure to keep pace with the increased number of services available to Users. Specifically, in order to offer wireless connections, the Exchange must install, test, maintain and operate the wireless equipment.

The Proposed Change Is Not Unfairly Discriminatory

The Exchange believes that the proposed rule change is not unfairly discriminatory for the following reasons.

Without this proposed rule change, Users would have fewer options for connectivity to CME Group Data. The proposed change would provide Users with an additional choice with respect to the form and optimal latency of the connectivity they use to receive CME Group market data, allowing a User to select the connectivity that better suits its needs, helping it tailor its colocation operations to the requirements of its business operations. Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data using other methods: From another User, a third party wireless connection, or through an IDS or third party fiber connection.

The Exchange believes that it is not unfairly discriminatory to not transport information for all of the symbols included in CME Group data feeds to the Data Center, but rather to transport a subset of that data. There is limited bandwidth available on the wireless network to co-location, and there are a number of CME Group data feeds. Limiting the feeds to the selection of CME Group market data regarding securities for which IDS determines there is demand would allow Users to receive the relevant CME Group Data over a wireless network. The User would then determine those symbols for which it will receive data, which could include data regarding some or all of the symbols for which IDS provides connectivity.

The Exchange believes that the proposed pricing is not unfairly discriminatory because the Exchange proposes to offer the wireless connection to CME Group Data described herein as a convenience to Users, but in order to do so must provide, maintain and operate the Data Center facility hardware and technology infrastructure. The Exchange must handle the installation, administration, monitoring, support and maintenance of such services, including by responding to any production issues. Since the inception of co-location, the Exchange has made numerous improvements to the network hardware and technology infrastructure and has established additional administrative controls. The Exchange has expanded the network infrastructure to keep pace with the increased number of services available to Users. Specifically, in order to offer wireless connections, the Exchange must install, test, maintain and operate the wireless equipment.

The Exchange believes that the proposed change is not unfairly discriminatory because it will result in fees being charged only to Users that voluntarily select to receive the corresponding services and because those services will be available to all Users. Furthermore, the Exchange believes that the services and fees proposed herein are not unfairly discriminatory because, in addition to the services being completely voluntary, they are available to all Users on an equal basis (*i.e.,* the same products and services are available to all Users). All Users that voluntarily select wireless connections to CME Group Data would be charged the same amount for the same services.

Users that opt to use wireless connections to CME Group Data would receive the CME Group Data that is available to all Users, as all market participants that contract with CME Group or its affiliate for CME Group Data, as required, may receive it.

The Proposed Change Is an Equitable Allocation of Fees and Credits

The Exchange believes that its proposal equitably allocates its fees among Users.

Without this proposed rule change, Users would have fewer options for connectivity to CME Group Data. The proposed change would provide Users with an additional choice with respect to the form and optimal latency of the connectivity they use to receive CME Group market data, allowing a User to select the connectivity that better suits

its needs, helping it tailor its colocation operations to the requirements of its business operations. Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data using other methods: From another User, a third party wireless connection, or through an IDS or third party fiber connection.

The Exchange believes that the proposed change is equitable because it will result in fees being charged only to Users that voluntarily select to receive the corresponding services and because those services will be available to all Users. Furthermore, the Exchange believes that the services and fees proposed herein are equitably allocated because, in addition to the services being completely voluntary, they are available to all Users on an equal basis (*i.e.,* the same products and services are available to all Users). All Users that voluntarily select wireless connections to CME Group Data would be charged the same amount for the same services.

The Exchange operates in a highly competitive market in which exchanges offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. Accordingly, fees charged for co-location services are constrained by the active competition for the order flow of, and other business from, such market participants. If a particular exchange charges excessive fees for co-location services, affected market participants will opt to terminate their co-location arrangements with that exchange, and adopt a possible range of alternative strategies, including placing their servers in a physically proximate location outside the exchange's data center (which could be a competing exchange), or pursuing strategies less dependent upon the lower exchange-to-participant latency associated with co-location. Accordingly, the exchange charging excessive fees would stand to lose not only co-location revenues but also the liquidity of the formerly co-located trading firms, which could have additional follow-on effects on the market share and revenue of the affected exchange.

For the reasons above, the proposed changes do not unfairly discriminate between or among market participants that are otherwise capable of satisfying any applicable co-location fees, requirements, terms and conditions established from time to time by the Exchange.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange believes that the proposal will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of Section 6(b)(8) of the Act.[19]

The proposed change does not affect competition among national securities exchanges or among members of the Exchange, but rather between IDS and its commercial competitors.

The wireless connection would provide Users with an alternative means of connectivity to CME Group Data. The proposed change would provide Users with an additional choice with respect to the form and optimal latency of the connectivity they use to receive CME Group market data, allowing a User to select the connectivity that better suits its needs, helping it tailor its colocation operations to the requirements of its business operations.

Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data using other methods: From another User, a third party wireless connection, or through an IDS or third party fiber connection. Based on the information available to it, the Exchange believes that at least one market participant provides wireless connectivity to CME Group market data in the Data Center. The Exchange believes that the wireless connection offered by this third party entity provides connectivity at the same or similar latency as the proposed connection to CME Group Data, and at the same or similar cost. The proposed connection to CME Group Data and the existing third party wireless connection to CME Group Data would follow the same route within the Data Center: They would both enter through a meet-me-room, connect to equipment in co-location, and then connect to any Users that are customers. Because of this, the Exchange does not believe that IDS has an advantage over the third party in providing the connectivity. The proposed wireless connection would lead to a pole, from where a fiber connection would lead into the Data Center. The pole is owned by a third party and is not on the grounds of the Data Center.

IDS already offers fiber connections to CME Group market data to Users.[20] The Exchange also believes that at least two third party market participants offer such fiber connections to CME Group. In addition to these options, a User may create a proprietary wireless connection or connect through another User in order to connect to CME Group market data. The Exchange believes that at least two market participants already provide wireless connectivity to CME Group market data to other data centers in New Jersey.

The Exchange notes that the proposed wireless connection would compete not just with other wireless connections to CME Group market data, but also with fiber network connections, which may be more attractive to some market participants as they are more reliable and less susceptible to weather conditions. Market participants' considerations in determining what connectivity to purchase may include latency; the amount of network uptime; the equipment that the network uses; the cost of the connection; and the applicable contractual provisions. As noted above, a User may purchase a fiber connection to CME Group market data from at least three providers, including IDS.

The Exchange operates in a highly competitive market in which exchanges and other vendors (*e.g.,* Hosting Users) offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [21]

*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

[19] 15 U.S.C. 78f(b)(8).

[20] *See* 84 FR 58778, *supra* note 4, at 58788.

[21] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

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 [22] and Rule 19b–4(f)(6) thereunder.[23]

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–NYSECHX–2021–17 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–2021–17. 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–2021–17, and should be submitted on or before December 9, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[24]

**J. Matthew DeLesDernier,**

*Assistant Secretary.*

[FR Doc. 2021–25123 Filed 11–17–21; 8:45 am]

**BILLING CODE 8011–01–P**

[22] 15 U.S.C. 78s(b)(3)(A).

[23] 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.

[24] 17 CFR 200.30–3(a)(12).

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## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–93563; File No. SR–NYSE–2021–67]**

## Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the New York Stock Exchange Price List Regarding Colocation Services

November 12, 2021.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act''),[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on November 3, 2021, New York Stock Exchange LLC (''NYSE'' 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.

[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 New York Stock Exchange Price List (''Price List'') regarding colocation services and fees to provide Users with wireless connectivity to CME Group market data. 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 Statutory Basis for, the Proposed Rule Change*

1. Purpose

The Exchange proposes to amend the Price List regarding colocation services and fees to provide Users [4] with wireless connectivity to CME Group market data.[5]

The Exchange currently provides Users with wireless connections to eight market data feeds or combinations of feeds from third party markets (the

[4] 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. 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 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 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–2021–43, SR–NYSEArca–2021–97, SR–NYSECHX–2021–17, and SR–NYSENAT–2021–23.

[5] 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. 62960 (September 21, 2010), 75 FR 59310 (September 27, 2010) (SR–NYSE–2010–56).

''Existing Third Party Data''),[6] and wired connections to 43 market data feeds.[7] The Exchange now proposes to add to its Price List wireless connections to CME Group, Inc. (''CME Group'') market data (such data, ''CME Group Data'' and, together with the Existing Third Party Data, the ''Third Party Data''). Users would be offered the proposed wireless connection to the CME Group Data through connections into the colocation center in the Mahwah, New Jersey data center (''Data Center'').[8]

The Exchange expects that the proposed rule change would become operative no later than March 31, 2022. The Exchange will announce the date that the wireless connection to the CME Group Data will be available through a customer notice.

To receive CME Group Data, the User would enter into an agreement with a non-Exchange affiliated party for permission to receive the data, if required. The User would pay this third party any fees for the data content.

For each wireless connection to CME Group Data, a User would be charged a $5,000 non-recurring initial charge and a monthly recurring charge of $6,000. The Exchange proposes to revise its Price List to reflect fees related to the wireless connection to CME Group Data.

The CME Group Data would not include all possible CME Group data feeds. There is limited bandwidth available on the wireless network to co-location, and there are currently dozens of CME Group data feeds. To provide connectivity to all of them would use a large amount of bandwidth.

Accordingly, rather than provide connectivity to all possible symbols included in the CME Group data feeds, the wireless connection would only provide connectivity to a selection of CME Group market data for which IDS determines there is User demand. IDS similarly provides connectivity to a selection of data, rather than entire feeds, over a wireless connection to the Markham, Canada third party data center.[9] The User would then determine the symbols for which it would receive data, which could include data regarding some or all of the symbols for which IDS provides connectivity.[10] The Exchange would not have visibility into which portion of the CME Group Data a given User receives.

As with the Existing Third Party Data, if a User purchased two wireless connections, it would pay two non-recurring initial charges. Each wireless connection would include the use of one port for connectivity to CME Group Data. A User would not pay a fee for the use of such port. If a User also connects to Existing Third Party Data, it would not be able to use the same port that it uses for connectivity to CME Group Data to connect to such Existing Third Party Data. Accordingly, a User that connects to both CME Group Data and Existing Third Party Data would have at least two ports, and would not be separately charged for two ports.[11]

## Application and Impact of the Proposed Changes

The proposed changes would not apply differently to distinct types or sizes of market participants. Rather, they would apply to all Users equally.

As is currently the case, the purchase of any co-location service, including connectivity to Third Party Data, is completely voluntary and the Price List is applied uniformly to all Users.

## Competitive Environment

Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data using other methods: From another User, a third party wireless connection, or through an IDS or third party fiber connection.

Based on the information available to it, the Exchange believes that at least one market participant provides wireless connectivity to CME Group market data in the Data Center. The Exchange believes that the wireless connection offered by this third party entity provides connectivity at the same or similar speed as the proposed connection to CME Group Data, and at the same or similar cost.[12] The proposed connection to CME Group Data and the existing third party wireless connection to CME Group Data would follow the same route within the Data Center: They would both enter through a meet-me-room, connect to equipment in co-location, and then connect to any Users that are customers. Because of this, the Exchange does not believe that IDS has an advantage over the third party in providing the connectivity. The proposed wireless connection would lead to a pole, from where a fiber connection would lead into the Data Center. The pole is owned by a third party and is not on the grounds of the Data Center.

IDS already offers fiber connections to CME Group market data to Users.[13] The Exchange also believes that at least two third party market participants offer such fiber connections to CME Group market data. In addition to these options, a User may create a proprietary wireless connection or connect through another User in order to connect to CME Group market data. The Exchange believes that at least two market participants already provide wireless connectivity to CME Group market data to other data centers in New Jersey.

Wireless connections involve beaming signals through the air between antennas that are within line of sight of one another. Because the signals travel a straight, unimpeded line, and because light waves travel faster through air than through glass (fiber optics), wireless messages have lower latency than messages travelling through fiber optics. At the same time, as a general rule wireless networks have less uptime than fiber networks. Wireless networks are directly and immediately affected by adverse weather conditions, which can cause message loss and outage periods. Wireless networks cannot be configured with redundancy in the same way that fiber networks can. As a result, an equipment or weather issue at any one location on the network will cause the entire network to have an outage. In addition, maintenance can take longer than it would with a fiber based

[6] *See* Securities Exchange Act Release Nos. 76748 (December 23, 2015), 80 FR 81609 (December 30, 2015) (SR–NYSE–2015–52); 78378 (July 21, 2016), 81 FR 49315 (July 27, 2016) (SR–NYSE–2016–49); and 80215 (February 28, 2017), 82 FR 12658 (March 6, 2017) (SR–NYSE–2017–05).

[7] *See* Securities Exchange Act Release No. 80311 (March 24, 2017), 82 FR 15741 (March 30, 2017) (SR–NYSE–2016–45).

[8] Through its ICE Data Services (''IDS'') business, Intercontinental Exchange, Inc. (''ICE'') operates the Data Center in Mahwah, New Jersey. The Exchange and the Affiliate SROs are indirect subsidiaries of ICE. The proposed service would be provided by IDS pursuant to an agreement with a non-ICE entity. IDS does not own the wireless network that would be used to provide the service.

[9] *See* Securities Exchange Act Release No. 88237 (February 19, 2020), 85 FR 10752 (February 25, 2020) (SR–NYSE–2020–11), at 10756. *See also* Securities Exchange Act Release No. 90209 (October 15, 2020), 85 FR 67044 (October 21, 2020) (SR–NYSE–2020–05, SR–NYSEAMER–2020–05, SR–NYSEArca–2020–08, SR–NYSECHX–2020–02, SR–NYSENAT–2020–03, SR–NYSE–2020–11, SR–NYSEAMER–2020–10, SR–NYSEArca–2020–15, SR–NYSECHX–2020–05, SR–NYSENAT–2020–08).

[10] The Exchange understands that the third parties that provide wireless connectivity to CME Group market data to the Data Center and other data centers in New Jersey follow a substantially similar model, offering connectivity to a selection of market data rather than entire feeds.

[11] If a User purchased a wireless connection to CME Group Data, that connection would include the use of one port for connectivity to CME Group Data. If the same User connected to Existing Third Party Data, it would receive the use of one port for connectivity to the Existing Third Party Data. It would not be separately charged for such ports. A User may purchase additional ports. *See* 80 FR 81609, *supra* note 6 at 81610.

[12] Because the third party is not a regulated entity, it is not obligated to make its latency figures or fees publicly available or the same for all entities.

[13] *See* Securities Exchange Act Release No. 81014 (June 23, 2017), 82 FR 29615 (June 29, 2017) (SR–NYSE–2017–25).

network, as the relevant tower may be in a hard to reach location, or weather conditions may present safety issues, delaying technicians servicing equipment. Even under normal conditions, a wireless network will have a higher error rate than a fiber network of the same length.

The latency of a wireless network depends on several factors. Variables include the wireless equipment utilized; the route of, and number of towers or buildings in, the network; their proximity to the data centers on either end; and the fiber equipment used at either end of the connection. Moreover, latency is not the only consideration that a customer may have in selecting a wireless network to connect to CME Group market data. Other considerations may include the amount of network uptime; the equipment that the network uses; the cost of the connection; and the applicable contractual provisions. Indeed, fiber network connections may be more attractive to some market participants as they are more reliable and less susceptible to weather conditions.

The Exchange operates in a highly competitive market in which exchanges and other vendors (*e.g.,* Hosting Users) offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [14]

The proposed change is not otherwise intended to address any other issues relating to co-location services and/or related fees, and the Exchange is not aware of any problems that Users 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,[15] in general, and furthers the objectives of Section 6(b)(5) of the Act,[16] 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,[17] 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 Proposed Change Is Reasonable

The Exchange believes that the proposed rule change is reasonable.

The wireless connection would provide Users with an alternative means of connectivity to CME Group Data. The proposed change would provide Users with an additional choice with respect to the form and optimal latency of the connectivity they use to receive CME Group market data, allowing a User to select the connectivity that better suits its needs, helping it tailor its colocation operations to the requirements of its business operations. Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data using other methods: from another User, a third party wireless connection, or through an IDS or third party fiber connection.

Based on the information available to it, the Exchange believes that at least one market participant provides wireless connectivity to CME Group market data in the Data Center. The Exchange believes that the wireless connection offered by this third party entity provides connectivity at the same or similar speed as the proposed connection to CME Group Data, and at the same or similar cost. The proposed connection to CME Group Data and the existing third party wireless connection to CME Group Data would follow the same route within the Data Center: They would both enter through a meet-me-room, connect to equipment in co-location, and then connect to any Users that are customers. Because of this, the Exchange does not believe that IDS has an advantage over the third party in providing the connectivity. The proposed wireless connection would lead to a pole, from where a fiber connection would lead into the Data Center. The pole is owned by a third party and is not on the grounds of the Data Center.

IDS already offers fiber connections to CME Group market data to Users.[18] The Exchange also believes that at least two third party market participants offer such fiber connections to CME Group. In addition to these options, a User may create a proprietary wireless connection or connect through another User in order to connect to CME Group market data. The Exchange believes that at least two market participants already provide wireless connectivity to CME Group market data to other data centers in New Jersey.

Market participants' considerations in determining what connectivity to purchase may include latency; the amount of network uptime; the equipment that the network uses; the cost of the connection; and the applicable contractual provisions. Indeed, fiber network connections may be more attractive to some market participants as they are more reliable and less susceptible to weather conditions.

The Exchange believes that it is reasonable to not transport information for all of the symbols included in CME Group data feeds to the Data Center, but rather to transport a subset of that data. There is limited bandwidth available on the wireless network to co-location, and there are a number of CME Group data feeds. Limiting the feeds to the selection of CME Group market data regarding securities for which IDS determines there is demand would allow Users to receive the relevant CME Group Data over a wireless network, which could include data regarding some or all of the symbols for which IDS provides connectivity. The User would then determine those symbols for which it will receive data.

The Exchange believes that it is reasonable that a User that has already purchased wireless connections to other Third Party Data would be charged a non-recurring charge when it purchases a wireless connection to the CME Group Data, because it would allow the Exchange to defray or cover certain costs it incurs in installing the wireless connection to the CME Group Data, which costs it incurs irrespective of

[14] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[15] 15 U.S.C. 78f(b).

[16] 15 U.S.C. 78f(b)(5).

[17] 15 U.S.C. 78f(b)(4).

[18] *See* 82 FR 29615, *supra* note 12.

whether the User has existing wireless connections to Third Party Data, while providing the User the benefit of the installation, which would allow it to receive CME Group Data within co-location and with a lower latency over the fiber optics option. To do the initial installation, the Exchange must provide the personnel required for initial installation and testing. The costs associated with installing wireless connections are incrementally higher than those associated with installing fiber optics-based solutions.

The Exchange believes that it is reasonable that a User that connects to both CME Group Data and Existing Third Party Data may not use the same port for connectivity to both, and so would have at least two ports, because the proposed wireless connection would include the use of one port for connectivity to CME Group Data and connectivity to the Existing Third Party Data includes the use of one port for connectivity to Existing Third Party Data. A User would not pay a separate fee for using such ports.

The Exchange believes the proposed pricing for the wireless connection to CME Group Data is reasonable because it would allow the Exchange to defray or cover the costs associated with offering Users a wireless connection to CME Group Data while providing Users the benefit of receiving CME Group Data within co-location and with a lower latency over the fiber optics option. The wireless connection for CME Group Data would allow Users to select the CME Group Data connectivity option that better suits their needs.

The Exchange believes that the proposed pricing is reasonable because the Exchange proposes to offer the wireless connection to CME Group Data described herein as a convenience to Users, but in order to do so must provide, maintain and operate the Data Center facility hardware and technology infrastructure. The Exchange must handle the installation, administration, monitoring, support and maintenance of such services, including by responding to any production issues. Since the inception of co-location, the Exchange has made numerous improvements to the network hardware and technology infrastructure and has established additional administrative controls. The Exchange has expanded the network infrastructure to keep pace with the increased number of services available to Users. Specifically, in order to offer wireless connections, the Exchange must install, test, maintain and operate the wireless equipment.

The Proposed Change Is Not Unfairly Discriminatory

The Exchange believes that the proposed rule change is not unfairly discriminatory for the following reasons.

Without this proposed rule change, Users would have fewer options for connectivity to CME Group Data. The proposed change would provide Users with an additional choice with respect to the form and optimal latency of the connectivity they use to receive CME Group market data, allowing a User to select the connectivity that better suits its needs, helping it tailor its colocation operations to the requirements of its business operations. Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data using other methods: From another User, a third party wireless connection, or through an IDS or third party fiber connection.

The Exchange believes that it is not unfairly discriminatory to not transport information for all of the symbols included in CME Group data feeds to the Data Center, but rather to transport a subset of that data. There is limited bandwidth available on the wireless network to co-location, and there are a number of CME Group data feeds. Limiting the feeds to the selection of CME Group market data regarding securities for which IDS determines there is demand would allow Users to receive the relevant CME Group Data over a wireless network. The User would then determine those symbols for which it will receive data, which could include data regarding some or all of the symbols for which IDS provides connectivity.

The Exchange believes that the proposed pricing is not unfairly discriminatory because the Exchange proposes to offer the wireless connection to CME Group Data described herein as a convenience to Users, but in order to do so must provide, maintain and operate the Data Center facility hardware and technology infrastructure. The Exchange must handle the installation, administration, monitoring, support and maintenance of such services, including by responding to any production issues. Since the inception of co-location, the Exchange has made numerous improvements to the network hardware and technology infrastructure and has established additional administrative controls. The Exchange has expanded the network infrastructure to keep pace with the increased number of services available to Users. Specifically, in order to offer wireless connections, the Exchange must install, test, maintain and operate the wireless equipment.

The Exchange believes that the proposed change is not unfairly discriminatory because it will result in fees being charged only to Users that voluntarily select to receive the corresponding services and because those services will be available to all Users. Furthermore, the Exchange believes that the services and fees proposed herein are not unfairly discriminatory because, in addition to the services being completely voluntary, they are available to all Users on an equal basis (*i.e.,* the same products and services are available to all Users). All Users that voluntarily select wireless connections to CME Group Data would be charged the same amount for the same services.

Users that opt to use wireless connections to CME Group Data would receive the CME Group Data that is available to all Users, as all market participants that contract with CME Group or its affiliate for CME Group Data, as required, may receive it.

The Proposed Change Is an Equitable Allocation of Fees and Credits

The Exchange believes that its proposal equitably allocates its fees among Users.

Without this proposed rule change, Users would have fewer options for connectivity to CME Group Data. The proposed change would provide Users with an additional choice with respect to the form and optimal latency of the connectivity they use to receive CME Group market data, allowing a User to select the connectivity that better suits its needs, helping it tailor its colocation operations to the requirements of its business operations. Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data using other methods: From another User, a third party wireless connection, or through an IDS or third party fiber connection.

The Exchange believes that the proposed change is equitable because it will result in fees being charged only to Users that voluntarily select to receive the corresponding services and because those services will be available to all Users. Furthermore, the Exchange believes that the services and fees proposed herein are equitably allocated because, in addition to the services being completely voluntary, they are available to all Users on an equal basis (*i.e.,* the same products and services are available to all Users). All Users that voluntarily select wireless connections

to CME Group Data would be charged the same amount for the same services.

The Exchange operates in a highly competitive market in which exchanges offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. Accordingly, fees charged for co-location services are constrained by the active competition for the order flow of, and other business from, such market participants. If a particular exchange charges excessive fees for co-location services, affected market participants will opt to terminate their co-location arrangements with that exchange, and adopt a possible range of alternative strategies, including placing their servers in a physically proximate location outside the exchange's data center (which could be a competing exchange), or pursuing strategies less dependent upon the lower exchange-to-participant latency associated with co-location. Accordingly, the exchange charging excessive fees would stand to lose not only co-location revenues but also the liquidity of the formerly co-located trading firms, which could have additional follow-on effects on the market share and revenue of the affected exchange.

For the reasons above, the proposed changes do not unfairly discriminate between or among market participants that are otherwise capable of satisfying any applicable co-location fees, requirements, terms and conditions established from time to time by the Exchange.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange believes that the proposal will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of Section 6(b)(8) of the Act.[19]

The proposed change does not affect competition among national securities exchanges or among members of the Exchange, but rather between IDS and its commercial competitors.

The wireless connection would provide Users with an alternative means of connectivity to CME Group Data. The proposed change would provide Users with an additional choice with respect to the form and optimal latency of the connectivity they use to receive CME Group market data, allowing a User to select the connectivity that better suits its needs, helping it tailor its colocation operations to the requirements of its business operations.

Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data using other methods: From another User, a third party wireless connection, or through an IDS or third party fiber connection. Based on the information available to it, the Exchange believes that at least one market participant provides wireless connectivity to CME Group market data in the Data Center. The Exchange believes that the wireless connection offered by this third party entity provides connectivity at the same or similar latency as the proposed connection to CME Group Data, and at the same or similar cost. The proposed connection to CME Group Data and the existing third party wireless connection to CME Group Data would follow the same route within the Data Center: They would both enter through a meet-me-room, connect to equipment in co-location, and then connect to any Users that are customers. Because of this, the Exchange does not believe that IDS has an advantage over the third party in providing the connectivity. The proposed wireless connection would lead to a pole, from where a fiber connection would lead into the Data Center. The pole is owned by a third party and is not on the grounds of the Data Center.

IDS already offers fiber connections to CME Group market data to Users.[20] The Exchange also believes that at least two third party market participants offer such fiber connections to CME Group. In addition to these options, a User may create a proprietary wireless connection or connect through another User in order to connect to CME Group market data. The Exchange believes that at least two market participants already provide wireless connectivity to CME Group market data to other data centers in New Jersey.

The Exchange notes that the proposed wireless connection would compete not just with other wireless connections to CME Group market data, but also with fiber network connections, which may be more attractive to some market participants as they are more reliable and less susceptible to weather conditions. Market participants' considerations in determining what connectivity to purchase may include latency; the amount of network uptime; the equipment that the network uses; the cost of the connection; and the applicable contractual provisions. As noted above, a User may purchase a fiber connection to CME Group market data from at least three providers, including IDS.

The Exchange operates in a highly competitive market in which exchanges and other vendors (*e.g.,* Hosting Users) offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [21]

*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 [22] and Rule 19b–4(f)(6) thereunder.[23]

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

[19] 15 U.S.C. 78f(b)(8).

[20] *See* 82 FR 29615, *supra* note 12.

[21] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[22] 15 U.S.C. 78s(b)(3)(A).

[23] 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.

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–2021–67 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–2021–67. 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–2021–67, and should be submitted on or before December 9, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[24]

**J. Matthew DeLesDernier,**

*Assistant Secretary.*

[FR Doc. 2021–25125 Filed 11–17–21; 8:45 am]

**BILLING CODE 8011–01–P**

[24] 17 CFR 200.30–3(a)(12).

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## SECURITIES AND EXCHANGE COMMISSION

**[SEC File No. 270–653, OMB Control No. 3235–0703]**

## Proposed Collection; Comment Request

*Upon Written Request, Copies Available From:* Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

*Extension:*
Regulation SCI, Form SCI

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the collection of information provided for in Regulation Systems Compliance and Integrity (''Regulation SCI'') (17 CFR 242.1000–1007) and Form SCI (17 CFR 249.1900) under the Securities Exchange Act of 1934 (''Exchange Act'') (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Regulation SCI requires certain key market participants to, among other things: (1) Have comprehensive policies and procedures in place to help ensure the robustness and resiliency of their technological systems, and also that their technological systems operate in compliance with the federal securities laws and with their own rules; and (2) provide certain notices and reports to the Commission to improve Commission oversight of securities market infrastructure.

Regulation SCI advances the goals of the national market system by enhancing the capacity, integrity, resiliency, availability, and security of the automated systems of entities important to the functioning of the U.S. securities markets, as well as reinforcing the requirement that such systems operate in compliance with the Exchange Act and rules and regulations thereunder, thus strengthening the infrastructure of the U.S. securities markets and improving its resilience when technological issues arise. In this respect, Regulation SCI establishes an updated and formalized regulatory framework, thereby helping to ensure more effective Commission oversight of such systems.

Respondents consist of national securities exchanges and associations, registered clearing agencies, exempt clearing agencies, plan processors, and alternative trading systems. There are currently 47 respondents, and the Commission staff estimates that, on average, 2 new respondents may become SCI entities each year, 1 of which would be a self-regulatory organization (''SRO''). Accordingly, Commission staff estimates that over the next three years there will be an average of 49 respondents per year.

In addition, in December 2020, the Commission adopted amendments to Regulation SCI in connection with updates to the national market system for the collection, consolidation, and dissemination of information with respect to quotations for and transactions in national market system (''NMS'') stocks (''Infrastructure Amendments''). Specifically, the Commission adopted a definition of ''SCI competing consolidator'' that will subject competing consolidators to Regulation SCI, after a transition period, if they are above a specified consolidated market data gross revenue threshold.[1] The Infrastructure Amendments increased the number of respondents to the collections of information in Regulation SCI, and the Commission estimates that seven competing consolidators will meet this definition and be subject to the requirements of Regulation SCI.[2] Rule 1001(a) requires each SCI entity to establish, maintain, and enforce written policies and procedures reasonably designed to ensure that its SCI systems and, for purposes of security standards, indirect SCI systems, have levels of capacity, integrity, resiliency, availability, and security, adequate to maintain the SCI entity's operational capability and promote the maintenance of fair and orderly markets. The Commission staff estimates that the total annual initial recordkeeping burden for 7 new respondents will be 4,511 hours, and the annual ongoing recordkeeping burden for all 54 respondents will be,

[1] *See* Securities Exchange Act Release No. 34–90610 (December 9, 2020), 86 FR 18596 (April 9, 2021) (File No. S7–03–20) (''Infrastructure Adopting Release'').

[2] Some of these respondents were estimated to incur no, or only part of, the estimated initial burdens because they were already subject to Regulation SCI (*i.e.,* as plan processors, SROs or affiliates of SROs).

on average, 12,528 hours. The Commission staff estimates that the 7 new respondents would incur, on average, an annual initial internal cost of compliance of $1,513,382, as well as outside legal or consulting costs of $305,500. In addition, all respondents will incur, on average, an estimated ongoing annual internal cost of compliance of $4,205,412.

Rule 1001(b) requires each SCI entity to establish, maintain, and enforce written policies and procedures reasonably designed to ensure that its SCI systems operate in a manner that complies with the Exchange Act and the rules and regulations thereunder and the entity's rules and governing documents, as applicable. The Commission staff estimates that the total annual initial recordkeeping burden for 7 new respondents will be 1,755 hours, and the annual ongoing recordkeeping burden for all respondents will be, on average, 8,010 hours. The Commission staff estimates that the 7 new respondents would incur an initial internal cost of compliance of $660,270, as well as outside legal or consulting costs of $175,500. In addition, all respondents will incur, on average, an estimated ongoing annual internal cost of compliance of $2,539,890.

Rule 1001(c) requires each SCI entity to establish, maintain, and enforce reasonably designed written policies and procedures that include the criteria for identifying responsible SCI personnel, the designation and documentation of responsible SCI personnel, and escalation procedures to quickly inform responsible SCI personnel of potential SCI events. The Commission staff estimates that the total annual initial recordkeeping burden for 7 new respondents will be 741 hours, and the annual ongoing recordkeeping burden for all respondents will be, on average, 2,106. The Commission staff estimates that the 7 new respondents would incur an initial internal cost of compliance of $276,432, and all respondents will incur, on average, an estimated ongoing annual internal cost of compliance of $839,592.

Rule 1004 requires each SCI entity to establish standards for the designation of certain members or participants for BC/DR plan testing, to designate members or participants in accordance with these standards, to require participation by designated members or participants in such testing at least annually, and to coordinate such testing on an industry- or sector-wide basis with other SCI entities. The Commission staff estimates that the total annual initial recordkeeping burden for 9 new respondents will be 2,700 hours, and the annual ongoing recordkeeping burden for all respondents that are not plan processors will be, on average, 7,290 hours. The Commission staff estimates that the 7 new respondents would incur an initial internal cost of compliance of $804,735. In addition, all respondents that are not plan processors will incur, on average, an estimated ongoing annual internal cost of compliance of $1,939,950. In addition, the Commission staff estimates that the 2 plan processor respondents will incur an estimated ongoing annual cost of $108,000 for outside legal services ($54,000 per plan processor respondent × 2 respondents).

Rule 1002(b)(1) requires each SCI entity, upon any responsible SCI personnel having a reasonable basis to conclude that an SCI event has occurred, to notify the Commission immediately. The Commission staff estimates that the total annual ongoing burden for all 54 respondents will be, on average, 432 hours. The Commission staff estimates that respondents will incur, on average, an estimated ongoing annual internal cost of compliance of $133,030.

Rule 1002(b)(2) requires each SCI entity, within 24 hours of any responsible SCI personnel having a reasonable basis to conclude that the SCI event has occurred, to submit a written notification to the Commission pertaining to the SCI event on a good faith, best efforts basis. These notifications are required to be submitted on Form SCI. The Commission staff estimates that the total annual ongoing burden for all 54 respondents will be, on average, 6,480 hours. The Commission staff estimates that respondents will incur, on average, an estimated ongoing annual internal cost of compliance of $2,134,890.

Rule 1002(b)(3) requires each SCI entity to provide updates to the Commission pertaining to an SCI event on a regular basis, or at such frequency as reasonably requested by a representative of the Commission, until the SCI event is resolved and the SCI entity's investigation of the SCI event is closed. The Commission staff estimates that the total annual ongoing burden for all 54 respondents will be, on average, 567 hours. The Commission staff estimates that all respondents will incur, on average, an estimated ongoing annual internal cost of compliance of $177,106.50.

Rule 1002(b)(4) requires each SCI entity to submit written interim reports, as necessary, and a written final report regarding an SCI event to the Commission. These reports are required to be submitted on Form SCI. The Commission staff estimates that the total annual ongoing burden for all 54 respondents will be, on average, 9,450 hours. The Commission staff estimates that all respondents will incur, on average, an estimated ongoing annual internal cost of compliance of $3,297,510.

Rule 1002(b)(5) requires each SCI entity to submit to the Commission quarterly reports containing a summary description of any systems disruption or systems intrusion that has had, or the SCI entity reasonably estimates would have, no or a de minimis impact on the SCI entity's operations or on market participants. These reports are required to be submitted on Form SCI. The Commission staff estimates that the total annual ongoing burden for all 54 respondents will be, on average, 8,640 hours. The Commission staff estimates that respondents will incur, on average, an estimated ongoing annual internal cost of compliance of $2,919,348.

In addition, the Commission staff estimates that all 54 respondents will incur, on average, annual costs of $313,200 for outside legal advice in preparation of certain notifications required by Rule 1002(b).

Rule 1002(c)(1)(i) requires each SCI entity, promptly after any responsible SCI personnel has a reasonable basis to conclude that an SCI event (other than a systems intrusion) has occurred, to disseminate certain information to its members or participants. The Commission staff estimates that the total annual ongoing burden for all 54 respondents will be, on average, 1,134 hours. The Commission staff estimates that all respondents will incur, on average, an estimated ongoing annual internal cost of compliance of $741,557.50.

Rule 1002(c)(1)(ii) requires each SCI entity, when known, to promptly disseminate additional information about an SCI event (other than a systems intrusion) to its members or participants. Rule 1002(c)(1)(iii) requires each SCI entity to provide to its members or participants regular updates of any information required to be disseminated under Rules 1002(c)(1)(i) and (ii) until the SCI event is resolved. The Commission staff estimates that the total annual ongoing burden for all 54 respondents will be, on average, 6,318 hours. The Commission staff estimates that all respondents will incur, on average, an estimated ongoing annual internal cost of compliance of $2,496,096.

Rule 1002(c)(2) requires each SCI entity to disseminate certain information regarding a systems intrusion to its members or participants,

and provides an exception when the SCI entity determines that dissemination of such information would likely compromise the security of its SCI systems or indirect SCI systems, or an investigation of the systems intrusion, and documents the reasons for such determination. The Commission staff estimates that the total annual ongoing burden for all 54 respondents will be, on average, 540 hours. The Commission staff estimates that all respondents will incur, on average, an estimated ongoing annual internal cost of compliance of $212,827.25.

In addition, the Commission staff estimates that all 54 respondents will incur, on average, annual costs of $179,280 for outside legal advice in preparation of certain notifications required by Rule 1002(c).

Rule 1003(a)(1) requires each SCI entity to submit to the Commission quarterly reports describing completed, ongoing, and planned material changes to its SCI systems and security of indirect SCI systems during the prior, current, and subsequent calendar quarters. These reports are required to be submitted on Form SCI. The Commission staff estimates that the total annual ongoing burden for all 54 respondents will be, on average, 27,000 hours. The Commission staff estimates that all respondents will incur, on average, an estimated ongoing annual internal cost of compliance of $8,063,820.

Rule 1003(a)(2) requires each SCI entity to promptly submit a supplemental report notifying the Commission of a material error in or material omission from a report previously submitted under Rule 1003(a)(1). These reports are required to be submitted on Form SCI. The Commission staff estimates that the total annual ongoing burden for all 54 respondents will be, on average, 810 hours. The Commission staff estimates that all respondents will incur, on average, an estimated ongoing annual internal cost of compliance of $256,716.

Rule 1003(b)(1) requires each SCI entity to conduct an SCI review of its compliance with Regulation SCI not less than once each calendar year, with an exception for penetration test reviews, which are required to be conducted not less than once every three years. Rule 1003(b)(1) also provides an exception for assessments of SCI systems directly supporting market regulation or market surveillance, which are required to be conducted at a frequency based on the risk assessment conducted as part of the SCI review, but in no case less than once every three years. Rule 1003(b)(2) requires each SCI entity to submit a report of the SCI review to senior management no more than 30 calendar days after completion of the review. The Commission staff estimates that the total annual ongoing burden for all 54 respondents will be, on average, 37,260 hours. The Commission staff estimates that all respondents will incur, on average, an estimated ongoing annual internal cost of compliance of $11,934,810.

Rule 1003(b)(3) requires each SCI entity to submit the report of the SCI review to the Commission and to its board of directors or the equivalent of such board, together with any response by senior management, within 60 calendar days after its submission to senior management. These reports are required to be submitted on Form SCI. The Commission staff estimates that the total annual ongoing burden for all 54 respondents will be, on average, 54 hours. The Commission staff estimates that all respondents will incur, on average, an estimated ongoing annual internal cost of compliance of $22,248.

In addition, the Commission staff estimates that all respondents will incur, on average, annual costs of $2,700,000 for outside legal advice in preparation of certain notifications required by Rule 1003(b).

Rule 1006 requires each SCI entity, with a few exceptions, to file any notification, review, description, analysis, or report to the Commission required under Regulation SCI electronically on Form SCI through the EFFS. An SCI entity will submit to the Commission an EAUF to register each individual at the SCI entity who will access the EFFS system on behalf of the SCI entity. The Commission staff estimates that the total annual initial burden for 7 new respondents will be 1.95 hours, and the annual ongoing burden for all respondents will be, on average, 8.1 hours. The Commission staff estimates that the 7 new respondents would incur an initial internal cost of compliance of $806. In addition, all 54 respondents will incur, on average, an estimated ongoing annual internal cost of compliance of $3,348, as well as outside costs to obtain a digital ID of $2,700.

Rule 1002(a) requires each SCI entity, upon any responsible SCI personnel having a reasonable basis to conclude that an SCI event has occurred, to begin to take appropriate corrective action. The Commission staff estimates that the total annual initial recordkeeping burden for 7 new respondents will be 741 hours, and the annual ongoing recordkeeping burden for all 54 respondents will be, on average, 2,106 hours. The Commission staff estimates that the 7 new respondents would incur an initial internal cost of compliance of $276,432. In addition, all 54 respondents will incur, on average, an estimated ongoing annual internal cost of compliance of $831,438.

Rule 1003(a)(1) requires each SCI entity to establish reasonable written criteria for identifying a change to its SCI systems and the security of indirect SCI systems as material. The Commission staff estimates that the total annual initial recordkeeping burden for 7 new respondents will be 741 hours, and the annual ongoing recordkeeping burden for all 54 respondents will be, on average, 1,458 hours. The Commission staff estimates that the 7 new respondents would incur an initial internal cost of compliance of $276,432. In addition, all 54 respondents will incur, on average, an estimated ongoing annual internal cost of compliance of $622,944.

Regulation SCI also requires SCI entities to identify certain types of events and systems. The Commission staff estimates that the total annual initial recordkeeping burden for 7 new respondents will be 1,287 hours, and the annual ongoing recordkeeping burden for all 54 respondents will be, on average, 2,106 hours. The Commission staff estimates that the 7 new respondents would incur an initial internal cost of compliance of $453,089. In addition, all 54 respondents will incur, on average, an estimated ongoing annual internal cost of compliance of $831,438.

Rules 1005 and 1007 establish recordkeeping requirements for SCI entities other than SROs. The Commission staff estimates that for 6 new respondents that are not SROs the average annual initial burden would be 935 hours, and the annual ongoing burden for all 18 respondents will be, on average, 450 hours. The Commission staff estimates that 6 new respondents would incur an estimated internal initial internal cost of compliance of $64,515, as well as a one-time cost of $5,400 to modify existing recordkeeping systems. In addition, all 18 respondents will incur, on average, an estimated ongoing internal cost of compliance of $31,050.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and

(d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: November 15, 2021.

**J. Matthew DeLesDernier,**

*Assistant Secretary.*

[FR Doc. 2021–25173 Filed 11–17–21; 8:45 am]

**BILLING CODE 8011–01–P**

## SECURITIES AND EXCHANGE COMMISSION

**[Release Nos. 33–11007; 34–93573; File No. 265–28]**

## Investor Advisory Committee Meeting

**AGENCY:** Securities and Exchange Commission.

**ACTION:** Notice of meeting.

**SUMMARY:** The Securities and Exchange Commission Investor Advisory Committee, established pursuant to Section 911 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, is providing notice that it will hold a public meeting. The public is invited to submit written statements to the Committee.

**DATES:** The meeting will be held on Thursday, December 2, 2021 from 10:00 a.m. until 4:00 p.m. (ET). Written statements should be received on or before December 1, 2021.

**ADDRESSES:** The meeting will be conducted by remote means and/or at the Commission's headquarters, 100 F St NE, Washington, DC 20549. The meeting will be webcast on the Commission's website at *www.sec.gov.* Written statements may be submitted by any of the following methods:

*Electronic Statements*

- Use the Commission's internet submission form (*http://www.sec.gov/rules/other.shtml*); or
- Send an email message to *rules-comments@sec.gov.* Please include File No. 265–28 on the subject line; or

*Paper Statements*

- Send paper statements to Vanessa A. Countryman, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File No. 265–28. This file number should be included on the subject line if email is used. To help us process and review your statement more efficiently, please use only one method.

Statements also will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Room 1503, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. All statements 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.

**FOR FURTHER INFORMATION CONTACT:** Marc Oorloff Sharma, Chief Counsel, Office of the Investor Advocate, at (202) 551–3302, Securities and Exchange Commission, 100 F Street, NE, Washington, DC 20549.

**SUPPLEMENTARY INFORMATION:** The meeting will be open to the public, except during that portion of the meeting reserved for an administrative work session during lunch. Persons needing special accommodations to take part because of a disability should notify the contact person listed in the section above entitled **FOR FURTHER INFORMATION CONTACT**.

The agenda for the meeting includes: opening remarks, announcement of new officers, and announcement regarding a disclosure subcommittee; welcome remarks; approval of previous meeting minutes; a panel discussion regarding crypto and digital assets: helping to ensure investor protection and market integrity in the face of new technologies; a panel discussion regarding the SEC's potential role in addressing elder financial abuse issues; a discussion of a recommendation regarding individual retirement accounts; subcommittee reports; and a non-public administrative session.

Dated: November 15, 2021.

**Vanessa A. Countryman,**

*Secretary.*

[FR Doc. 2021–25188 Filed 11–17–21; 8:45 am]

**BILLING CODE 8011–01–P**

## SECURITIES AND EXCHANGE COMMISSION

**[SEC File No. 270–603, OMB Control No. 3235–0658]**

## Proposed Collection; Comment Request

*Upon Written Request, Copies Available From:* Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

*Extension:*
Rule 22e–3

Notice is hereby given that, under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

Section 22(e) of the Investment Company Act [15 U.S.C. 80a–22(e)] (''Act'') generally prohibits funds, including money market funds, from suspending the right of redemption, and from postponing the payment or satisfaction upon redemption of any redeemable security for more than seven days. The provision was designed to prevent funds and their investment advisers from interfering with the redemption rights of shareholders for improper purposes, such as the preservation of management fees. Although section 22(e) permits funds to postpone the date of payment or satisfaction upon redemption for up to seven days, it does not permit funds to suspend the right of redemption for any amount of time, absent certain specified circumstances or a Commission order.

Rule 22e–3 under the Act [17 CFR 270.22e–3] exempts money market funds from section 22(e) to permit them to suspend redemptions in order to facilitate an orderly liquidation of the fund. Specifically, rule 22e–3 permits a money market fund to suspend redemptions and postpone the payment of proceeds pending board-approved liquidation proceedings if: (i) The fund's board of directors, including a majority of disinterested directors, determines pursuant to § 270.2a–7(c)(8)(ii)(C) that the extent of the deviation between the fund's amortized cost price per share and its current net asset value per share calculated using available market quotations (or an appropriate substitute that reflects current market conditions) may result in material dilution or other unfair results to investors or existing shareholders; (ii) the fund's board of directors, including a majority of

disinterested directors, irrevocably approves the liquidation of the fund; and (iii) the fund, prior to suspending redemptions, notifies the Commission of its decision to liquidate and suspend redemptions. Rule 22e–3 also provides an exemption from section 22(e) for registered investment companies that own shares of a money market fund pursuant to section 12(d)(1)(E) of the Act (''conduit funds''), if the underlying money market fund has suspended redemptions pursuant to the rule. A conduit fund that suspends redemptions in reliance on the exemption provided by rule 22e–3 is required to provide prompt notice of the suspension of redemptions to the Commission. Notices required by the rule must be provided by electronic mail, directed to the attention of the Director of the Division of Investment Management or the Director's designee.[1] Compliance with the notification requirement is mandatory for money market funds and conduit funds that rely on rule 22e–3 to suspend redemptions and postpone payment of proceeds pending a liquidation, and are not kept confidential.

Commission staff estimates that, on average, one fund would be required to make the required notice every year.[2] Commission staff further estimates that a money market fund or conduit fund would spend approximately one hour of an in-house attorney's time to prepare and submit the notice required by the rule. Given these estimates, the total annual burden of the notification requirement of rule 22e–3 for all money market funds and conduit funds would be approximately one hour at a cost of $425.[3] The Commission staff estimates that there is no cost burden associated with the information collection requirement of rule 22e–3 other than this cost. The estimate of average burden hours is made solely for the purposes of the Paperwork Reduction Act, and is not derived from a comprehensive or even a representative survey or study of the costs of Commission rules and forms.

Compliance with the collection of information requirements of the rule is necessary to obtain the benefit of relying on the rule. 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 control number.

Written comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information has practical utility; (b) the accuracy of the Commission's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days after this publication.

Please direct your written comments to David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, C/O John R. Pezzullo, 100 F Street NE, Washington, DC 20549; or send an email to: *PRA_Mailbox@sec.gov.*

Dated: November 15, 2021.

**J. Matthew DeLesDernier,**

*Assistant Secretary.*

[FR Doc. 2021–25172 Filed 11–17–21; 8:45 am]

**BILLING CODE 8011–01–P**

[1] *See* rule 22e–3(a)(3).

[2] The Commission has not received any notices invoking rule 22e–3 to halt redemptions. However, for administrative purposes, we are reporting one respondent and one annual response.

[3] This figure for an Attorney is from SIFMA's *Management & Professional Earnings in the Securities Industry 2013,* modified by Commission staff to account for an 1800-hour work-year and inflation, and multiplied by 5.35 to account for bonuses, firm size, employee benefits and overhead.

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–93564; File No. SR–NYSEArca–2021–97]**

## Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the NYSE Arca Options Fees and Charges and the NYSE Arca Equities Fees and Charges Regarding Colocation Services

November 12, 2021.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act''),[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on November 3, 2021, NYSE Arca, Inc. (''NYSE Arca'' 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.

[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 NYSE Arca Options Fees and Charges and the NYSE Arca Equities Fees and Charges (together, the ''Fee Schedules'') regarding colocation services and fees to provide Users with wireless connectivity to CME Group market data. 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 Statutory Basis for, the Proposed Rule Change*

1. Purpose

The Exchange proposes to amend the Fee Schedules regarding colocation services and fees to provide Users [4] with wireless connectivity to CME Group market data.[5]

The Exchange currently provides Users with wireless connections to eight

[4] 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. 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 co-location 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–2021–67, SR–NYSEAMER–2021–43, SR–NYSECHX–2021–17, and SR–NYSENAT–2021–23.

[5] 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).

market data feeds or combinations of feeds from third party markets (the ''Existing Third Party Data''),[6] and wired connections to 43 market data feeds.[7] The Exchange now proposes to add to its Fee Schedules wireless connections to CME Group, Inc. (''CME Group'') market data (such data, ''CME Group Data'' and, together with the Existing Third Party Data, the ''Third Party Data''). Users would be offered the proposed wireless connection to the CME Group Data through connections into the colocation center in the Mahwah, New Jersey data center (''Data Center'').[8]

The Exchange expects that the proposed rule change would become operative no later than March 31, 2022. The Exchange will announce the date that the wireless connection to the CME Group Data will be available through a customer notice.

To receive CME Group Data, the User would enter into an agreement with a non-Exchange affiliated party for permission to receive the data, if required. The User would pay this third party any fees for the data content.

For each wireless connection to CME Group Data, a User would be charged a $5,000 non-recurring initial charge and a monthly recurring charge of $6,000. The Exchange proposes to revise its Fee Schedules to reflect fees related to the wireless connection to CME Group Data.

The CME Group Data would not include all possible CME Group data feeds. There is limited bandwidth available on the wireless network to co-location, and there are currently dozens of CME Group data feeds. To provide connectivity to all of them would use a large amount of bandwidth.

Accordingly, rather than provide connectivity to all possible symbols included in the CME Group data feeds, the wireless connection would only provide connectivity to a selection of CME Group market data for which IDS determines there is User demand. IDS similarly provides connectivity to a selection of data, rather than entire feeds, over a wireless connection to the Markham, Canada third party data center.[9] The User would then determine the symbols for which it would receive data, which could include data regarding some or all of the symbols for which IDS provides connectivity.[10] The Exchange would not have visibility into which portion of the CME Group Data a given User receives.

As with the Existing Third Party Data, if a User purchased two wireless connections, it would pay two non-recurring initial charges. Each wireless connection would include the use of one port for connectivity to CME Group Data. A User would not pay a fee for the use of such port. If a User also connects to Existing Third Party Data, it would not be able to use the same port that it uses for connectivity to CME Group Data to connect to such Existing Third Party Data. Accordingly, a User that connects to both CME Group Data and Existing Third Party Data would have at least two ports, and would not be separately charged for two ports.[11]

## Application and Impact of the Proposed Changes

The proposed changes would not apply differently to distinct types or sizes of market participants. Rather, they would apply to all Users equally.

As is currently the case, the purchase of any co-location service, including connectivity to Third Party Data, is completely voluntary and the Fee Schedules are applied uniformly to all Users.

## Competitive Environment

Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data using other methods: From another User, a third party wireless connection, or through an IDS or third party fiber connection. Based on the information available to it, the Exchange believes that at least one market participant provides wireless connectivity to CME Group market data in the Data Center. The Exchange believes that the wireless connection offered by this third party entity provides connectivity at the same or similar speed as the proposed connection to CME Group Data, and at the same or similar cost.[12] The proposed connection to CME Group Data and the existing third party wireless connection to CME Group Data would follow the same route within the Data Center: They would both enter through a meet-me-room, connect to equipment in co-location, and then connect to any Users that are customers. Because of this, the Exchange does not believe that IDS has an advantage over the third party in providing the connectivity. The proposed wireless connection would lead to a pole, from where a fiber connection would lead into the Data Center. The pole is owned by a third party and is not on the grounds of the Data Center.

IDS already offers fiber connections to CME Group market data to Users.[13] The Exchange also believes that at least two third party market participants offer such fiber connections to CME Group market data. In addition to these options, a User may create a proprietary wireless connection or connect through another User in order to connect to CME Group market data. The Exchange believes that at least two market participants already provide wireless connectivity to CME Group market data to other data centers in New Jersey.

Wireless connections involve beaming signals through the air between antennas that are within line of sight of one another. Because the signals travel a straight, unimpeded line, and because light waves travel faster through air than through glass (fiber optics), wireless messages have lower latency than messages travelling through fiber optics. At the same time, as a general rule wireless networks have less uptime than fiber networks. Wireless networks are directly and immediately affected by adverse weather conditions, which can cause message loss and outage periods. Wireless networks cannot be configured with redundancy in the same way that fiber networks can. As a result, an equipment or weather issue at any one location on the network will cause the entire network to have an outage. In

[6] *See* Securities Exchange Act Release Nos. 76749 (December 23, 2015), 80 FR 81640 (December 30, 2015) (SR–NYSEArca–2015–99); 78377 (July 21, 2016), 81 FR 49327 (July 27, 2016) (SR–NYSEArca–2016–99); and 80116 (February 28, 2017), 82 FR 12663 (March 6, 2017) (SR–NYSEArca–2017–18).

[7] *See* Securities Exchange Act Release No. 80310 (March 24, 2017), 82 FR 15763 (March 30, 2017) (SR–NYSEArca–2016–89).

[8] Through its ICE Data Services (''IDS'') business, Intercontinental Exchange, Inc. (''ICE'') operates the Data Center in Mahwah, New Jersey. The Exchange and the Affiliate SROs are indirect subsidiaries of ICE. The proposed service would be provided by IDS pursuant to an agreement with a non-ICE entity. IDS does not own the wireless network that would be used to provide the service.

[9] *See* Securities Exchange Act Release No. 88298 (February 19, 2020), 85 FR 10786 (February 25, 2020) (SR–NYSEArca–2020–15). *See also* Securities Exchange Act Release No. 90209 (October 15, 2020), 85 FR 67044 (October 21, 2020) (SR–NYSE–2020–05, SR–NYSEAMER–2020–05, SR–NYSEArca–2020–08, SR–NYSECHX–2020–02, SR–NYSENAT–2020–03, SR–NYSE–2020–11, SR–NYSEAMER–2020–10, SR–NYSEArca–2020–15, SR–NYSECHX–2020–05, SR–NYSENAT–2020–08).

[10] The Exchange understands that the third parties that provide wireless connectivity to CME Group market data to the Data Center and other data centers in New Jersey follow a substantially similar model, offering connectivity to a selection of market data rather than entire feeds.

[11] If a User purchased a wireless connection to CME Group Data, that connection would include the use of one port for connectivity to CME Group Data. If the same User connected to Existing Third Party Data, it would receive the use of one port for connectivity to the Existing Third Party Data. It would not be separately charged for such ports. A User may purchase additional ports. *See* 80 FR 81640, *supra* note 6, at 81641.

[12] Because the third party is not a regulated entity, it is not obligated to make its latency figures or fees publicly available or the same for all entities.

[13] *See* Securities Exchange Act Release No. 81013 (June 23, 2017), 82 FR 29604 (June 29, 2017) (SR–NYSEArca–2017–62).

addition, maintenance can take longer than it would with a fiber based network, as the relevant tower may be in a hard to reach location, or weather conditions may present safety issues, delaying technicians servicing equipment. Even under normal conditions, a wireless network will have a higher error rate than a fiber network of the same length.

The latency of a wireless network depends on several factors. Variables include the wireless equipment utilized; the route of, and number of towers or buildings in, the network; their proximity to the data centers on either end; and the fiber equipment used at either end of the connection. Moreover, latency is not the only consideration that a customer may have in selecting a wireless network to connect to CME Group market data. Other considerations may include the amount of network uptime; the equipment that the network uses; the cost of the connection; and the applicable contractual provisions. Indeed, fiber network connections may be more attractive to some market participants as they are more reliable and less susceptible to weather conditions.

The Exchange operates in a highly competitive market in which exchanges and other vendors (*e.g.,* Hosting Users) offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [14]

The proposed change is not otherwise intended to address any other issues relating to co-location services and/or related fees, and the Exchange is not aware of any problems that Users 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,[15] in general, and furthers the objectives of Section 6(b)(5) of the Act,[16] 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,[17] 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 Proposed Change Is Reasonable

The Exchange believes that the proposed rule change is reasonable.

The wireless connection would provide Users with an alternative means of connectivity to CME Group Data. The proposed change would provide Users with an additional choice with respect to the form and optimal latency of the connectivity they use to receive CME Group market data, allowing a User to select the connectivity that better suits its needs, helping it tailor its colocation operations to the requirements of its business operations. Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data using other methods: From another User, a third party wireless connection, or through an IDS or third party fiber connection.

Based on the information available to it, the Exchange believes that at least one market participant provides wireless connectivity to CME Group market data in the Data Center. The Exchange believes that the wireless connection offered by this third party entity provides connectivity at the same or similar speed as the proposed connection to CME Group Data, and at the same or similar cost. The proposed connection to CME Group Data and the existing third party wireless connection to CME Group Data would follow the same route within the Data Center: They would both enter through a meet-me-room, connect to equipment in co-location, and then connect to any Users that are customers. Because of this, the Exchange does not believe that IDS has an advantage over the third party in providing the connectivity. The proposed wireless connection would lead to a pole, from where a fiber connection would lead into the Data Center. The pole is owned by a third party and is not on the grounds of the Data Center.

IDS already offers fiber connections to CME Group market data to Users.[18] The Exchange also believes that at least two third party market participants offer such fiber connections to CME Group. In addition to these options, a User may create a proprietary wireless connection or connect through another User in order to connect to CME Group market data. The Exchange believes that at least two market participants already provide wireless connectivity to CME Group market data to other data centers in New Jersey.

Market participants' considerations in determining what connectivity to purchase may include latency; the amount of network uptime; the equipment that the network uses; the cost of the connection; and the applicable contractual provisions. Indeed, fiber network connections may be more attractive to some market participants as they are more reliable and less susceptible to weather conditions.

The Exchange believes that it is reasonable to not transport information for all of the symbols included in CME Group data feeds to the Data Center, but rather to transport a subset of that data. There is limited bandwidth available on the wireless network to co-location, and there are a number of CME Group data feeds. Limiting the feeds to the selection of CME Group market data regarding securities for which IDS determines there is demand would allow Users to receive the relevant CME Group Data over a wireless network, which could include data regarding some or all of the symbols for which IDS provides connectivity. The User would then determine those symbols for which it will receive data.

The Exchange believes that it is reasonable that a User that has already purchased wireless connections to other Third Party Data would be charged a non-recurring charge when it purchases a wireless connection to the CME Group Data, because it would allow the Exchange to defray or cover certain costs it incurs in installing the wireless connection to the CME Group Data,

[14] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[15] 15 U.S.C. 78f(b).

[16] 15 U.S.C. 78f(b)(5).

[17] 15 U.S.C. 78f(b)(4).

[18] *See* 82 FR 29604, *supra* note 12.

which costs it incurs irrespective of whether the User has existing wireless connections to Third Party Data, while providing the User the benefit of the installation, which would allow it to receive CME Group Data within co-location and with a lower latency over the fiber optics option. To do the initial installation, the Exchange must provide the personnel required for initial installation and testing. The costs associated with installing wireless connections are incrementally higher than those associated with installing fiber optics-based solutions.

The Exchange believes that it is reasonable that a User that connects to both CME Group Data and Existing Third Party Data may not use the same port for connectivity to both, and so would have at least two ports, because the proposed wireless connection would include the use of one port for connectivity to CME Group Data and connectivity to the Existing Third Party Data includes the use of one port for connectivity to Existing Third Party Data. A User would not pay a separate fee for using such ports.

The Exchange believes the proposed pricing for the wireless connection to CME Group Data is reasonable because it would allow the Exchange to defray or cover the costs associated with offering Users a wireless connection to CME Group Data while providing Users the benefit of receiving CME Group Data within co-location and with a lower latency over the fiber optics option. The wireless connection for CME Group Data would allow Users to select the CME Group Data connectivity option that better suits their needs.

The Exchange believes that the proposed pricing is reasonable because the Exchange proposes to offer the wireless connection to CME Group Data described herein as a convenience to Users, but in order to do so must provide, maintain and operate the Data Center facility hardware and technology infrastructure. The Exchange must handle the installation, administration, monitoring, support and maintenance of such services, including by responding to any production issues. Since the inception of co-location, the Exchange has made numerous improvements to the network hardware and technology infrastructure and has established additional administrative controls. The Exchange has expanded the network infrastructure to keep pace with the increased number of services available to Users. Specifically, in order to offer wireless connections, the Exchange must install, test, maintain and operate the wireless equipment.

The Proposed Change Is Not Unfairly Discriminatory

The Exchange believes that the proposed rule change is not unfairly discriminatory for the following reasons.

Without this proposed rule change, Users would have fewer options for connectivity to CME Group Data. The proposed change would provide Users with an additional choice with respect to the form and optimal latency of the connectivity they use to receive CME Group market data, allowing a User to select the connectivity that better suits its needs, helping it tailor its colocation operations to the requirements of its business operations. Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data using other methods: From another User, a third party wireless connection, or through an IDS or third party fiber connection.

The Exchange believes that it is not unfairly discriminatory to not transport information for all of the symbols included in CME Group data feeds to the Data Center, but rather to transport a subset of that data. There is limited bandwidth available on the wireless network to co-location, and there are a number of CME Group data feeds. Limiting the feeds to the selection of CME Group market data regarding securities for which IDS determines there is demand would allow Users to receive the relevant CME Group Data over a wireless network. The User would then determine those symbols for which it will receive data, which could include data regarding some or all of the symbols for which IDS provides connectivity.

The Exchange believes that the proposed pricing is not unfairly discriminatory because the Exchange proposes to offer the wireless connection to CME Group Data described herein as a convenience to Users, but in order to do so must provide, maintain and operate the Data Center facility hardware and technology infrastructure. The Exchange must handle the installation, administration, monitoring, support and maintenance of such services, including by responding to any production issues. Since the inception of co-location, the Exchange has made numerous improvements to the network hardware and technology infrastructure and has established additional administrative controls. The Exchange has expanded the network infrastructure to keep pace with the increased number of services available to Users. Specifically, in order to offer wireless connections, the Exchange must install, test, maintain and operate the wireless equipment.

The Exchange believes that the proposed change is not unfairly discriminatory because it will result in fees being charged only to Users that voluntarily select to receive the corresponding services and because those services will be available to all Users. Furthermore, the Exchange believes that the services and fees proposed herein are not unfairly discriminatory because, in addition to the services being completely voluntary, they are available to all Users on an equal basis (*i.e.,* the same products and services are available to all Users). All Users that voluntarily select wireless connections to CME Group Data would be charged the same amount for the same services.

Users that opt to use wireless connections to CME Group Data would receive the CME Group Data that is available to all Users, as all market participants that contract with CME Group or its affiliate for CME Group Data, as required, may receive it.

The Proposed Change Is an Equitable Allocation of Fees and Credits

The Exchange believes that its proposal equitably allocates its fees among Users.

Without this proposed rule change, Users would have fewer options for connectivity to CME Group Data. The proposed change would provide Users with an additional choice with respect to the form and optimal latency of the connectivity they use to receive CME Group market data, allowing a User to select the connectivity that better suits its needs, helping it tailor its colocation operations to the requirements of its business operations. Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data using other methods: From another User, a third party wireless connection, or through an IDS or third party fiber connection.

The Exchange believes that the proposed change is equitable because it will result in fees being charged only to Users that voluntarily select to receive the corresponding services and because those services will be available to all Users. Furthermore, the Exchange believes that the services and fees proposed herein are equitably allocated because, in addition to the services being completely voluntary, they are available to all Users on an equal basis (*i.e.,* the same products and services are available to all Users). All Users that voluntarily select wireless connections

to CME Group Data would be charged the same amount for the same services.

The Exchange operates in a highly competitive market in which exchanges offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. Accordingly, fees charged for co-location services are constrained by the active competition for the order flow of, and other business from, such market participants. If a particular exchange charges excessive fees for co-location services, affected market participants will opt to terminate their co-location arrangements with that exchange, and adopt a possible range of alternative strategies, including placing their servers in a physically proximate location outside the exchange's data center (which could be a competing exchange), or pursuing strategies less dependent upon the lower exchange-to-participant latency associated with co-location. Accordingly, the exchange charging excessive fees would stand to lose not only co-location revenues but also the liquidity of the formerly co-located trading firms, which could have additional follow-on effects on the market share and revenue of the affected exchange.

For the reasons above, the proposed changes do not unfairly discriminate between or among market participants that are otherwise capable of satisfying any applicable co-location fees, requirements, terms and conditions established from time to time by the Exchange.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange believes that the proposal will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of Section 6(b)(8) of the Act.[19]

The proposed change does not affect competition among national securities exchanges or among members of the Exchange, but rather between IDS and its commercial competitors.

The wireless connection would provide Users with an alternative means of connectivity to CME Group Data. The proposed change would provide Users with an additional choice with respect to the form and optimal latency of the connectivity they use to receive CME Group market data, allowing a User to select the connectivity that better suits its needs, helping it tailor its colocation operations to the requirements of its business operations.

Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data using other methods: From another User, a third party wireless connection, or through an IDS or third party fiber connection. Based on the information available to it, the Exchange believes that at least one market participant provides wireless connectivity to CME Group market data in the Data Center. The Exchange believes that the wireless connection offered by this third party entity provides connectivity at the same or similar latency as the proposed connection to CME Group Data, and at the same or similar cost. The proposed connection to CME Group Data and the existing third party wireless connection to CME Group Data would follow the same route within the Data Center: They would both enter through a meet-me-room, connect to equipment in co-location, and then connect to any Users that are customers. Because of this, the Exchange does not believe that IDS has an advantage over the third party in providing the connectivity. The proposed wireless connection would lead to a pole, from where a fiber connection would lead into the Data Center. The pole is owned by a third party and is not on the grounds of the Data Center.

IDS already offers fiber connections to CME Group market data to Users.[20] The Exchange also believes that at least two third party market participants offer such fiber connections to CME Group. In addition to these options, a User may create a proprietary wireless connection or connect through another User in order to connect to CME Group market data. The Exchange believes that at least two market participants already provide wireless connectivity to CME Group market data to other data centers in New Jersey.

The Exchange notes that the proposed wireless connection would compete not just with other wireless connections to CME Group market data, but also with fiber network connections, which may be more attractive to some market participants as they are more reliable and less susceptible to weather conditions. Market participants' considerations in determining what connectivity to purchase may include latency; the amount of network uptime; the equipment that the network uses; the cost of the connection; and the applicable contractual provisions. As noted above, a User may purchase a fiber connection to CME Group market data from at least three providers, including IDS.

The Exchange operates in a highly competitive market in which exchanges and other vendors (*e.g.,* Hosting Users) offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [21]

*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 [22] and Rule 19b–4(f)(6) thereunder.[23]

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

[19] 15 U.S.C. 78f(b)(8).

[20] *See* 82 FR 29604, *supra* note 12.

[21] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[22] 15 U.S.C. 78s(b)(3)(A).

[23] 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.

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–2021–97 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–2021–97. 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–2021–97, and should be submitted on or before December 9, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[24]

**J. Matthew DeLesDernier,**

*Assistant Secretary.*

[FR Doc. 2021–25124 Filed 11–17–21; 8:45 am]

**BILLING CODE 8011–01–P**

[24] 17 CFR 200.30–3(a)(12).

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## SECURITIES AND EXCHANGE COMMISSION

**[SEC File No. 270–491, OMB Control No. 3235–0548]**

## Submission for OMB Review; Comment Request

*Upon Written Request, Copies Available From:* Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

*Extension:*
Rule 35d–1

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for extension of the previously approved collection of information discussed below.

Rule 35d–1 (17 CFR 270.35d–1) under the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*) defines as ''materially deceptive and misleading'' for purposes of Section 35(d), among other things, a name suggesting that a registered investment company or series thereof (a ''fund'') focuses its investments in a particular type of investment or investments, in investments in a particular industry or group of industries, or in investments in a particular country or geographic region, unless, among other things, the fund adopts a certain investment policy. Rule 35d–1 further requires either that the investment policy is fundamental or that the fund has adopted a policy to provide its shareholders with at least 60 days prior notice of any change in the investment policy (''notice to shareholders''). The rule's notice to shareholders provision is intended to ensure that when shareholders purchase shares in a fund based, at least in part, on its name, and with the expectation that it will follow the investment policy suggested by that name, they will have sufficient time to decide whether to redeem their shares in the event that the fund decides to pursue a different investment policy.

The Commission estimates that there are approximately 11,502 open-end and closed-end funds that have names that are covered by the rule. The Commission estimates that of these 11,502 funds, approximately 38 will provide prior notice to shareholders pursuant to a policy adopted in accordance with this rule per year. The Commission estimates that the annual burden associated with the notice to shareholders requirement of the rule is 20 hours per response, for annual total of 760 hours per year.

Estimates of average burden hours are made solely for the purposes of the Paperwork Reduction Act and are not derived from a comprehensive or even representative survey or study of the costs of Commission rules and forms. Providing prior notice to shareholders under rule 35d-1 is not mandatory. An investment company may choose to have a name that does not indicate that the fund focuses its investments in a particular type of investment or investments, or in investments in a particular industry or group of industry. If an investment company does choose such a name, it will only need to provide prior notice to shareholders of a change in its 80% investment policy if it first has adopted a policy to provide notice and then has decided to change this investment policy. The information provided under rule 35d–1 will not be kept confidential. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The public may view background documentation for this information collection at the following website: *www.reginfo.gov.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to (i) *www.reginfo.gov/public/do/PRAMain* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John R. Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

Dated: November 15, 2021.

**J. Matthew DeLesDernier,**

*Assistant Secretary.*

[FR Doc. 2021–25171 Filed 11–17–21; 8:45 am]

**BILLING CODE 8011–01–P**

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–93567; File No. SR–NYSENAT–2021–23]**

## Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Exchange's Price List Regarding Colocation Services

November 12, 2021.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act''),[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on November 3, 2021, NYSE National, Inc. (''NYSE National'' 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 the Exchange's Price List regarding colocation services and fees to provide Users with wireless connectivity to CME Group market data. 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

*A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

1. Purpose

The Exchange proposes to amend the Price List regarding colocation services and fees to provide Users [4] with wireless connectivity to CME Group market data.[5]

The Exchange currently provides Users with wireless connections to eight market data feeds or combinations of feeds from third party markets (the ''Existing Third Party Data''),[6] and wired connections to 43 market data feeds.[7] The Exchange now proposes to add to its Price List wireless connections to CME Group, Inc. (''CME Group'') market data (such data, ''CME Group Data'' and, together with the Existing Third Party Data, the ''Third Party Data''). Users would be offered the proposed wireless connection to the CME Group Data through connections into the colocation center in the Mahwah, New Jersey data center (''Data Center'').[8]

The Exchange expects that the proposed rule change would become operative no later than March 31, 2022. The Exchange will announce the date that the wireless connection to the CME Group Data will be available through a customer notice.

To receive CME Group Data, the User would enter into an agreement with a non-Exchange affiliated party for permission to receive the data, if required. The User would pay this third party any fees for the data content.

For each wireless connection to CME Group Data, a User would be charged a $5,000 non-recurring initial charge and a monthly recurring charge of $6,000. The Exchange proposes to revise its Price List to reflect fees related to the wireless connection to CME Group Data.

The CME Group Data would not include all possible CME Group data feeds. There is limited bandwidth available on the wireless network to co-location, and there are currently dozens of CME Group data feeds. To provide connectivity to all of them would use a large amount of bandwidth.

Accordingly, rather than provide connectivity to all possible symbols included in the CME Group data feeds, the wireless connection would only provide connectivity to a selection of CME Group market data for which IDS determines there is User demand. IDS similarly provides connectivity to a selection of data, rather than entire feeds, over a wireless connection to the Markham, Canada third party data center.[9] The User would then determine the symbols for which it would receive data, which could include data regarding some or all of the symbols for which IDS provides connectivity.[10] The Exchange would not have visibility into which portion of the CME Group Data a given User receives.

As with the Existing Third Party Data, if a User purchased two wireless connections, it would pay two non-recurring initial charges. Each wireless connection would include the use of one port for connectivity to CME Group Data. A User would not pay a fee for the use of such port. If a User also connects to Existing Third Party Data, it would not be able to use the same port that it uses for connectivity to CME Group Data to connect to such Existing Third Party Data. Accordingly, a User that connects to both CME Group Data and Existing Third Party Data would have at least two ports, and would not be separately charged for two ports.[11]

[4] 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. 83351 (May 31, 2018), 83 FR 26314 (June 6, 2018) (SR–NYSENAT–2018–07). 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–2021–67, SR–NYSEAMER–2021–43, SR–NYSEArca–2021–97, and SR–NYSECHX–2021–17.

[5] The Exchange initially filed rule changes relating to its co-location services with the Securities and Exchange Commission (''Commission'') in 2018. *See* 83 FR 26314, *supra* note 4.

[6] *See id.,* at 26319–26320.

[7] *See id.,* at 26322–26323.

[8] Through its ICE Data Services (''IDS'') business, Intercontinental Exchange, Inc. (''ICE'') operates the Data Center in Mahwah, New Jersey. The Exchange and the Affiliate SROs are indirect subsidiaries of ICE. The proposed service would be provided by IDS pursuant to an agreement with a non-ICE entity. IDS does not own the wireless network that would be used to provide the service.

[9] *See* Securities Exchange Act Release No. 88241 (February 19, 2020), 85 FR 10738 (February 25, 2020) (SR–NYSENAT–2020–08). *See also* Securities Exchange Act Release No. 90209 (October 15, 2020), 85 FR 67044 (October 21, 2020) (SR–NYSE–2020–05, SR–NYSEAMER–2020–05, SR–NYSEArca–2020–08, SR–NYSECHX–2020–02, SR–NYSENAT–2020–03, SR–NYSE–2020–11, SR–NYSEAMER–2020–10, SR–NYSEArca–2020–15, SR–NYSECHX–2020–05, SR–NYSENAT–2020–08).

[10] The Exchange understands that the third parties that provide wireless connectivity to CME Group market data to the Data Center and other data centers in New Jersey follow a substantially similar model, offering connectivity to a selection of market data rather than entire feeds.

[11] If a User purchased a wireless connection to CME Group Data, that connection would include

Application and Impact of the Proposed Changes

The proposed changes would not apply differently to distinct types or sizes of market participants. Rather, they would apply to all Users equally.

As is currently the case, the purchase of any co-location service, including connectivity to Third Party Data, is completely voluntary and the Price List is applied uniformly to all Users.

Competitive Environment

Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data using other methods: From another User, a third party wireless connection, or through an IDS or third party fiber connection.

Based on the information available to it, the Exchange believes that at least one market participant provides wireless connectivity to CME Group market data in the Data Center. The Exchange believes that the wireless connection offered by this third party entity provides connectivity at the same or similar speed as the proposed connection to CME Group Data, and at the same or similar cost.[12] The proposed connection to CME Group Data and the existing third party wireless connection to CME Group Data would follow the same route within the Data Center: They would both enter through a meet-me-room, connect to equipment in co-location, and then connect to any Users that are customers. Because of this, the Exchange does not believe that IDS has an advantage over the third party in providing the connectivity. The proposed wireless connection would lead to a pole, from where a fiber connection would lead into the Data Center. The pole is owned by a third party and is not on the grounds of the Data Center.

IDS already offers fiber connections to CME Group market data to Users.[13] The Exchange also believes that at least two third party market participants offer such fiber connections to CME Group market data. In addition to these options, a User may create a proprietary wireless connection or connect through another User in order to connect to CME Group market data. The Exchange believes that at least two market participants already provide wireless connectivity to CME Group market data to other data centers in New Jersey.

Wireless connections involve beaming signals through the air between antennas that are within line of sight of one another. Because the signals travel a straight, unimpeded line, and because light waves travel faster through air than through glass (fiber optics), wireless messages have lower latency than messages travelling through fiber optics. At the same time, as a general rule wireless networks have less uptime than fiber networks. Wireless networks are directly and immediately affected by adverse weather conditions, which can cause message loss and outage periods. Wireless networks cannot be configured with redundancy in the same way that fiber networks can. As a result, an equipment or weather issue at any one location on the network will cause the entire network to have an outage. In addition, maintenance can take longer than it would with a fiber based network, as the relevant tower may be in a hard to reach location, or weather conditions may present safety issues, delaying technicians servicing equipment. Even under normal conditions, a wireless network will have a higher error rate than a fiber network of the same length.

The latency of a wireless network depends on several factors. Variables include the wireless equipment utilized; the route of, and number of towers or buildings in, the network; their proximity to the data centers on either end; and the fiber equipment used at either end of the connection. Moreover, latency is not the only consideration that a customer may have in selecting a wireless network to connect to CME Group market data. Other considerations may include the amount of network uptime; the equipment that the network uses; the cost of the connection; and the applicable contractual provisions. Indeed, fiber network connections may be more attractive to some market participants as they are more reliable and less susceptible to weather conditions.

The Exchange operates in a highly competitive market in which exchanges and other vendors (*e.g.,* Hosting Users) offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [14]

The proposed change is not otherwise intended to address any other issues relating to co-location services and/or related fees, and the Exchange is not aware of any problems that Users 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,[15] in general, and furthers the objectives of Section 6(b)(5) of the Act,[16] 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,[17] 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 Proposed Change Is Reasonable

The Exchange believes that the proposed rule change is reasonable.

The wireless connection would provide Users with an alternative means of connectivity to CME Group Data. The proposed change would provide Users with an additional choice with respect to the form and optimal latency of the connectivity they use to receive CME Group market data, allowing a User to select the connectivity that better suits its needs, helping it tailor its colocation operations to the requirements of its

the use of one port for connectivity to CME Group Data. If the same User connected to Existing Third Party Data, it would receive the use of one port for connectivity to the Existing Third Party Data. It would not be separately charged for such ports. A User may purchase additional ports. *See* 83 FR 26314, *supra* note 4, at 26318.

[12] Because the third party is not a regulated entity, it is not obligated to make its latency figures or fees publicly available or the same for all entities.

[13] *See id.,* at 26323.

[14] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[15] 15 U.S.C. 78f(b).

[16] 15 U.S.C. 78f(b)(5).

[17] 15 U.S.C. 78f(b)(4).

business operations. Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data using other methods: From another User, a third party wireless connection, or through an IDS or third party fiber connection.

Based on the information available to it, the Exchange believes that at least one market participant provides wireless connectivity to CME Group market data in the Data Center. The Exchange believes that the wireless connection offered by this third party entity provides connectivity at the same or similar speed as the proposed connection to CME Group Data, and at the same or similar cost. The proposed connection to CME Group Data and the existing third party wireless connection to CME Group Data would follow the same route within the Data Center: They would both enter through a meet-me-room, connect to equipment in co-location, and then connect to any Users that are customers. Because of this, the Exchange does not believe that IDS has an advantage over the third party in providing the connectivity. The proposed wireless connection would lead to a pole, from where a fiber connection would lead into the Data Center. The pole is owned by a third party and is not on the grounds of the Data Center.

IDS already offers fiber connections to CME Group market data to Users.[18] The Exchange also believes that at least two third party market participants offer such fiber connections to CME Group. In addition to these options, a User may create a proprietary wireless connection or connect through another User in order to connect to CME Group market data. The Exchange believes that at least two market participants already provide wireless connectivity to CME Group market data to other data centers in New Jersey.

Market participants' considerations in determining what connectivity to purchase may include latency; the amount of network uptime; the equipment that the network uses; the cost of the connection; and the applicable contractual provisions. Indeed, fiber network connections may be more attractive to some market participants as they are more reliable and less susceptible to weather conditions.

The Exchange believes that it is reasonable to not transport information for all of the symbols included in CME Group data feeds to the Data Center, but rather to transport a subset of that data. There is limited bandwidth available on the wireless network to co-location, and there are a number of CME Group data feeds. Limiting the feeds to the selection of CME Group market data regarding securities for which IDS determines there is demand would allow Users to receive the relevant CME Group Data over a wireless network, which could include data regarding some or all of the symbols for which IDS provides connectivity. The User would then determine those symbols for which it will receive data.

The Exchange believes that it is reasonable that a User that has already purchased wireless connections to other Third Party Data would be charged a non-recurring charge when it purchases a wireless connection to the CME Group Data, because it would allow the Exchange to defray or cover certain costs it incurs in installing the wireless connection to the CME Group Data, which costs it incurs irrespective of whether the User has existing wireless connections to Third Party Data, while providing the User the benefit of the installation, which would allow it to receive CME Group Data within co-location and with a lower latency over the fiber optics option. To do the initial installation, the Exchange must provide the personnel required for initial installation and testing. The costs associated with installing wireless connections are incrementally higher than those associated with installing fiber optics-based solutions.

The Exchange believes that it is reasonable that a User that connects to both CME Group Data and Existing Third Party Data may not use the same port for connectivity to both, and so would have at least two ports, because the proposed wireless connection would include the use of one port for connectivity to CME Group Data and connectivity to the Existing Third Party Data includes the use of one port for connectivity to Existing Third Party Data. A User would not pay a separate fee for using such ports.

The Exchange believes the proposed pricing for the wireless connection to CME Group Data is reasonable because it would allow the Exchange to defray or cover the costs associated with offering Users a wireless connection to CME Group Data while providing Users the benefit of receiving CME Group Data within co-location and with a lower latency over the fiber optics option. The wireless connection for CME Group Data would allow Users to select the CME Group Data connectivity option that better suits their needs.

The Exchange believes that the proposed pricing is reasonable because the Exchange proposes to offer the wireless connection to CME Group Data described herein as a convenience to Users, but in order to do so must provide, maintain and operate the Data Center facility hardware and technology infrastructure. The Exchange must handle the installation, administration, monitoring, support and maintenance of such services, including by responding to any production issues. Since the inception of co-location, the Exchange has made numerous improvements to the network hardware and technology infrastructure and has established additional administrative controls. The Exchange has expanded the network infrastructure to keep pace with the increased number of services available to Users. Specifically, in order to offer wireless connections, the Exchange must install, test, maintain and operate the wireless equipment.

The Proposed Change Is Not Unfairly Discriminatory

The Exchange believes that the proposed rule change is not unfairly discriminatory for the following reasons.

Without this proposed rule change, Users would have fewer options for connectivity to CME Group Data. The proposed change would provide Users with an additional choice with respect to the form and optimal latency of the connectivity they use to receive CME Group market data, allowing a User to select the connectivity that better suits its needs, helping it tailor its colocation operations to the requirements of its business operations. Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data using other methods: From another User, a third party wireless connection, or through an IDS or third party fiber connection.

The Exchange believes that it is not unfairly discriminatory to not transport information for all of the symbols included in CME Group data feeds to the Data Center, but rather to transport a subset of that data. There is limited bandwidth available on the wireless network to co-location, and there are a number of CME Group data feeds. Limiting the feeds to the selection of CME Group market data regarding securities for which IDS determines there is demand would allow Users to receive the relevant CME Group Data over a wireless network. The User would then determine those symbols for which it will receive data, which could include data regarding some or all of the symbols for which IDS provides connectivity.

[18] *See* 83 FR 26314, *supra* note 4, at 26323.

The Exchange believes that the proposed pricing is not unfairly discriminatory because the Exchange proposes to offer the wireless connection to CME Group Data described herein as a convenience to Users, but in order to do so must provide, maintain and operate the Data Center facility hardware and technology infrastructure. The Exchange must handle the installation, administration, monitoring, support and maintenance of such services, including by responding to any production issues. Since the inception of co-location, the Exchange has made numerous improvements to the network hardware and technology infrastructure and has established additional administrative controls. The Exchange has expanded the network infrastructure to keep pace with the increased number of services available to Users. Specifically, in order to offer wireless connections, the Exchange must install, test, maintain and operate the wireless equipment.

The Exchange believes that the proposed change is not unfairly discriminatory because it will result in fees being charged only to Users that voluntarily select to receive the corresponding services and because those services will be available to all Users. Furthermore, the Exchange believes that the services and fees proposed herein are not unfairly discriminatory because, in addition to the services being completely voluntary, they are available to all Users on an equal basis (*i.e.,* the same products and services are available to all Users). All Users that voluntarily select wireless connections to CME Group Data would be charged the same amount for the same services.

Users that opt to use wireless connections to CME Group Data would receive the CME Group Data that is available to all Users, as all market participants that contract with CME Group or its affiliate for CME Group Data, as required, may receive it.

The Proposed Change Is an Equitable Allocation of Fees and Credits

The Exchange believes that its proposal equitably allocates its fees among Users.

Without this proposed rule change, Users would have fewer options for connectivity to CME Group Data. The proposed change would provide Users with an additional choice with respect to the form and optimal latency of the connectivity they use to receive CME Group market data, allowing a User to select the connectivity that better suits its needs, helping it tailor its colocation operations to the requirements of its business operations. Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data using other methods: From another User, a third party wireless connection, or through an IDS or third party fiber connection.

The Exchange believes that the proposed change is equitable because it will result in fees being charged only to Users that voluntarily select to receive the corresponding services and because those services will be available to all Users. Furthermore, the Exchange believes that the services and fees proposed herein are equitably allocated because, in addition to the services being completely voluntary, they are available to all Users on an equal basis (*i.e.,* the same products and services are available to all Users). All Users that voluntarily select wireless connections to CME Group Data would be charged the same amount for the same services.

The Exchange operates in a highly competitive market in which exchanges offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. Accordingly, fees charged for co-location services are constrained by the active competition for the order flow of, and other business from, such market participants. If a particular exchange charges excessive fees for co-location services, affected market participants will opt to terminate their co-location arrangements with that exchange, and adopt a possible range of alternative strategies, including placing their servers in a physically proximate location outside the exchange's data center (which could be a competing exchange), or pursuing strategies less dependent upon the lower exchange-to-participant latency associated with co-location. Accordingly, the exchange charging excessive fees would stand to lose not only co-location revenues but also the liquidity of the formerly co-located trading firms, which could have additional follow-on effects on the market share and revenue of the affected exchange.

For the reasons above, the proposed changes do not unfairly discriminate between or among market participants that are otherwise capable of satisfying any applicable co-location fees, requirements, terms and conditions established from time to time by the Exchange.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange believes that the proposal will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of Section 6(b)(8) of the Act.[19]

The proposed change does not affect competition among national securities exchanges or among members of the Exchange, but rather between IDS and its commercial competitors.

The wireless connection would provide Users with an alternative means of connectivity to CME Group Data. The proposed change would provide Users with an additional choice with respect to the form and optimal latency of the connectivity they use to receive CME Group market data, allowing a User to select the connectivity that better suits its needs, helping it tailor its colocation operations to the requirements of its business operations.

Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data using other methods: From another User, a third party wireless connection, or through an IDS or third party fiber connection. Based on the information available to it, the Exchange believes that at least one market participant provides wireless connectivity to CME Group market data in the Data Center. The Exchange believes that the wireless connection offered by this third party entity provides connectivity at the same or similar latency as the proposed connection to CME Group Data, and at the same or similar cost. The proposed connection to CME Group Data and the existing third party wireless connection to CME Group Data would follow the same route within the Data Center: They would both enter through a meet-me-room, connect to equipment in co-location, and then connect to any Users that are customers. Because of this, the Exchange does not believe that IDS has an advantage over the third party in providing the connectivity. The proposed wireless connection would lead to a pole, from where a fiber connection would lead into the Data Center. The pole is owned by a third party and is not on the grounds of the Data Center.

IDS already offers fiber connections to CME Group market data to Users.[20] The Exchange also believes that at least two third party market participants offer such fiber connections to CME Group. In addition to these options, a User may

[19] 15 U.S.C. 78f(b)(8).

[20] *See* 83 FR 26314, *supra* note 4, at 26323.

create a proprietary wireless connection or connect through another User in order to connect to CME Group market data. The Exchange believes that at least two market participants already provide wireless connectivity to CME Group market data to other data centers in New Jersey.

The Exchange notes that the proposed wireless connection would compete not just with other wireless connections to CME Group market data, but also with fiber network connections, which may be more attractive to some market participants as they are more reliable and less susceptible to weather conditions. Market participants' considerations in determining what connectivity to purchase may include latency; the amount of network uptime; the equipment that the network uses; the cost of the connection; and the applicable contractual provisions. As noted above, a User may purchase a fiber connection to CME Group market data from at least three providers, including IDS.

The Exchange operates in a highly competitive market in which exchanges and other vendors (*e.g.,* Hosting Users) offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [21]

*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 [22] and Rule 19b–4(f)(6) thereunder.[23]

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–NYSENAT–2021–23 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–2021–23. 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–2021–23, and should be submitted on or before December 9, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[24]

**J. Matthew DeLesDernier,**

*Assistant Secretary.*

[FR Doc. 2021–25122 Filed 11–17–21; 8:45 am]

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[21] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[22] 15 U.S.C. 78s(b)(3)(A).

[23] 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.

[24] 17 CFR 200.30–3(a)(12).

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## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–93561; File No. SR–NYSEAMER–2021–43]**

## 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 Regarding Colocation Services

November 12, 2021.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act''),[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on November 3, 2021, NYSE American LLC (''NYSE American'' 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.

[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 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 provide Users with wireless connectivity to CME Group market data. 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 Statutory Basis for, the Proposed Rule Change*

1. Purpose

The Exchange proposes to amend the Price List and Fee Schedule regarding colocation services and fees to provide Users [4] with wireless connectivity to CME Group market data.[5]

The Exchange currently provides Users with wireless connections to eight market data feeds or combinations of feeds from third party markets (the ''Existing Third Party Data''),[6] and wired connections to 43 market data feeds.[7] The Exchange now proposes to add to its Price List and Fee Schedule wireless connections to CME Group, Inc. (''CME Group'') market data (such data, ''CME Group Data'' and, together with the Existing Third Party Data, the ''Third Party Data''). Users would be offered the proposed wireless connection to the CME Group Data through connections into the colocation center in the Mahwah, New Jersey data center (''Data Center'').[8]

The Exchange expects that the proposed rule change would become operative no later than March 31, 2022. The Exchange will announce the date that the wireless connection to the CME Group Data will be available through a customer notice.

To receive CME Group Data, the User would enter into an agreement with a non-Exchange affiliated party for permission to receive the data, if required. The User would pay this third party any fees for the data content.

For each wireless connection to CME Group Data, a User would be charged a $5,000 non-recurring initial charge and a monthly recurring charge of $6,000. The Exchange proposes to revise its Price List and Fee Schedule to reflect fees related to the wireless connection to CME Group Data.

The CME Group Data would not include all possible CME Group data feeds. There is limited bandwidth available on the wireless network to co-location, and there are currently dozens of CME Group data feeds. To provide connectivity to all of them would use a large amount of bandwidth.

Accordingly, rather than provide connectivity to all possible symbols included in the CME Group data feeds, the wireless connection would only provide connectivity to a selection of CME Group market data for which IDS determines there is User demand. IDS similarly provides connectivity to a selection of data, rather than entire feeds, over a wireless connection to the Markham, Canada third party data center.[9] The User would then determine the symbols for which it would receive data, which could include data regarding some or all of the symbols for which IDS provides connectivity.[10] The Exchange would not have visibility into which portion of the CME Group Data a given User receives.

As with the Existing Third Party Data, if a User purchased two wireless connections, it would pay two non-recurring initial charges. Each wireless connection would include the use of one port for connectivity to CME Group Data. A User would not pay a fee for the use of such port. If a User also connects to Existing Third Party Data, it would not be able to use the same port that it uses for connectivity to CME Group Data to connect to such Existing Third Party Data. Accordingly, a User that connects to both CME Group Data and Existing Third Party Data would have at least two ports, and would not be separately charged for two ports.[11]

Application and Impact of the Proposed Changes

The proposed changes would not apply differently to distinct types or sizes of market participants. Rather, they would apply to all Users equally.

As is currently the case, the purchase of any co-location service, including connectivity to Third Party Data, is completely voluntary and the Price List and Fee Schedule are applied uniformly to all Users.

Competitive Environment

Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data using other methods: From another User, a third

[4] 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. 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 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 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–2021–67, SR–NYSEArca–2021–97, SR–NYSECHX–2021–17, and SR–NYSENAT–2021–23.

[5] 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).

[6] *See* Securities Exchange Act Release Nos. 76748 (December 23, 2015), 80 FR 81648 (December 30, 2015) (SR–NYSEMKT–2015–85); 78376 (July 21, 2016), 81 FR 49311 (July 27, 2016) (SR–NYSEMKT–2016–17); and 80117 (February 28, 2017), 82 FR 12646 (March 6, 2017) (SR–NYSEMKT–2017–09).

[7] *See* Securities Exchange Act Release No. 80309 (March 24, 2017), 82 FR 15725 (March 30, 2017) (SR–NYSEMKT–2016–63).

[8] Through its ICE Data Services (''IDS'') business, Intercontinental Exchange, Inc. (''ICE'') operates the Data Center in Mahwah, New Jersey. The Exchange and the Affiliate SROs are indirect subsidiaries of ICE. The proposed service would be provided by IDS pursuant to an agreement with a non-ICE entity. IDS does not own the wireless network that would be used to provide the service.

[9] *See* Securities Exchange Act Release No. 88238 (February 19, 2020), 85 FR 10776 (February 25, 2020) (SR–NYSEAMER–2020–10). *See also* Securities Exchange Act Release No. 90209 (October 15, 2020), 85 FR 67044 (October 21, 2020) (SR–NYSE–2020–05, SR–NYSEAMER–2020–05, SR–NYSEArca–2020–08, SR–NYSECHX–2020–02, SR–NYSENAT–2020–03, SR–NYSE–2020–11, SR–NYSEAMER–2020–10, SR–NYSEArca–2020–15, SR–NYSECHX–2020–05, SR–NYSENAT–2020–08).

[10] The Exchange understands that the third parties that provide wireless connectivity to CME Group market data to the Data Center and other data centers in New Jersey follow a substantially similar model, offering connectivity to a selection of market data rather than entire feeds.

[11] If a User purchased a wireless connection to CME Group Data, that connection would include the use of one port for connectivity to CME Group Data. If the same User connected to Existing Third Party Data, it would receive the use of one port for connectivity to the Existing Third Party Data. It would not be separately charged for such ports. A User may purchase additional ports. *See* 80 FR 81648, *supra* note 6, at 81649.

party wireless connection, or through an IDS or third party fiber connection.

Based on the information available to it, the Exchange believes that at least one market participant provides wireless connectivity to CME Group market data in the Data Center. The Exchange believes that the wireless connection offered by this third party entity provides connectivity at the same or similar speed as the proposed connection to CME Group Data, and at the same or similar cost.[12] The proposed connection to CME Group Data and the existing third party wireless connection to CME Group Data would follow the same route within the Data Center: They would both enter through a meet-me-room, connect to equipment in co-location, and then connect to any Users that are customers. Because of this, the Exchange does not believe that IDS has an advantage over the third party in providing the connectivity. The proposed wireless connection would lead to a pole, from where a fiber connection would lead into the Data Center. The pole is owned by a third party and is not on the grounds of the Data Center.

IDS already offers fiber connections to CME Group market data to Users.[13] The Exchange also believes that at least two third party market participants offer such fiber connections to CME Group market data. In addition to these options, a User may create a proprietary wireless connection or connect through another User in order to connect to CME Group market data. The Exchange believes that at least two market participants already provide wireless connectivity to CME Group market data to other data centers in New Jersey.

Wireless connections involve beaming signals through the air between antennas that are within line of sight of one another. Because the signals travel a straight, unimpeded line, and because light waves travel faster through air than through glass (fiber optics), wireless messages have lower latency than messages travelling through fiber optics. At the same time, as a general rule wireless networks have less uptime than fiber networks. Wireless networks are directly and immediately affected by adverse weather conditions, which can cause message loss and outage periods. Wireless networks cannot be configured with redundancy in the same way that fiber networks can. As a result, an equipment or weather issue at any one location on the network will cause the entire network to have an outage. In addition, maintenance can take longer than it would with a fiber based network, as the relevant tower may be in a hard to reach location, or weather conditions may present safety issues, delaying technicians servicing equipment. Even under normal conditions, a wireless network will have a higher error rate than a fiber network of the same length.

The latency of a wireless network depends on several factors. Variables include the wireless equipment utilized; the route of, and number of towers or buildings in, the network; their proximity to the data centers on either end; and the fiber equipment used at either end of the connection. Moreover, latency is not the only consideration that a customer may have in selecting a wireless network to connect to CME Group market data. Other considerations may include the amount of network uptime; the equipment that the network uses; the cost of the connection; and the applicable contractual provisions. Indeed, fiber network connections may be more attractive to some market participants as they are more reliable and less susceptible to weather conditions.

The Exchange operates in a highly competitive market in which exchanges and other vendors (*e.g.,* Hosting Users) offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [14]

The proposed change is not otherwise intended to address any other issues relating to co-location services and/or related fees, and the Exchange is not aware of any problems that Users 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,[15] in general, and furthers the objectives of Section 6(b)(5) of the Act,[16] 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,[17] 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 Proposed Change Is Reasonable

The Exchange believes that the proposed rule change is reasonable.

The wireless connection would provide Users with an alternative means of connectivity to CME Group Data. The proposed change would provide Users with an additional choice with respect to the form and optimal latency of the connectivity they use to receive CME Group market data, allowing a User to select the connectivity that better suits its needs, helping it tailor its colocation operations to the requirements of its business operations. Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data using other methods: From another User, a third party wireless connection, or through an IDS or third party fiber connection.

Based on the information available to it, the Exchange believes that at least one market participant provides wireless connectivity to CME Group market data in the Data Center. The Exchange believes that the wireless connection offered by this third party entity provides connectivity at the same or similar speed as the proposed connection to CME Group Data, and at the same or similar cost. The proposed connection to CME Group Data and the existing third party wireless connection to CME Group Data would follow the

[12] Because the third party is not a regulated entity, it is not obligated to make its latency figures or fees publicly available or the same for all entities.

[13] *See* Securities Exchange Act Release No. 81015 (June 23, 2017), 82 FR 29610 (June 29, 2017) (SR–NYSEMKT–2017–32).

[14] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[15] 15 U.S.C. 78f(b).

[16] 15 U.S.C. 78f(b)(5).

[17] 15 U.S.C. 78f(b)(4).

same route within the Data Center: They would both enter through a meet-me-room, connect to equipment in co-location, and then connect to any Users that are customers. Because of this, the Exchange does not believe that IDS has an advantage over the third party in providing the connectivity. The proposed wireless connection would lead to a pole, from where a fiber connection would lead into the Data Center. The pole is owned by a third party and is not on the grounds of the Data Center.

IDS already offers fiber connections to CME Group market data to Users.[18] The Exchange also believes that at least two third party market participants offer such fiber connections to CME Group. In addition to these options, a User may create a proprietary wireless connection or connect through another User in order to connect to CME Group market data. The Exchange believes that at least two market participants already provide wireless connectivity to CME Group market data to other data centers in New Jersey.

Market participants' considerations in determining what connectivity to purchase may include latency; the amount of network uptime; the equipment that the network uses; the cost of the connection; and the applicable contractual provisions. Indeed, fiber network connections may be more attractive to some market participants as they are more reliable and less susceptible to weather conditions.

The Exchange believes that it is reasonable to not transport information for all of the symbols included in CME Group data feeds to the Data Center, but rather to transport a subset of that data. There is limited bandwidth available on the wireless network to co-location, and there are a number of CME Group data feeds. Limiting the feeds to the selection of CME Group market data regarding securities for which IDS determines there is demand would allow Users to receive the relevant CME Group Data over a wireless network, which could include data regarding some or all of the symbols for which IDS provides connectivity. The User would then determine those symbols for which it will receive data.

The Exchange believes that it is reasonable that a User that has already purchased wireless connections to other Third Party Data would be charged a non-recurring charge when it purchases a wireless connection to the CME Group Data, because it would allow the Exchange to defray or cover certain costs it incurs in installing the wireless connection to the CME Group Data, which costs it incurs irrespective of whether the User has existing wireless connections to Third Party Data, while providing the User the benefit of the installation, which would allow it to receive CME Group Data within co-location and with a lower latency over the fiber optics option. To do the initial installation, the Exchange must provide the personnel required for initial installation and testing. The costs associated with installing wireless connections are incrementally higher than those associated with installing fiber optics-based solutions.

The Exchange believes that it is reasonable that a User that connects to both CME Group Data and Existing Third Party Data may not use the same port for connectivity to both, and so would have at least two ports, because the proposed wireless connection would include the use of one port for connectivity to CME Group Data and connectivity to the Existing Third Party Data includes the use of one port for connectivity to Existing Third Party Data. A User would not pay a separate fee for using such ports.

The Exchange believes the proposed pricing for the wireless connection to CME Group Data is reasonable because it would allow the Exchange to defray or cover the costs associated with offering Users a wireless connection to CME Group Data while providing Users the benefit of receiving CME Group Data within co-location and with a lower latency over the fiber optics option. The wireless connection for CME Group Data would allow Users to select the CME Group Data connectivity option that better suits their needs.

The Exchange believes that the proposed pricing is reasonable because the Exchange proposes to offer the wireless connection to CME Group Data described herein as a convenience to Users, but in order to do so must provide, maintain and operate the Data Center facility hardware and technology infrastructure. The Exchange must handle the installation, administration, monitoring, support and maintenance of such services, including by responding to any production issues. Since the inception of co-location, the Exchange has made numerous improvements to the network hardware and technology infrastructure and has established additional administrative controls. The Exchange has expanded the network infrastructure to keep pace with the increased number of services available to Users. Specifically, in order to offer wireless connections, the Exchange must install, test, maintain and operate the wireless equipment.

The Proposed Change Is Not Unfairly Discriminatory

The Exchange believes that the proposed rule change is not unfairly discriminatory for the following reasons.

Without this proposed rule change, Users would have fewer options for connectivity to CME Group Data. The proposed change would provide Users with an additional choice with respect to the form and optimal latency of the connectivity they use to receive CME Group market data, allowing a User to select the connectivity that better suits its needs, helping it tailor its colocation operations to the requirements of its business operations. Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data using other methods: From another User, a third party wireless connection, or through an IDS or third party fiber connection.

The Exchange believes that it is not unfairly discriminatory to not transport information for all of the symbols included in CME Group data feeds to the Data Center, but rather to transport a subset of that data. There is limited bandwidth available on the wireless network to co-location, and there are a number of CME Group data feeds. Limiting the feeds to the selection of CME Group market data regarding securities for which IDS determines there is demand would allow Users to receive the relevant CME Group Data over a wireless network. The User would then determine those symbols for which it will receive data, which could include data regarding some or all of the symbols for which IDS provides connectivity.

The Exchange believes that the proposed pricing is not unfairly discriminatory because the Exchange proposes to offer the wireless connection to CME Group Data described herein as a convenience to Users, but in order to do so must provide, maintain and operate the Data Center facility hardware and technology infrastructure. The Exchange must handle the installation, administration, monitoring, support and maintenance of such services, including by responding to any production issues. Since the inception of co-location, the Exchange has made numerous improvements to the network hardware and technology infrastructure and has established additional administrative controls. The Exchange has expanded the network infrastructure to keep pace with the

[18] *See* 82 FR 29610, *supra* note 12.

increased number of services available to Users. Specifically, in order to offer wireless connections, the Exchange must install, test, maintain and operate the wireless equipment.

The Exchange believes that the proposed change is not unfairly discriminatory because it will result in fees being charged only to Users that voluntarily select to receive the corresponding services and because those services will be available to all Users. Furthermore, the Exchange believes that the services and fees proposed herein are not unfairly discriminatory because, in addition to the services being completely voluntary, they are available to all Users on an equal basis (*i.e.,* the same products and services are available to all Users). All Users that voluntarily select wireless connections to CME Group Data would be charged the same amount for the same services.

Users that opt to use wireless connections to CME Group Data would receive the CME Group Data that is available to all Users, as all market participants that contract with CME Group or its affiliate for CME Group Data, as required, may receive it.

The Proposed Change Is an Equitable Allocation of Fees and Credits

The Exchange believes that its proposal equitably allocates its fees among Users.

Without this proposed rule change, Users would have fewer options for connectivity to CME Group Data. The proposed change would provide Users with an additional choice with respect to the form and optimal latency of the connectivity they use to receive CME Group market data, allowing a User to select the connectivity that better suits its needs, helping it tailor its colocation operations to the requirements of its business operations. Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data using other methods: From another User, a third party wireless connection, or through an IDS or third party fiber connection.

The Exchange believes that the proposed change is equitable because it will result in fees being charged only to Users that voluntarily select to receive the corresponding services and because those services will be available to all Users. Furthermore, the Exchange believes that the services and fees proposed herein are equitably allocated because, in addition to the services being completely voluntary, they are available to all Users on an equal basis (*i.e.,* the same products and services are available to all Users). All Users that voluntarily select wireless connections to CME Group Data would be charged the same amount for the same services.

The Exchange operates in a highly competitive market in which exchanges offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. Accordingly, fees charged for co-location services are constrained by the active competition for the order flow of, and other business from, such market participants. If a particular exchange charges excessive fees for co-location services, affected market participants will opt to terminate their co-location arrangements with that exchange, and adopt a possible range of alternative strategies, including placing their servers in a physically proximate location outside the exchange's data center (which could be a competing exchange), or pursuing strategies less dependent upon the lower exchange-to-participant latency associated with co-location. Accordingly, the exchange charging excessive fees would stand to lose not only co-location revenues but also the liquidity of the formerly co-located trading firms, which could have additional follow-on effects on the market share and revenue of the affected exchange.

For the reasons above, the proposed changes do not unfairly discriminate between or among market participants that are otherwise capable of satisfying any applicable co-location fees, requirements, terms and conditions established from time to time by the Exchange.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange believes that the proposal will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of Section 6(b)(8) of the Act.[19]

The proposed change does not affect competition among national securities exchanges or among members of the Exchange, but rather between IDS and its commercial competitors.

The wireless connection would provide Users with an alternative means of connectivity to CME Group Data. The proposed change would provide Users with an additional choice with respect to the form and optimal latency of the connectivity they use to receive CME Group market data, allowing a User to select the connectivity that better suits its needs, helping it tailor its colocation operations to the requirements of its business operations.

Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data using other methods: From another User, a third party wireless connection, or through an IDS or third party fiber connection. Based on the information available to it, the Exchange believes that at least one market participant provides wireless connectivity to CME Group market data in the Data Center. The Exchange believes that the wireless connection offered by this third party entity provides connectivity at the same or similar latency as the proposed connection to CME Group Data, and at the same or similar cost. The proposed connection to CME Group Data and the existing third party wireless connection to CME Group Data would follow the same route within the Data Center: They would both enter through a meet-me-room, connect to equipment in co-location, and then connect to any Users that are customers. Because of this, the Exchange does not believe that IDS has an advantage over the third party in providing the connectivity. The proposed wireless connection would lead to a pole, from where a fiber connection would lead into the Data Center. The pole is owned by a third party and is not on the grounds of the Data Center.

IDS already offers fiber connections to CME Group market data to Users.[20] The Exchange also believes that at least two third party market participants offer such fiber connections to CME Group. In addition to these options, a User may create a proprietary wireless connection or connect through another User in order to connect to CME Group market data. The Exchange believes that at least two market participants already provide wireless connectivity to CME Group market data to other data centers in New Jersey.

The Exchange notes that the proposed wireless connection would compete not just with other wireless connections to CME Group market data, but also with fiber network connections, which may be more attractive to some market participants as they are more reliable and less susceptible to weather conditions. Market participants' considerations in determining what connectivity to purchase may include latency; the amount of network uptime; the equipment that the network uses; the cost of the connection; and the applicable contractual provisions. As noted above, a User may purchase a

[19] 15 U.S.C. 78f(b)(8).

[20] *See* 82 FR 29610, *supra* note 12.

fiber connection to CME Group market data from at least three providers, including IDS.

The Exchange operates in a highly competitive market in which exchanges and other vendors (*e.g.,* Hosting Users) offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [21]

*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 [22] and Rule 19b–4(f)(6) thereunder.[23]

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–NYSEAMER–2021–43 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–2021–43. 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–NYSEAMER–2021–43, and should be submitted on or before December 9, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[24]

**J. Matthew DeLesDernier,**

*Assistant Secretary.*

[FR Doc. 2021–25127 Filed 11–17–21; 8:45 am]

**BILLING CODE 8011–01–P**

[21] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[22] 15 U.S.C. 78s(b)(3)(A).

[23] 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.

[24] 17 CFR 200.30–3(a)(12).

## SOCIAL SECURITY ADMINISTRATION

**[Docket No: SSA–2021–0045]**

## Agency Information Collection Activities: Comment Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes revisions of OMB-approved information collections.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

(OMB) Office of Management and Budget, Attn: Desk Officer for SSA

Comments: *https://www.reginfo.gov/public/do/PRAMain.* Submit your comments online referencing Docket ID Number [SSA–2021–0045].

(SSA) Social Security Administration, OLCA, Attn: Reports Clearance Director, 3100 West High Rise, 6401 Security Blvd., Baltimore, MD 21235, Fax: 410–966–2830, Email address: *OR.Reports.Clearance@ssa.gov*

Or you may submit your comments online through *https://www.reginfo.gov/public/do/PRAMain,* referencing Docket ID Number [SSA–2021–0045].

SSA submitted the information collections below to OMB for clearance. Your comments regarding these information collections would be most useful if OMB and SSA receive them within 30 days from the date of this publication. To be sure we consider your comments, we must receive them no later than December 20, 2021. Individuals can obtain copies of these

OMB clearance packages by writing to *OR.Reports.Clearance@ssa.gov.*

1. *Certificate of Support—20 CFR 404.370, 404.408a, and 404.750—0960–0001.* A parent of a deceased, fully insured worker may be entitled to Social Security Old-Age, Survivors, and Disability Insurance (OASDI) benefits based on the earnings record of the deceased worker under certain conditions. One of the conditions is when the parent receives at least one-half support from the deceased worker at certain points in time. The one-half support requirement also applies to a spousal applicant in determining whether OASDI benefits are subject to Government Pension Offset (GPO). SSA uses Form SSA–760, Certificate of Support, to determine if the parent of a deceased worker or a spouse applicant meets the one-half support requirement. Respondents are parents of deceased workers and spouses who may meet the GPO exception.

*Type of Request:* Revision of an OMB-approved information collection.

| Modality of completion | Number of respondents | Frequency of response | Average burden per response (minutes) | Estimated total annual burden (hours) | Average theoretical hourly cost amount (dollars) * | Total annual opportunity cost (dollars) ** |
|---|---|---|---|---|---|---|
| SSA–760 | 18,000 | 1 | 15 | 4,500 | * $27.07 | ** $121,815 |

* We based this figure on the average U.S. worker's hourly wages, as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes_nat.htm#00-0000*).

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

2. *Medical Source Opinion of Patient's Capability to Manage Benefits—20 CFR 404.2015 and 416.615—0960–0024.* SSA appoints a representative payee in cases where we determine beneficiaries are not capable of managing their own benefits. In these instances, we require medical evidence to determine the beneficiaries' capability of managing or directing their benefit payments. SSA collects medical evidence on Form SSA–787, Medical Source Opinion of Patient's Capability to Manage Benefits, to: (1) Determine beneficiaries' capability or inability to handle their own benefits; and (2) assist in determining the beneficiaries' need for a representative payee. The respondents are the beneficiary's physicians or medical officers of the institution in which the beneficiary resides.

*Type of Request:* Revision of an OMB-approved information collection.

| Modality of completion | Number of respondents | Frequency of response | Average burden per response (minutes) | Estimated total annual burden (hours) | Average theoretical hourly cost amount (dollars) * | Total annual opportunity cost (dollars) ** |
|---|---|---|---|---|---|---|
| SSA–787 | 767,737 | 1 | 20 | 255,912 | * $105.22 | ** $26,927,061 |

* We based this figure on the national average medical professionals' salaries as reported by the U.S. Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes291228.htm*).

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

3. *Work Activity Report—Employee—20 CFR 404.1520(b), 404.1571–404.1576, 404.1584–404.1593, and 416.971–404.976—0960–0059.* SSA uses Form SSA–821–BK, Work Activity Report—Employee, and its electronic version, the SSA–821–APP, to collect recipient employment information to determine whether recipients worked after becoming disabled and, if so, whether the work is substantial gainful activity. SSA uses the SSA–821–BK and SSA–821–APP to obtain work information during the initial claims process, the continuing disability review process, post-adjudicative work issue actions, and for Supplemental Security Income (SSI) claims involving work issues. SSA reviews and evaluates the data to determine if the applicant or recipient meets the disability requirements of the law. The respondents are applicants or recipients of Title II Social Security Disability, and Title XVI SSI applicants.

*Type of Request:* Revision of an OMB-approved information collection.

| Modality of completion | Number of respondents | Frequency of response | Average burden per response (minutes) | Estimated total annual burden (hours) | Average theoretical hourly cost amount (dollars) * | Average wait time in field office or for teleservice centers (minutes) ** | Total annual opportunity cost (dollars) ** |
|---|---|---|---|---|---|---|---|
| SSA–821–BK (Paper) | 319,900 | 1 | 30 | 159,950 | * $10.95 | ** 21 | *** $2,977,469 |
| SSA–821–APP (Electronic) | 91,400 | 1 | 30 | 45,700 | * 10.95 | | *** 500,415 |
| Totals | 411,300 | | | 205,650 | | | *** 3,477,884 |

* We based this figure on the average DI payments based on SSA's current FY 2021 data (*https://www.ssa.gov/legislation/2021FactSheet.pdf*).

** We based this figure on averaging both the average FY 2021 wait times for field offices and teleservice centers, based on SSA's current management information data.

*** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

4. *Application for Supplemental Security Income—20 CFR 416.207 and 416.305–416.335, Subpart C—0960–0229.* The SSI program provides aged, blind, and disabled individuals who have little or no income, with funds for food, clothing, and shelter. Individuals complete Form SSA–8000–BK, Application for Supplemental Security Income, to apply for SSI. SSA uses the information from Form SSA–8000–BK, and its electronic Intranet counterpart, the SSI Claim System, to: (1) Determine whether SSI claimants meet all statutory and regulatory eligibility requirements; and (2) calculate SSI payment amounts. The respondents are applicants for SSI or their representative payees.

*Type of Request:* Revision of an OMB-approved information collection.

**Note:** This is a correction notice: SSA published the incorrect burden information for this collection at 86 FR 47190, on 8/23/21. We are correcting this error here.

| Modality of completion | Number of respondents | Frequency of response | Average burden per response (minutes) | Estimated total annual burden (hours) | Average theoretical hourly cost amount (dollars) * | Average wait time in field office or for teleservice centers (minutes) ** | Total annual opportunity cost (dollars) ** |
|---|---|---|---|---|---|---|---|
| SSI Claim System | 1,646,520 | 1 | 35 | 960,470 | * $19.01 | ** 21 | $29,213,656 |
| SSA–8000–BK (Paper Form) | 705 | 1 | 40 | 470 | * 19.01 | ** 21 | *** 13,630 |
| Totals | 1,647,225 | | | 960,940 | | | *** 29,227,286 |

* We based this figure by averaging both the average DI payments based on SSA's current FY 2021 data (*https://www.ssa.gov/legislation/2021FactSheet.pdf*), and the average U.S. worker's hourly wages, as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes_nat.htm*).

** We based this figure on averaging both the average FY 2021 wait times for field offices and teleservice centers, based on SSA's current management information data.

*** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

5. *State Supplementation Provisions: Agreement; Payments—20 CFR 416.2095–416.2098, and 416.2099—0960–0240.* Section 1618 of the Social Security Act (Act) requires those states administering their own supplementary income payment program(s) to demonstrate compliance with the Act by passing Federal cost-of-living increases on to individuals who are eligible for state supplementary payments. SSA requires states to report to SSA their compliance of the passing-along of such increases. In general, states report their supplementary payment information annually through the maintenance-of-payment levels method. However, SSA may ask them to report up to four times in a year through the total-expenditures method. Regardless of the method, the states confirm their compliance with the requirements, and provide any changes to their optional supplementary payment rates. SSA uses the information to determine each state's compliance or noncompliance with the pass-along requirements of the Act to determine eligibility for Medicaid reimbursement. If a state fails to keep payments at the required level, it becomes ineligible for Medicaid reimbursement under Title XIX of the Act. Respondents are state agencies administering supplementary income payment programs.

*Type of Request:* Revision of an OMB-approved information collection.

| Modality of completion | Number of respondents | Frequency of response | Average burden per response (minutes) | Estimated total annual burden (hours) | Average theoretical hourly cost amount (dollars) * | Total annual opportunity cost (dollars) ** |
|---|---|---|---|---|---|---|
| Total Expenditures | 11 | 1 | 60 | 11 | * $21.46 | ** $236 |
| Maintenance of Payment Levels | 22 | 1 | 60 | 22 | * 21.46 | ** 472 |
| Totals | 33 | | | 33 | | ** 708 |

* We based this figure on the average state Eligibility for Government Programs Interviewers hourly wages, as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes434061.htm*).

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

6. *Representative Payee Report of Benefits and Dedicated Account—20 CFR 416.546, 416.635, 416.640, and 416.665—0960–0576.* SSA requires representative payees to submit a written report accounting for the use of money paid to Social Security or SSI recipients, and to establish and maintain a dedicated account for these payments. SSA uses Form SSA–6233, Representative Payee Report of Benefits and Dedicated Account, to: (1) Ensure the representative payees use the payments for the recipient's current maintenance and personal needs; and (2) confirm the expenditures of funds from the dedicated account remain in compliance with the law. Respondents are representative payees for SSI and Social Security recipients.

*Type of Request:* Revision of an OMB approved information collection.

| Modality of completion | Number of respondents | Frequency of response | Average burden per response (minutes) | Estimated total annual burden (hours) | Average theoretical hourly cost amount (dollars) * | Average wait time in field office or for teleservice centers (minutes) ** | Total annual opportunity cost (dollars) ** |
|---|---|---|---|---|---|---|---|
| SSA–6233 ..... | 31,500 | 1 | 20 | 10,500 | * $27.07 | ** 21 | *** $582,682 |

* We based this figure on average U.S. worker's hourly wages, as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes_nat.htm#00-0000*).

** We based this figure on averaging both the average FY 2021 wait times for field offices and teleservice centers, based on SSA's current management information data.

*** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

7. *Credit Card Payment Form—0960–0648.* SSA uses Form SSA–1414, Credit Card Payment Form, to process: (1) Credit card payments from former employees and vendors with outstanding debts to the agency; (2) advance payments for reimbursable agreements; and (3) credit card payments for all Freedom of Information Act (FOIA) requests requiring payment. The respondents are former employees and vendors who have outstanding debts to the agency; entities who have reimbursable agreements with SSA; and individuals who request information through FOIA.

*Type of Request:* Revision of an OMB-approved information collection.

| Modality of completion | Number of respondents | Frequency of response | Average burden per response (minutes) | Estimated total annual burden (hours) | Average theoretical hourly cost amount (dollars) * | Total annual opportunity cost (dollars) ** |
|---|---|---|---|---|---|---|
| SSA–1414 ..... | 6,000 | 1 | 2 | 200 | * $27.07 | ** $5,414 |

* We based this figure on the average U.S. worker's hourly wages, as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes_nat.htm#00-0000*).

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

8. *Registration for Appointed Representative Services and Direct Payment—0960–0732.* SSA uses Form SSA–1699, Registration for Appointed Representative Services and Direct Payment, to register appointed representatives of claimants before SSA who:

- Want to register for direct payment of fees;
- Registered for direct payment of fees prior to 10/31/09, but need to update their information;
- Registered as appointed representatives on or after 10/31/09, but need to update their information; or
- Received a notice from SSA instructing them to complete this form.

By registering these individuals, SSA: (1) Authenticates and authorizes them to do business with us; (2) allows them to access our records for the claimants they represent; (3) facilitates direct payment of authorized fees to appointed representatives; and, (4) collects the information we need to meet Internal Revenue Service (IRS) requirements to issue specific IRS forms if we pay an appointed representative in excess of a specific amount ($600). The respondents are appointed representatives who want to use Form SSA–1699 for any of the purposes cited in this Notice.

*Type of Request:* Revision of an OMB-approved information collection.

| Modality of completion | Number of respondents | Frequency of response | Average burden per response (minutes) | Estimated total annual burden (hours) | Average theoretical hourly cost amount (dollars) * | Total annual opportunity cost (dollars) ** |
|---|---|---|---|---|---|---|
| SSA–1699 ..... | 10,382 | 1 | 20 | 3,461 | * $71.59 | ** $247,773 |

* We based this figure on average Lawyers hourly wages, as reported by Bureau of Labor Statistics data (*www.bls.gov/oes/current/oes231011.htm*).

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

9. *Notification of a Social Security Number (SSN) to an Employer for Wage Reporting Purposes—20 CFR 422.103(a)—0960–0778.* Individuals applying for employment must provide an SSN or indicate they have applied for one. However, when an individual applies for an initial SSN, there is a delay between the assignment of the number and the delivery of the SSN card. At an individual's request, SSA uses Form SSA–132, Notification of a Social Security Number (SSN) to an Employer for Wage Reporting Purposes, to send the individual's SSN to an

employer. Mailing this information to the employer: (1) Ensures the employer has the correct SSN for the individual; (2) allows SSA to receive correct earnings information for wage reporting purposes; and (3) reduces the delay in the initial SSN assignment and delivery of the SSN information directly to the employer. It also enables SSA to verify the employer as a safeguard for the applicant's personally identifiable information. The respondents are individuals applying for an initial SSN who ask SSA to mail confirmation of their application or the SSN to their employers.

*Type of Request:* Revision of an OMB-approved information collection.

| Modality of completion | Number of respondents | Frequency of response | Average burden per response (minutes) | Estimated total annual burden (hours) | Average theoretical hourly cost amount (dollars) * | Average wait time in field office or for teleservice centers (minutes) ** | Total annual opportunity cost (dollars) ** |
|---|---|---|---|---|---|---|---|
| SSA–132 ..... | 124,668 | 1 | 2 | 4,156 | * $27.07 | ** 24 | *** $1,462,403 |

* We based this figure on average U.S. worker's hourly wages, as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes_nat.htm#00-0000*).

** We based this figure on the average FY 2021 wait times for field offices, based on SSA's current management information data.

*** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

10. *Data Exchange Request Form—20 CFR 401.100—0960–0802.* SSA maintains approximately 3,000 data exchange agreements and regularly receives new requests from Federal, State, local, and foreign governments, as well as private organizations, to share data electronically. SSA engages in various forms of data exchanges from Social Security number verifications to computer matches for benefit eligibility, depending on the requestor's business needs. Section 1106 of the Act requires we consider the requestor's legal authority to receive the data, our disclosure policies, systems' feasibility, systems' security, and costs before entering into a data exchange agreement. We use Form SSA–157, Data Exchange Request Form, for this purpose. Requesting agencies, governments, or private organizations will use the form when voluntarily initiating a request for data exchange from SSA. Respondents are Federal, State, local, and foreign governments, as well as private organizations seeking to share data electronically with SSA.

*Type of Request:* Revision of an OMB-approved information collection.

| Modality of completion | Number of respondents | Frequency of response | Average burden per response (minutes) | Estimated total annual burden (hours) | Average theoretical hourly cost amount (dollars) * | Total annual opportunity cost (dollars) ** |
|---|---|---|---|---|---|---|
| State, local, and tribal governments ..... | 139 | 1 | 45 | 104 | * $42.85 | ** $4,456 |
| Private sector organizations ..... | 74 | 1 | 45 | 56 | * 42.85 | ** 2,400 |
| Totals ..... | 213 | ..... | ..... | 160 | ..... | ** 6,856 |

* We based this figure by averaging the average Management Analyst hourly salary, as reported by Bureau of Labor Statistics data (*www.bls.gov/oes/current/oes131111.htm*); the average Business and Financial Operations hourly salary (*www.bls.gov/oes/current/oes130000.htm*); and the average Epidemiologist hourly salary (*www.bls.gov/oes/current/oes191041.htm*).

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

11. *Fee Agreement for Representation before the Social Security Administration—0960–0810.* The Act requires individuals who represent a claimant before the agency and want to receive a fee for their services to obtain SSA's authorization of the fee. One way to obtain the authorization is to submit the fee agreement to the agency either in writing or by using Form SSA–1693, Fee Agreement for Representation before the Social Security Administration. Since representatives currently use fee agreements which vary in length, content, and complexity, submission of a free-form fee agreement may cause delays in SSA's review time. Therefore, SSA encourages respondents to use Form SSA–1693 to submit the information either using the paper form or the electronically submittable e1693 through SSA's website. SSA uses the information from the SSA–1693 to review the request and authorize any fee to representatives who seek to charge and collect a fee from a claimant. The respondents are the representatives who help claimants through the application process, and the claimants who they represent.

*Type of Request:* Revision of an OMB-approved information collection.

| Modality of completion | Number of respondents | Frequency of response | Average burden per response (minutes) | Estimated total annual burden (hours) | Average theoretical hourly cost amount (dollars) * | Total annual opportunity cost (dollars) ** |
|---|---|---|---|---|---|---|
| SSA–1693 | 5,000 | 1 | 13 | 1,083 | * $50.47 | ** $54,659 |

* We based this figure on the averaged total of the average Lawyer's Legal Services wages, as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes231011.htm*), and the average U.S. worker's hourly wages, as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes_nat.htm#00-0000*).

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

Dated: November 15, 2021.

**Naomi Sipple,**

*Reports Clearance Officer, Social Security Administration.*

[FR Doc. 2021–25138 Filed 11–17–21; 8:45 am]

**BILLING CODE 4191–02–P**

## OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

### Termination of Actions in the Section 301 Digital Services Tax Investigations of Austria, France, Italy, Spain, and the United Kingdom and Further Monitoring

**AGENCY:** Office of the United States Trade Representative (USTR).

**ACTION:** Notice.

**SUMMARY:** On October 8, 2021, Austria, France, Italy, Spain, and the United Kingdom joined the United States and 130 other jurisdictions participating in the OECD/G20 Inclusive Framework on Base Erosion and Profit Shifting in reaching a political agreement on a two-pillar solution to address tax challenges arising from the digitalization of the world economy. As part of Pillar 1, all parties agreed to remove existing Digital Services Taxes (DSTs) and other relevant similar measures, and to coordinate the withdrawal of these taxes. On October 21, 2021, the U.S. Department of the Treasury (Treasury) issued a joint statement with Austria, France, Italy, Spain, and the United Kingdom on a transitional approach to those countries' DSTs prior to entry into force of Pillar 1. The joint statement reflects a political agreement that DST liabilities accrued during the transitional period will be creditable in defined circumstances against future income taxes due under Pillar 1. Based on the commitments of Austria, France, Italy, Spain, and the United Kingdom to remove their DSTs pursuant to Pillar 1 and on their political agreement to the transitional approach prior to Pillar 1's entry into force, the U.S. Trade Representative has determined to terminate the section 301 actions taken in the respective investigations of these countries' DSTs. In coordination with Treasury, USTR will monitor implementation of the removal of these countries' DSTs as provided for under Pillar 1 and the transitional approach as provided in the joint statement.

**FOR FURTHER INFORMATION CONTACT:** For questions concerning the actions, please contact Benjamin Allen, Thomas Au, Patrick Childress, or Kate Hadley, Assistant General Counsels at (202) 395–9439, (202) 395–0380, (202) 395–9531, and (202) 395–3911, respectively, Robert Tanner, Director, Services and Investment at (202) 395–6125, or Michael Rogers, Director for Europe at (202) 395–2684.

**SUPPLEMENTARY INFORMATION:**

### I. Proceedings in the Investigations

For background on the proceedings in the section 301 investigations of DSTs adopted by Austria, France, Italy, Spain, and the United Kingdom, please see prior notices including: 84 FR 34042 (July 16, 2019) (France); 84 FR 66956 (December 6, 2019) (France); 85 FR 43292 (July 16, 2020) (France); 85 FR 34709 (June 5, 2020) (Austria, Italy, Spain, United Kingdom); 86 FR 2477 (January 12, 2021) (Italy); 86 FR 6406 (January 21, 2021) (Austria); 86 FR 6407 (January 21, 2021) (Spain); 86 FR 6406 (January 21, 2021) (United Kingdom); 86 FR 16816 (Austria); 86 FR 16819 (Italy); 86 FR 16813 (Spain); and 86 FR 16829 (United Kingdom).

In January 2021, the U.S. Trade Representative indefinitely suspended the section 301 action in the investigation of France's DST in light of the ongoing DST investigations of other jurisdictions. 86 FR 2479 (January 12, 2021). On June 2, 2021, the U.S. Trade Representative determined to take action in the form of additional duties on certain products of Austria, Italy, Spain, and the United Kingdom, and to immediately suspend those additional duties for up to 180 days. 86 FR 30361 (June 7, 2021) (Austria); 86 FR 30350 (June 7, 2021) (Italy); 86 FR 30358 (June 7, 2021) (Spain); 86 FR 30364 (June 7, 2021) (United Kingdom).

### II. OECD/G20 Negotiations

One-hundred forty-one jurisdictions are engaged in international tax negotiations under the OECD/G20 Inclusive Framework on Base Erosion and Profit Shifting. On October 8, 2021, Austria, France, Italy, Spain, and the United Kingdom joined the United States and 130 other participants in reaching political agreement on a Statement on a Two-Pillar Solution to Address the Tax Challenges Arising from the Digitalisation of the Economy. OECD/G20 Base Erosion and Profit Shifting Project, *Statement on a Two-Pillar Solution to Address the Tax Challenges Arising from the Digitalisation of the Economy* (Oct. 8, 2021) at *https://www.oecd.org/tax/beps/statement-on-a-two-pillar-solution-to-address-the-tax-challenges-arising-from-the-digitalisation-of-the-economy-october-2021.pdf* (the OECD/G20 Two-Pillar Solution). The statement provides that Pillar 1 will be implemented through a multilateral convention. With respect to DSTs, the statement provides:

The Multilateral Convention (MLC) will require all parties to remove all Digital Services Taxes and other relevant similar measures with respect to all companies, and to commit not to introduce such measures in the future. No newly enacted Digital Services Taxes or other relevant similar measures will be imposed on any company from 8 October 2021 and until the earlier of 31 December 2023 or the coming into force of the MLC. The modality for the removal of existing Digital Services Taxes and other relevant similar measures will be appropriately coordinated.

### III. Joint Statement

On October 21, 2021, the United States, Austria, France, Italy, Spain, and the United Kingdom issued a joint statement that describes a political compromise reached among these countries on a transitional approach to existing Unilateral Measures while implementing Pillar 1. *Joint Statement from the United States, Austria, France, Italy, Spain, and the United Kingdom*

*Regarding a Compromise on a Transitional Approach to Existing Unilateral Measures During the Interim Period Before Pillar 1 is in Effect,* U.S. Dep't of the Treas. (Oct. 21, 2021) at *https://home.treasury.gov/news/press-releases/jy0419.* Under the transitional approach in the joint statement, DST liability that accrues during the transitional period prior to implementation of Pillar 1 will be creditable in defined circumstances against future income taxes due under Pillar 1. In return, the United States commits to terminating the existing section 301 trade actions on goods of Austria, France, Italy, Spain, and the United Kingdom, and not to impose further trade actions against Austria, France, Italy, Spain, and the United Kingdom with respect to their existing DSTs until the earlier of the date the Pillar 1 multilateral convention comes into force or December 31, 2023.

**IV. Termination of Action**

Section 307 of the Trade Act of 1974, as amended (Trade Act) (19 U.S.C. 2417), provides that ''[t]he Trade Representative may modify or terminate any action, subject to the specific direction, if any, of the President with respect to such action, that is being taken under section [301] of this title if . . . such action is being taken under section [301(b)] of this title and is no longer appropriate.'' The U.S. Trade Representative has found that that the political agreement of Austria, France, Italy, Spain, and the United Kingdom to the OECD/G20 Two-Pillar Solution, which provides for the removal of DSTs upon entry into force of Pillar 1, and the transitional approach in the joint statement, provide a satisfactory resolution of the matters covered by the section 301 DST investigations of Austria, France, Italy, Spain, and the United Kingdom. Accordingly, pursuant to section 307 of the Trade Act, the U.S. Trade Representative has determined that the suspended trade actions in these investigations are no longer appropriate and that these actions should be terminated.

The U.S. Trade Representative's determination was made in consultation with Treasury and considers the advice of the interagency Section 301 Committee, consultations with representatives of the domestic industry concerned, and public comments and advisory committee advice received during the investigations.

In order to implement the termination of the section 301 actions in the DST investigations of Austria, France, Italy, Spain, and the United Kingdom, subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States (HTSUS) is modified by the Annex to this notice.

**V. Ongoing Monitoring**

Section 306(a) of the Trade Act (19 U.S.C. 2416(a)) provides that ''[t]he Trade Representative shall monitor the implementation of each measure undertaken, or agreement that is entered into, by a foreign country to provide a satisfactory resolution of a matter subject to investigation. . . .'' Section 306(b) (19 U.S.C. 2416(b)) provides that ''[i]f, on the basis of the monitoring carried out under subsection (a), the Trade Representative considers that a foreign country is not satisfactorily implementing a measure or agreement referred to in subsection (a), the Trade Representative shall determine what further action the Trade Representative shall take under section [301(a)].'' Pursuant to section 306(a) of the Trade Act, the U.S. Trade Representative, in coordination with Treasury, will monitor the implementation of the political agreement on an OECD/G20 Two-Pillar Solution as pertaining to DSTs, the commitments under the joint statement, and associated measures. Pursuant to section 306(b) of the Trade Act, if the U.S. Trade Representative, in consultation with Treasury, subsequently considers that Austria, France, Italy, Spain, or the United Kingdom is not satisfactorily implementing these political agreements or associated measures, then the U.S. Trade Representative will consider further action under section 301.

*Annex*

The U.S. Trade Representative has decided to terminate:

(1) The additional duties under heading 9903.90.01 of the HTSUS on articles the product of France, as provided for in U.S. notes 22(a) and 22(b) to subchapter III of chapter 99 of the HTSUS.

(2) the additional duties under heading 9903.90.02 of the HTSUS on articles the product of Austria, as provided for in U.S. notes 23(a) and 23(b) to subchapter III of chapter 99 of the HTSUS.

(3) the additional duties under heading 9903.90.04 of the HTSUS on articles the product of Italy, as provided for in U.S. notes 25(a) and 25(b) to subchapter III of chapter 99 of the HTSUS.

(4) the additional duties under heading 9903.90.05 of the HTSUS on articles the product of Spain, as provided for in U.S. notes 26(a) and 26(b) to subchapter III of chapter 99 of the HTSUS.

(5) additional duties under heading 9903.90.07 of the HTSUS on articles the product of the United Kingdom, as provided for in U.S. notes 28(a) and 28(b) to subchapter III of chapter 99 of the HTSUS.

The termination of these additional duties is effective on the date this determination is published in the **Federal Register**.

In accordance with these determinations, the U.S. Trade Representative has determined to modify the HTSUS:

(1) By deleting U.S. notes 22(a), 22(b), 23(a), 23(b), 25(a), 25(b), 26(a), 26(b), 28(a) and 28(b) to subchapter III of chapter 99 of the HTSUS.

(2) by deleting HTSUS headings 9903.90.01, 9903.90.02, 9903.90.04, 9903.90.05 and 9903.90.07.

The modifications of the HTSUS are effective on the date this determination is published in the **Federal Register**.

Any provisions of previous notices issued in these investigations that are inconsistent with this notice are superseded to the extent of such inconsistency.

**Greta Peisch,**

*General Counsel, Office of the United States Trade Representative.*

[FR Doc. 2021–25199 Filed 11–17–21; 8:45 am]

BILLING CODE 3290–F2–P

## DEPARTMENT OF TRANSPORTATION

### Federal Motor Carrier Safety Administration

**[Docket No. FMCSA–2021–0131]**

### Entry-Level Driver Training: Application for Exemption; Ohio Department of Education

**AGENCY:** Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

**ACTION:** Notice of application for exemption; request for comments.

**SUMMARY:** FMCSA announces that the Ohio Department of Education (ODE) has requested an exemption from the Entry-Level Driver Training (ELDT) requirements that will be implemented in February 2022. The exemption request applies to drivers, trained through ODE's ''Pre-Service School Bus Driver Training'' curriculum, who are seeking to obtain their Class B Commercial Driver's License (CDL) with school bus (S) and passenger (P) endorsements, and to current Class B CDL holders wishing to add the P and S endorsements. The ODE believes the Ohio theory (*i.e.,* classroom) curriculum

and behind-the-wheel (BTW) instruction meet or exceeds all the new ELDT requirements.

**DATES:** Comments must be received on or before December 20, 2021.

**ADDRESSES:** You may submit comments identified by Federal Docket Management System Number FMCSA–2021–0131 by any of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* See the Public Participation and Request for Comments section below for further information.
- *Mail:* Docket Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, between 9 a.m. and 5 p.m. E.T., Monday through Friday, except Federal holidays.
- *Fax:* 1–202–493–2251.

Each submission must include the Agency name and the docket number for this notice (FMCSA–2021–0131). Note that DOT posts all comments received without change to *www.regulations.gov,* including any personal information included in a comment. Please see the Privacy Act heading below.

*Docket:* For access to the docket to read background documents or comments, go to *www.regulations.gov* at any time or visit Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Docket Operations.

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

**FOR FURTHER INFORMATION CONTACT:** Mr. Richard Clemente, FMCSA Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards; 202–366–2722 or *MCPSD@dot.gov.* If you have questions on viewing or submitting material to the docket, contact Docket Operations, telephone (202) 366–9826.

**SUPPLEMENTARY INFORMATION:**

## I. Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials.

*Submitting Comments*

If you submit a comment, please include the docket number for this notice (FMCSA–2021–0131), indicate the specific section of this document to which the comment applies, and provide a reason for suggestions or recommendations. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to *www.regulations.gov* and put the docket number, ''FMCSA–2021–0131'' in the ''Search'' box, and click ''Search.'' When the new screen appears, click on ''Documents'' button, then click the ''Comment'' button associated with the latest notice posted. Another screen will appear, insert the required information. Choose whether you are submitting your comment as an individual, an organization, or anonymous. Click ''Submit Comment.''

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope. FMCSA will consider all comments and materials received during the comment period.

## II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315 to grant exemptions from certain Federal Motor Carrier Safety Regulations. FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must also provide an opportunity for public comment on the request.

The Agency reviews safety analyses and public comments submitted and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305). The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)) with the reasons for denying or granting the application and, if granted, the name of the person or class of persons receiving the exemption, and the regulatory provision from which the exemption is granted. The notice must also specify the effective period (up to 5 years) and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.300(b)).

## III. Background

*Current Regulation(s) Requirements*

FMCSA's entry-level driver training (ELDT) regulations set forth minimum training standards for certain individuals applying for a Class A or Class B CDL for the first time; an upgrade of their CDL (*e.g.,* a Class B CDL holder seeking a Class A CDL); or a hazardous materials (H), passenger (P), or school bus (S) endorsement for the first time (49 CFR part 380, subpart F). These individuals are subject to the ELDT requirements and must complete a prescribed program of instruction provided by an entity that is listed on FMCSA's Training Provider Registry (TPR). The training requirements do not mandate a minimum number of theory or behind-the-wheel (BTW) hours for the completion of the Class A and B CDL or the S, P, or H endorsement curricula. FMCSA will submit driver-specific training certification information to State driver licensing agencies, which can administer CDL skills tests to applicants for the Class A and B CDL, and/or the P or S endorsements, or knowledge test for the H endorsement, only after verifying the driver completed the required training. The compliance date for the ELDT regulations is February 7, 2022.

*Applicant's Request*

The ODE requests an exemption from the ELDT requirements as set forth in 49 CFR part 380.[1] The exemption request applies to drivers, trained through ODE's ''Pre-Service School Bus Driver Training'' curriculum, who are seeking to obtain their Class B Commercial Driver's License (CDL) with school bus (S), passenger (P), and air brake endorsements and to current Class B CDL holders wishing to add the P and

[1] ODE did not specify which subparts within 49 CFR part 380 are included within the scope of its application for exemption. However, based on the application's reference to ''the new Entry Level Driver Training regulations,'' FMCSA interprets that ODE is requesting exemption from 49 CFR part 380, subpart F, which includes the ELDT requirements for drivers as set forth in § 380.609.

S endorsements. If granted the exemption, ODE requests it remain in effect as long as the Ohio Pre-Service theory and BTW curricula meet or exceed all of the Federal training standards. The ODE states that the Ohio Pre-Service School Bus Driver Training program was established in 1978, and periodic review and upgrades to the program are continuous. With more than 25,000 school buses operated in Ohio, safety is of greatest importance for the ODE's Office of Pupil Transportation, and thousands of drivers are trained through the Department's program each year, including new and ''existing'' drivers seeking their initial CDL and applicable P and S endorsements.

The ODE's application explains that all drivers who operate school buses in Ohio must be listed in the ODE's School Foundation Payment System (SFPS) portal which tracks driver license information and assures drivers complete the necessary training requirements to transport students in Ohio. The SFPS verifies that drivers participated in both theory and BTW instruction, and also completes daily checks of driver certificates to ensure certificates are not expired. All drivers are required to attend theory training and have skill evaluations at least every 6 years. Most drivers are evaluated annually by their supervisors and/or on-the-bus instructors.

The ODE contends that without this requested exemption, ''Ohio school bus drivers would be required to have more training than anyone in the industry.'' School bus drivers who complete the Ohio Pre-Service School Bus Driver Training meet all the criteria to operate any Group-B commercial motor vehicle (CMV). This training program enables a driver to obtain a Class B CDL and provides the training to obtain either the P, S, or air brake endorsements, which allow for the driver to operate multiple Group B-regulated CMVs.

## IV. Equivalent Level of Safety

The ODE believes the current State revised and administrative codes that requires new Ohio school bus drivers to successfully complete 15 hours of theory instruction and a minimum of 12 hours of BTW instruction and the training instructors' credentials, exceeds the requirements set forth in the ELDT regulations. The ODE's application also references the Ohio law requiring ''existing'' drivers to successfully complete 9 hours of theory instruction once every six years after initial certification, and requiring school bus drivers to complete a minimum of 4 hours of annual in-service training specific to the operation of a school bus, as additional elements that exceed the level of safety of the ELDT regulations.

## V. Request for Comments

In accordance with 49 U.S.C. 31315(b), FMCSA requests public comment from all interested persons on the ODE's application for an exemption from the Federal ELDT regulations in 49 CFR part 380 subpart F for drivers trained through its Pre-Service School Bus Driver Training curriculum. All comments received before the close of business on the comment closing date indicated at the beginning of this notice will be considered and will be available for examination in the docket at the location listed under the Addresses section of this notice. Comments received after the comment closing date will be filed in the public docket and will be considered to the extent practicable.

In addition to late comments, FMCSA will also continue to file, in the public docket, relevant information that becomes available after the comment closing date. Interested persons should continue to examine the public docket for new material.

**Larry W. Minor,**

*Associate Administrator for Policy.*

[FR Doc. 2021–25118 Filed 11–17–21; 8:45 am]

BILLING CODE 4910–EX–P

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# DEPARTMENT OF TRANSPORTATION

## National Highway Traffic Safety Administration

**[Docket No. NHTSA–2019–0129; Notice 1]**

## Transamerica Tire Co. Ltd., Receipt of Petition for Decision of Inconsequential Noncompliance

**AGENCY:** National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

**ACTION:** Receipt of petition.

**SUMMARY:** Transamerica Tire Co. Ltd. (Transamerica) has determined that certain Transeagle ST tires manufactured by Shandong Yinbao Tyre (Yinbao) do not fully comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 119, *New Pneumatic Tires for Motor Vehicles with a GVWR of More than 4,536 kilograms (10,000 pounds) and Motorcycles.* Transamerica, on behalf of Yinbao, filed a noncompliance report dated November 21, 2019. Transamerica petitioned NHTSA on November 25, 2019, and amended its petition on April 22, 2021, for a decision that the subject noncompliance is inconsequential as it relates to motor vehicle safety. This document announces receipt of Transamerica's petition.

**DATES:** The closing date for comments on the petition is December 20, 2021.

**ADDRESSES:** Interested persons are invited to submit written data, views, and arguments on this petition. Comments must refer to the docket number and notice number cited in the title of this notice and may be submitted by any of the following methods:

- *Mail:* Send comments by mail addressed to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver comments by hand to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590. The Docket Section is open on weekdays from 10 a.m. to 5 p.m. except for Federal Holidays.
- *Electronically:* Submit comments electronically by logging onto the Federal Docket Management System (FDMS) website at *https://www.regulations.gov/.* Follow the online instructions for submitting comments.
- Comments may also be faxed to (202) 493–2251.

Comments must be written in the English language, and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that comments you have submitted by mail were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided.

All comments and supporting materials received before the close of business on the closing date indicated above will be filed in the docket and will be considered. All comments and supporting materials received after the closing date will also be filed and will be considered to the fullest extent possible.

When the petition is granted or denied, notice of the decision will also be published in the **Federal Register** pursuant to the authority indicated at the end of this notice.

All comments, background documentation, and supporting

materials submitted to the docket may be viewed by anyone at the address and times given above. The documents may also be viewed on the internet at *https://www.regulations.gov* by following the online instructions for accessing the dockets. The docket ID number for this petition is shown in the heading of this notice.

DOT's complete Privacy Act Statement is available for review in a **Federal Register** notice published on April 11, 2000, (65 FR 19477–78).

**SUPPLEMENTARY INFORMATION:**

## I. Overview

Transamerica has determined that certain tires manufactured by Yinbao do not fully comply with paragraphs S6.5 and S6.5(b) of FMVSS No. 119, *New Pneumatic Tires for Motor Vehicles with a GVWR of More than 4,536 kilograms (10,000 pounds) and Motorcycles* (49 CFR 571.119). Transamerica, on behalf of Yinbao, filed a noncompliance report dated November 21, 2019, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports.* Transamerica also petitioned NHTSA on November 25, 2019, for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential as it relates to motor vehicle safety, pursuant to 49 U.S.C. 30118(d) and 30120(h) and 49 CFR part 556, *Exemption for Inconsequential Defect or Noncompliance.*

This notice of receipt, of Transamerica's petition, is published under 49 U.S.C. 30118 and 30120 and does not represent any agency decision or other exercises of judgment concerning the merits of the petition.

## II. Tires Involved

Approximately 9,551 Transeagle ST radial tires, sizes ST235/85R16, ST235/80R16, and ST225/90R16, manufactured between September 23, 2017, and August 10, 2019, are potentially involved.

## III. Noncompliance

Transamerica explains that the noncompliance is that the subject tires were inadvertently labeled with a Tire Identification Number (TIN) that contains an incorrect manufacturer's code and, therefore, do not meet the requirements specified in paragraph S6.5(b) of FMVSS No. 119. The manufacturer's code is the part of the TIN that is comprised of a group of six symbols located immediately following the three-symbol plant code and before the date code, for all new tires. In addition, the manufacturer's code contains an additional character at the end of the labeled sequence, inadvertently producing a 14 character TIN instead of 8–13 character TIN. Specifically, the subject tires were incorrectly marked with the TIN as ''1BP TTFEFTL'' whereas they should have been marked as follows:

- ST235/85R16: ''1BP TTFEFT''
- ST235/80R16: ''1BP TFEFTL''
- ST225/90R16: ''1BP TTFEF'' [1]

## IV. Rule Requirements

Paragraphs S6.5 and S6.5(b) of FMVSS No. 119 include the requirements relevant to this petition. These requirements state that each tire shall be marked on one or both sidewalls with the TIN that meets the requirements of 49 CFR part 574.

## V. Summary of Transamerica's Petition

The following views and arguments presented in this section, ''V. Summary of Transamerica's Petition,'' are the views and arguments provided by Transamerica. They have not been evaluated by the Agency and do not reflect the views of the Agency.

Transamerica describes the subject noncompliance and contends that the noncompliance is inconsequential as it relates to motor vehicle safety.

*Background*

On October 21, 2019, Transamerica received a letter from NHTSA explaining that NHTSA's Office of Vehicle Safety Compliance ''has received information alleging that at least one of the tires manufactured by [Yinbao] and imported by [Transamerica] may not be in compliance with [FMVSS] No. 119.'' Accordingly, the letter included a ''photo showing a labeling failure on the tires branded Transeagle ST radial size 235/85R16.'' Specifically, it is alleged that ''[t]he tires appear to have an improper 14 character [TIN] instead of the 8–13 character TIN required by FMVSS No. 119.''

Transamerica offers the following views and arguments in support of its petition:

1. Upon the receipt of NHTSA's inquiry, Transamerica conducted an investigation to determine the validity of the allegations and the universe of tires affected by such noncompliance. Transamerica found that a total number of 9,551 tires branded Transeagle ST radial tires size ST235/85R16, ST235/80R16, and ST225/90R16 contained an incorrect manufacturer's code in their TIN labels molded on the sidewall of the tires. Transamerica says that except for the incorrect manufacturer's code, all other information labeled on the tires was correct, including the plant information and the date of production, and that the Transeagle ST tires otherwise comply with all applicable standards. Both Yinbao and Transamerica state that they are not aware of any crashes, injuries, customer complaints, or field reports in connection with this noncompliance.

2. Transamerica claims that the noncompliance is inconsequential because the subject tires meet all FMVSS and performance standards, the noncompliance is one of labeling, and the inaccurate manufacturer's code would not affect the manufacturer's or the consumers' ability to identify them should the tires be recalled for performance related noncompliance.

a. The sole noncompliance at issue relates to an inadvertently labeled manufacturer's code in the TIN on certain tires. While the subject tires contain an improper manufacturer's code, they are in all other respects properly labeled and meet all performance requirements under FMVSS. Inaccurate manufacturer's code identification upon which a consumer would not reasonably be expected to rely, does not have any effect on the operational safety of the vehicles on which these tires are mounted.

b. Furthermore, the inaccurate manufacturer's code identification will not affect Transamerica's, Yinbao's, or the consumers' ability to identify the subject tires, should they be recalled for performance related to the noncompliance. First, the tires' TIN bears the correct plant's code and date code, and is still tied to Yinbao's manufacturing facility. Thus, Transamerica, Yinbao, or the consumers would be reasonably able to identify the subject tires in the event of a recall.

c. Transamerica states that they have taken measures to ensure that the tires can be registered correctly. There is a ''Tire Registration'' option on Transamerica's website where consumers can register their TIN and contact information. Transamerica has taken steps to ensure that the incorrect TINs with the additional characters can also be registered for any future recalls or warranty issues. Furthermore, Transamerica has already corrected the molds at the applicable manufacturing plant, such that no additional tires were fabricated with the noncompliance. Transamerica stated that they will also improve their internal processes to prevent future TIN errors.

[1] In its amended petition submitted on April 22, 2021, Transamerica acknowledges that this TIN provided as the correction to these tires is also noncompliant because it does not contain six symbols as required.

d. Transamerica states that NHTSA has previously granted petitions for inconsequential noncompliance where TIN information labels are incorrect or missing information and that granting this petition would be consistent with NHTSA's prior decisions on petitions involving tires labeled with inaccurate TIN information. Transamerica cites the following petitions:

- Michelin North America, Inc., Grant of Petition for Decision of Inconsequential Noncompliance, 81 FR 76412 (November 2, 2016).
- Cooper Tire & Rubber Company, Grant of Application for Decision of Inconsequential Noncompliance, 63 FR 29059 (May 27, 1998).
- Tireco, Inc., Grant of Petition for Decision of Inconsequential Noncompliance, 80 FR 66614 (October 29, 2015).
- Cooper Tire & Rubber Company, Grant of Petition for Decision of Inconsequential Noncompliance, 71 FR 4397 (January 26, 2006).
- Cooper Tire & Rubber Company, Grant of Petition for Decision of Inconsequential Noncompliance, 82 FR 52966 (November 15, 2017).
- Yokohama Tire Corporation, Grant of Petition for Decision of Inconsequential Noncompliance, 84 FR 64403 (November 21, 2019).

Transamerica concludes by again contending that the subject noncompliance is inconsequential as it relates to motor vehicle safety, and asking that its petition to be exempted from providing notification of the noncompliance, as required by 49 U.S.C. 30118, and a remedy for the noncompliance, as required by 49 U.S.C. 30120, be granted.

Transamerica's complete petition and all supporting documents are available by logging onto the Federal Docket Management System (FDMS) website at: *https://www.regulations.gov* and following the online search instructions to locate the docket number listed in the title of this notice.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, any decision on this petition only applies to the subject tires that Transamerica and Yinbao no longer controlled at the time it determined that the noncompliance existed. However, any decision on this petition does not relieve tire distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant tires under their control after Transamerica and Yinbao notified them that the subject noncompliance existed.

(Authority: 49 U.S.C. 30118, 30120: delegations of authority at 49 CFR 1.95 and 501.8)

**Otto G. Matheke III,**

*Director, Office of Vehicle Safety Compliance.*

[FR Doc. 2021–25112 Filed 11–17–21; 8:45 am]

BILLING CODE 4910–59–P

## DEPARTMENT OF TRANSPORTATION

### National Highway Traffic Safety Administration

**[Docket No. NHTSA–2021–0035; Notice 1]**

### Michelin North America, Inc., Receipt of Petition for Decision of Inconsequential Noncompliance

**AGENCY:** National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

**ACTION:** Receipt of petition.

**SUMMARY:** Michelin North America, Inc. (''MNA''), has determined that certain Michelin Primacy Tour A/S replacement passenger car tires do not fully comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 139, *New Pneumatic Radial Tires for Light Vehicles.* MNA filed an original noncompliance report dated March 25, 2021, and subsequently, MNA petitioned NHTSA on April 7, 2021, for a decision that the subject noncompliance is inconsequential as it relates to motor vehicle safety. This notice announces receipt of MNA's petition.

**DATES:** Send comments on or before December 20, 2021.

**ADDRESSES:** Interested persons are invited to submit written data, views, and arguments on this petition. Comments must refer to the docket and notice number cited in the title of this notice and submitted by any of the following methods:

- *Mail:* Send comments by mail addressed to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver comments by hand to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590. The Docket Section is open on weekdays from 10 a.m. to 5 p.m. except for Federal holidays.
- *Electronically:* Submit comments electronically by logging onto the Federal Docket Management System (FDMS) website at *https://www.regulations.gov/.* Follow the online instructions for submitting comments.
- Comments may also be faxed to (202) 493–2251.

Comments must be written in the English language and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that comments you have submitted by mail were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided.

All comments and supporting materials received before the close of business on the closing date indicated above will be filed in the docket and will be considered. All comments and supporting materials received after the closing date will also be filed and will be considered to the fullest extent possible.

When the petition is granted or denied, notice of the decision will also be published in the **Federal Register** pursuant to the authority indicated at the end of this notice.

All comments, background documentation, and supporting materials submitted to the docket may be viewed by anyone at the address and times given above. The documents may also be viewed on the internet at *https://www.regulations.gov* by following the online instructions for accessing the docket. The docket ID number for this petition is shown in the heading of this notice.

DOT's complete Privacy Act Statement is available for review in a **Federal Register** notice published on April 11, 2000 (65 FR 19477–78).

**FOR FURTHER INFORMATION CONTACT:** Abraham Diaz, General Engineer, NHTSA, Office of Vehicle Safety Compliance, (202) 366–5310.

**SUPPLEMENTARY INFORMATION:**

### I. Overview

MNA has determined that certain Michelin Primacy Tour A/S replacement passenger car tires do not fully comply with the requirements of paragraph S5.5.1(b) of FMVSS No. 139,

*New Pneumatic Radial Tires for Light Vehicles* (49 CFR 571.139). MNA filed a noncompliance report dated March 25, 2021, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports.* MNA subsequently petitioned NHTSA on April 7, 2021, for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential as it relates to motor vehicle safety, pursuant to 49 U.S.C. 30118(d) and 30120(h) and 49 CFR part 556, *Exemption for Inconsequential Defect or Noncompliance.*

This notice of receipt of MNA's petition is published under 49 U.S.C. 30118 and 30120 and does not represent any Agency decision or other exercise of judgment concerning the merits of the petition.

**II. Tires Involved**

Approximately 1,196 Michelin Primacy Tour A/S replacement passenger car tires, size 235/65R18 106H, manufactured between January 3, 2021, and January 23, 2021, were identified by MNA as being potentially involved, however, MNA clarified that 1,139 tires were captured and retained in MNA's inventory. Any decision on this petition will only apply to the approximately 57 tires that MNA no longer controlled at the time it determined that the noncompliance existed.

**III. Noncompliance**

MNA explains that the noncompliance is due to a mold error in which the subject tires contain a tire identification number (TIN) with an inverted plant code and, therefore, do not comply with the requirements specified in paragraph S5.5.1(b) of FMVSS No. 139.

**IV. Rule Requirements**

Paragraph S5.5.1(b) of FMVSS No. 139 includes the requirements relevant to this petition.

- For tires manufactured on or after September 1, 2009, each tire must be labeled with the tire identification number required by 49 CFR part 574 on the intended outboard sidewall of the tire.
- Except for retreaded tires, if a tire does not have an intended outboard sidewall, the tire must be labeled with the tire identification number required by 49 CFR part 574 on one sidewall and with either the tire identification number or a partial tire identification number, containing all characters in the tire identification number except for the date code and, at the discretion of the manufacturer, any optional code, on the other sidewall.

**V. Summary of MNA's Petition**

The following views and arguments presented in this section, ''V. Summary of MNA's Petition,'' are the views and arguments provided by MNA. They have not been evaluated by the Agency and do not reflect the views of the Agency. MNA describes the subject noncompliance and contends that the noncompliance is inconsequential as it relates to motor vehicle safety.

In support of its petition, MNA submitted the following reasoning:

1. The TIN marking noncompliance does not create any operational safety risk for the vehicle. The tires comply with applicable FMVSS and all other applicable regulations.

2. The incorrect orientation of the TIN plant code has no bearing on tire performance.

3. The subject tires are marked with all other markings required under FMVSS No. 139, such as S5.5(c) maximum permissible inflation pressure and S5.5(d) maximum load rating. The necessary information is available on the sidewall of the tire to ensure proper application and usage.

4. The subject tires contain the DOT symbol on both sidewalls, thus, indicating conformance to applicable FMVSS.

5. The plant code on the intended outboard side of the tires contain all the information required by 49 CFR 574.5 for the TIN (plant code + size code + option code + date code), however the 3-digit plant code is inverted. The text should read "DOT 1M3" and instead reads "DOT ƐWꓵ ."

6. The plant code orientation discrepancy only exists on the intended inboard sidewall of the tire. The intended inboard sidewall has the correct sequence of DOT + plant code + size code + option code + manufacturing date, with all characters oriented in the proper direction.

7. For identification and traceability purposes the key information of plant code and manufacturing date is present on the tire.

8. In the event that dealer/owner notifications are required, either the intended marking (DOT 1M3) or the actual marking (DOT inverted ''1M3'') would serve as an identifier of the tire.

9. Upon identification of the mismarking, Michelin instituted a block on the affected tires and initiated a sorting of inventories. A total of 1,139 of the 1,196 tires produced with the incorrect marking were captured and retained in Michelin inventory.

10. The plant code plate in the affected mold has been restored to its correct orientation.

11. The mismarking has been communicated to Michelin Customer Care representatives in order to effectively handle any inquiries from dealers or owners regarding the subject tires.

12. MNA contends that NHTSA has concluded in other petitions related to similar TIN marking errors that this type of noncompliance is inconsequential to safety. Most notably, Cooper Tire & Rubber Company, 81 FR 43708 (July 5, 2016) petitioned for tires produced with an inverted date code. MNA states that NHTSA concluded that the inverted marking did not affect the consumers' ability to identify the tire and other examples exist where TIN information was incorrect, missing, or molded in the wrong sequence and NHTSA granted the petition.

MNA concludes that the subject noncompliance is inconsequential as it relates to motor vehicle safety and that its petition to be exempted from providing notification of the noncompliance, as required by 49 U.S.C. 30118, and a remedy for the noncompliance, as required by 49 U.S.C. 30120, should be granted.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to

file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, any decision on this petition only applies to the subject tires that MNA no longer controlled at the time it determined that the noncompliance existed. However, any decision on this petition does not relieve equipment distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant tires under their control after MNA notified them that the subject noncompliance existed.

(Authority: 49 U.S.C. 30118, 30120: delegations of authority at 49 CFR 1.95 and 501.8)

**Otto G. Matheke III,**

*Director, Office of Vehicle Safety Compliance.*

[FR Doc. 2021–25113 Filed 11–17–21; 8:45 am]

**BILLING CODE 4910–59–P**

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## DEPARTMENT OF TRANSPORTATION

### Office of the Secretary

**[Docket No. OST–2021–0135]**

### Privacy Act of 1974; DOT/ALL 028; Employee Accommodations Files

**AGENCY:** Office of the Departmental Chief Information Officer, Office of the Secretary of Transportation, Transportation (DOT).

**ACTION:** Notice of a new system of records.

**SUMMARY:** In accordance with the Privacy Act of 1974, the U.S. Department of Transportation (DOT) intends to establish a new system of records titled Employee Accommodations Files. This system allows DOT to collect, use, maintain, and disseminate the records needed to process, manage, maintain, and resolve reasonable accommodation requests from employees or applicants for employment based on a medical condition/disability or a sincerely held religious belief, practice, or observance. This includes requests for a medical or religious accommodation to decline the COVID–19 vaccination. The information will be used to determine whether accommodations are legally required in accordance with the Rehabilitation Act and Title VII of the Civil Rights Act of 1964.

**DATES:** This new system of records is effective upon publication; however, comments on the Routine Uses will be accepted on or before December 20, 2021. The Routine Uses will become effective at the close of the comment period. The Department may publish an amended System of Records Notice (SORN) in light of any comments received.

**ADDRESSES:** You may submit comments, identified by docket number OST–2021–0135 by any of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Ave. SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Ave. SE, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal Holidays.
- *Instructions:* You must include the agency name and docket number OST–2021–0135.
- All comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided.

*Privacy Act:* Anyone is able to search the electronic form of all comments received in any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the DOT's complete Privacy Act statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you may visit *https://DocketsInfo.dot.gov.*

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

**FOR FURTHER INFORMATION CONTACT:** For general and privacy questions, please contact: Karyn Gorman, Acting Departmental Chief Privacy Officer, Department of Transportation, S–83, Washington, DC 20590, Email: *privacy@dot.gov,* Tel. (202) 366–3140.

**SUPPLEMENTARY INFORMATION:**

### Background

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the U.S. Department of Transportation (DOT), Office of the Secretary, is proposing a new system of records titled Employee Accommodations Files. The Rehabilitation Act of 1973, as amended, 29 U.S.C. 791 and Title VII of the Civil Rights Act of 1964, as amended, 42 U.S.C. 2000e, require DOT to grant employee requests for medical/disability accommodations or religious accommodations because of a sincerely held religious belief, practice or observance unless an undue hardship would result. DOT is similarly required in some circumstances to grant employee requests for medical accommodations because of disability. The government-wide policy requiring all Federal employees as defined in 5 U.S.C. 2105 to be vaccinated against COVID–19 is expected to generate many requests for medical/disability and religious accommodations.

In order to process and make a determination on an accommodation request, DOT is required to collect information from Federal employees and applicants for federal employment making such requests.

This system will collect information related to individuals requesting medical/disability and religious accommodations. These accommodation requests include but are not limited to requests for exemptions from vaccines. By requesting an accommodation, individuals are authorizing DOT to collect and maintain a record of the information submitted to support the request for the accommodation. The information contained within this system of records will be collected directly from the individual employees or applicants for federal employment who have requested accommodations. This new system will be included in DOT's inventory of record systems.

DOT has also included DOT General Routine Uses, to the extent they are compatible with the purposes of this System. As recognized by the Office of Management and Budget (OMB) in its Privacy Act Implementation Guidance and Responsibilities (65 FR 19746 (July 9, 1975)), the routine uses include proper and necessary uses of information in the system, even if such uses occur infrequently. DOT has included in this notice routine uses for disclosures to law enforcement when the record, on its face, indicates a violation of law, to DOJ for litigation purposes, or when necessary in investigating or responding to a breach of this system or other agencies' systems. DOT may disclose to Federal, State, local, or foreign agency information relevant to law enforcement, litigation, and proceedings before any court or adjudicative or administrative body. OMB has long recognized that these types of routine uses are ''proper and necessary'' uses of

information and qualify as compatible with agency systems (65 FR 19476, April 11, 2000). In addition, OMB Memorandum M–17–12 directed agencies to include routine uses that will permit sharing of information when needed to investigate, respond to, and mitigate a breach of a Federal information system. DOT also has included routine uses that permit sharing with the National Archives and Records Administration when necessary for an inspection, or to any federal government agency engaged in audit or oversight related to this system. These types of disclosures are necessary and proper uses of information in this system because they further DOT's obligation to fulfil its records management and program management responsibilities by facilitating accountability to agencies charged with oversight in these areas.

## Privacy Act

The Privacy Act (5 U.S.C. 552a) governs the means by which the federal government agencies collect, maintain, use, and disseminate individuals' records. The Privacy Act applies to information that is maintained in a ''system of records.'' A ''system of records'' is a group of any records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. The Privacy Act extends rights and protections to individuals who are U.S. citizens and lawful permanent residents. Additionally, the Judicial Redress Act (JRA) provides a covered person with a statutory right to make requests for access and amendment to covered records, as defined by the JRA, along with judicial review for denials of such requests. In addition, the JRA prohibits disclosures of covered records, except as otherwise permitted by the Privacy Act.

Below is the description of the Employee Accommodations Files System of Records. In accordance with 5 U.S.C. 552a(r), DOT has provided a report of this system of records to the OMB and to Congress.

### SYSTEM NAME AND NUMBER:

DOT/ALL 28; Employee Accommodations Files.

### SECURITY CLASSIFICATION:

Unclassified.

### SYSTEM LOCATION:

Records are maintained in a FedRAMP-certified third-party cloud environment. Records may also be kept in other components and sub-offices of DOT.

### SYSTEM MANAGER(S):

Office of Civil Rights, at Department of Transportation at 1200 New Jersey Avenue SE, Washington, DC 20590. Yvette Rivera, Associate Director, Equity and Access Division, Departmental Office of Civil Rights, 202–366–5131. For the Federal Aviation Administration, the Office of Civil Rights, 800 Independence Ave. SW, Washington, DC 20591. Michael Looney, Program Manager, (202) 267–3258.

### AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

- Title VII of the Civil Rights Act of 1964 42 U.S.C. 2000e.
- Rehabilitation Act of 1973, as amended, 29 U.S.C. 791.
- Executive Order 13164.
- 29 CFR parts 1605, 1614.

### PURPOSE(S) OF THE SYSTEM:

The purpose of the system is to collect information from individuals seeking medical/disability and/or religious accommodations in order to approve or deny their requests.

### CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Categories of individuals within this system include: Individuals who are current DOT employees and applicants for federal employment who have requested medical/disability and/or religious accommodations.

### CATEGORIES OF RECORDS IN THE SYSTEM:

Records include the name of the individual seeking accommodations, nature of the accommodation sought, including but not limited for religious accommodations, how complying with such a requirement would burden religious exercise, how long the belief has been held and the reason for seeking exemption.

For accommodations based on medical/disability, the records will include information such as nature of the medical condition/disability, functional limitations caused by the medical condition/disability, how the requested accommodation would address the functional limitations, medical documentation of the medical condition/disability, and other information specific to the requested accommodation to determine whether DOT is legally required to grant the request.

PII elements: Name, title, email address, phone number, operating administration, pay grade or band, supervisor information, other information collected from requesters to make a determination regarding a specific medical and/or religious accommodation request.

### RECORD SOURCE CATEGORIES:

DOT employees and applicants seeking medical/disability and/or religious accommodations.

### ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

*Department General Routine Uses*

1. In the event that a system of records maintained by DOT to carry out its functions indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether Federal, State, local or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation, or order issued pursuant thereto.

2a. Routine Use for Disclosure for Use in Litigation. It shall be a routine use of the records in this system of records to disclose them to the Department of Justice or other federal agency conducting litigation when—(a) DOT, or any agency thereof, or (b) Any employee of DOT or any agency thereof, in his/her official capacity, or (c) Any employee of DOT or any agency thereof, in his/her individual capacity where the Department of Justice has agreed to represent the employee, or (d) The United States or any agency thereof, where DOT determines that litigation is likely to affect the United States, is a party to litigation or has an interest in such litigation, and the use of such records by the Department of Justice or other federal agency conducting the litigation is deemed by DOT to be relevant and necessary in the litigation, provided, however, that in each case, DOT determines that disclosure of the records in the litigation is a use of the information contained in the records that is compatible with the purpose for which the records were collected.

2b. Routine Use for Agency Disclosure in Other Proceedings. It shall be a routine use of records in this system to disclose them in proceedings before any court or adjudicative or administrative body before which DOT or any agency thereof, appears, when—(a) DOT, or any agency thereof, or (b) Any employee of DOT or any agency thereof in his/her official capacity, or (c) Any employee of DOT or any agency thereof in his/her individual capacity where DOT has

agreed to represent the employee, or (d) The United States or any agency thereof, where DOT determines that the proceeding is likely to affect the United States, is a party to the proceeding or has an interest in such proceeding, and DOT determines that use of such records is relevant and necessary in the proceeding, provided, however, that in each case, DOT determines that disclosure of the records in the proceeding is a use of the information contained in the records that is compatible with the purpose for which the records were collected.

3. Disclosure may be made to a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual. In such cases, however, the Congressional office does not have greater rights to records than the individual. Thus, the disclosure may be withheld from delivery to the individual where the file contains investigative or actual information or other materials which are being used, or are expected to be used, to support prosecution or fines against the individual for violations of a statute, or of regulations of the Department based on statutory authority. No such limitations apply to records requested for Congressional oversight or legislative purposes; release is authorized under 49 CFR 10.35(9).

4. One or more records from a system of records may be disclosed routinely to the National Archives and Records Administration (NARA) in records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

5. DOT may make available to another agency or instrumentality of any government jurisdiction, including State and local governments, listings of names from any system of records in DOT for use in law enforcement activities, either civil or criminal, or to expose fraudulent claims, regardless of the stated purpose for the collection of the information in the system of records. These enforcement activities are generally referred to as matching programs because two lists of names are checked for match using automated assistance. This routine use is advisory in nature and does not offer unrestricted access to systems of records for such law enforcement and related antifraud activities. Each request will be considered on the basis of its purpose, merits, cost effectiveness and alternatives using Instructions on reporting computer matching programs to the Office of Management and Budget, OMB, Congress, and the public, published by the Director, OMB, dated September 20, 1989.

6. DOT may disclose records from this system, as a routine use, to appropriate agencies, entities, and persons when (1) DOT suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised; (2) DOT has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by DOT or another agency or entity) that rely upon the compromised information; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with DOT's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

7. DOT may disclose records from this system, as a routine use, to the Office of Government Information Services for the purpose of (a) resolving disputes between FOIA requesters and federal agencies and (b) reviewing agencies' policies, procedures, and compliance in order to recommend policy changes to Congress and the President.

8. DOT may disclose records from the system, as a routine use, to contractors and their agents, experts, consultants, and others performing or working on a contract, service, cooperative agreement, or other assignment for DOT, when necessary to accomplish an agency function related to this system of records.

9. DOT may disclose records from this system, as a routine use, to an agency, organization, or individual for the purpose of performing audit or oversight operations related to this system of records, but only such records as are necessary and relevant to the audit or oversight activity. This routine use does not apply to intra-agency sharing authorized under Section (b)(1) of the Privacy Act.

10.

**POLICIES AND PRACTICES FOR STORAGE OF RECORDS:**

Records relating to requests for accommodation relating to mandatory COVID–19 vaccination are stored in the USDOT Vaccination Application. Records relating to other disability-related requests for accommodation are stored in the Reasonable Accommodation Management System (RAMS). Requests for religious accommodations may be stored in RAMS, or in systems at component or sub-office level.

**POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:**

Records on individuals will be retrieved by name.

**POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:**

Records will be held in accordance with NARA General Records Control Schedule 2.3, Employee Relations Records, item 20, Reasonable accommodation case files. Individual employee files created, received, and maintained by EEO reasonable accommodation, diversity/disability programs, employee relations coordinators, supervisors, administrators, or Human Resource specialists containing records of requests for reasonable accommodation and/or assistive technology devices and services that have been requested for or by an employee. Includes: Request, approvals and denials, notice of procedures for informal dispute resolution or appeal processes, forms, correspondence, records of oral conversations, policy guidance documents, medical records, supporting notes and documentation. These records are temporary and will be destroyed 3 years after employee separation from the agency or all appeals are concluded, whichever is later; however, longer retention is authorized if required for business use.

**ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:**

Records in this system are safeguarded in accordance with applicable rules and policies, including all applicable DOT automated systems security and access policies. Strict controls have been imposed to minimize the risk of compromising the information that is being stored. Data is encrypted at rest and in transit. Access to records in this system is limited to those individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions.

**RECORD ACCESS PROCEDURES:**

Individuals seeking notification of and access to any record contained in this system of records, or seeking to contest its content, may submit a request in writing to the System Manager at the address identified in ''System Manager and Address'' above.

When seeking records about yourself from this system of records or any other Departmental system of records your request must conform with the Privacy

Act regulations set forth in 49 CFR part 10. You must sign your request, and your signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. While no specific form is required, you may obtain forms for this purpose from the Chief Freedom of Information Act Officer, *http://www.dot.gov/foia* or 202.366.4542. In addition, you should provide the following:

- An explanation of why you believe the Department would have information on you;
- Identify which component(s) of the Department you believe may have the information about you;
- Specify when you believe the records would have been created;
- Provide any other information that will help the FOIA staff determine which DOT component agency may have responsive records; and

If your request is seeking records pertaining to another living individual, you must include a statement from that individual certifying his/her agreement for you to access his/her records.

Without this bulleted information the component(s) may not be able to conduct an effective search, and your request may be denied due to lack of specificity or lack of compliance with applicable regulations.

**CONTESTING RECORD PROCEDURES:**

See Record Access Procedures.

**NOTIFICATION PROCEDURES:**

See Record Access Procedures.

**EXEMPTIONS PROMULGATED FOR THE SYSTEM:**

None.

**HISTORY:**

None.

Issued in Washington, DC.

**Karyn Gorman,**

*Acting Departmental Chief Privacy Officer.*

[FR Doc. 2021–25153 Filed 11–17–21; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF THE TREASURY

### Terrorism Risk Insurance Program 2022 Data Call

**AGENCY:** Departmental Offices, U.S. Department of the Treasury.

**ACTION:** Request for comments.

**SUMMARY:** Pursuant to the Terrorism Risk Insurance Act of 2002 (TRIA), the Federal Insurance Office (FIO) requests public feedback on the proposed revisions to the data collection forms for use in the 2022 data call. Copies of these forms and associated instructions (which identify changes to the reporting templates and instructions as previously used by Treasury) are available for electronic review on the Treasury website at *https://home.treasury.gov/policy-issues/financial-markets-financial-institutions-and-fiscal-service/federal-insurance-office/terrorism-risk-insurance-program/annual-data-collection.* State insurance regulators, through the National Association of Insurance Commissioners (NAIC), will also be separately seeking comment from stakeholders on the proposal.

**DATES:** Submit comments on or before January 18, 2022.

**ADDRESSES:** Submit comments electronically through the Federal eRulemaking Portal: *http://www.regulations.gov,* or by mail to the Federal Insurance Office, Attn: Richard Ifft, Room 1410 MT, Department of the Treasury, 1500 Pennsylvania Avenue NW, Washington, DC 20220. Because postal mail may be subject to processing delays, it is recommended that comments be submitted electronically. If submitting comments by mail, please submit an original version with two copies. Comments concerning the proposed data collection forms and collection process should be captioned with ''2022 TRIP Data Collection Comments.'' Please include your name, group affiliation, address, email address, and telephone number(s) in your comment. Where appropriate, a comment should include a short Executive Summary (no more than five single-spaced pages).

**FOR FURTHER INFORMATION CONTACT:** Richard Ifft, Senior Insurance Regulatory Policy Analyst, Federal Insurance Office, Room 1410 MT, Department of the Treasury, 1500 Pennsylvania Avenue NW, Washington, DC 20220, at (202) 622–2922 (not a toll-free number), or Sherry Rowlett, Program Analyst, Federal Insurance Office, at (202) 622–1890. Persons who have difficulty hearing or speaking may access these numbers via TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

**SUPPLEMENTARY INFORMATION:**

### I. Background

TRIA [1] created the Terrorism Risk Insurance Program (Program) within the U.S. Department of the Treasury (Treasury) to address disruptions in the market for terrorism risk insurance, to help ensure the continued availability and affordability of commercial property and casualty insurance for terrorism risk, and to allow for the private markets to stabilize and build insurance capacity to absorb any future losses for terrorism events. TRIA requires the Secretary of the Treasury (Secretary) to perform periodic analyses of certain matters concerning the Program.[2] In order to assist the Secretary with this process, TRIA also requires insurers to submit on an annual basis certain insurance data and information regarding their participation in the Program.[3] FIO is authorized to assist the Secretary in the administration of the Program.[4]

Treasury began collecting data from insurers in 2016 on a voluntary basis,[5] and on a mandatory basis in 2017.[6] Treasury also arranged in 2017 for workers' compensation rating bureaus to provide most of the workers' compensation insurance data elements.[7] Beginning in 2018, Treasury and state insurance regulators have conducted a consolidated data call, in which participating insurers can, for the most part, submit the same reporting forms to Treasury and state regulators to satisfy the respective objectives of both Treasury and state insurance regulators.[8]

Program regulation 31 CFR 50.51(a) requires insurers to submit the specified data no later than May 15 of each calendar year. Treasury, through an insurance statistical aggregator, uses a web portal through which insurers must submit the requested data; state regulators collect the same data through a portal operated by New York State. All information submitted via the Treasury web portal operated by its insurance statistical aggregator is subject to the confidentiality and data protection provisions of applicable federal law.

[1] Public Law 107–297, 116 Stat. 2322, codified at 15 U.S.C. 6701, note. Because the provisions of TRIA (as amended) appear in a note, instead of particular sections, of the United States Code, the provisions of TRIA are identified by the sections of the law.

[2] TRIA, Section 104(h)(2) (requiring, *inter alia,* a report on the effectiveness of the Program); Section 108(h) (requiring a report on the competitiveness of small insurers in the terrorism risk insurance marketplace).

[3] TRIA, Section 104(h)(1). The data collection requirements were incorporated within TRIA by Section 111 of the Terrorism Risk Insurance Program Reauthorization Act of 2015 (2015 Reauthorization Act), Public Law 114–1, 129 Stat. 2.

[4] 31 U.S.C. 313(c)(1)(D).

[5] 81 FR 11649 (March 4, 2016).

[6] In 2016, a reporting exemption was extended to small insurers writing less than $10 million in TRIP-eligible lines premium in the reporting year. *See* 81 FR 95312 (December 27, 2016); 82 FR 20420 (May 1, 2017). As noted below, that exemption continues.

[7] 82 FR 20420 (May 1, 2017).

[8] *See* 83 FR 14718 (April 5, 2018).

Insurers subject to the consolidated data call report on a group basis, if part of a group, and otherwise report on an individual company basis.

## II. General Reporting Issues and Proposed Changes to Data Collection Templates

Pursuant to TRIA, Treasury has coordinated with publicly available sources to collect information for the 2022 data call. Information relating to workers' compensation exposures continues to be available from the workers' compensation rating bureaus, and those entities have again agreed to provide that information on behalf of participating insurers. Treasury has determined, however, that all other data components remain unavailable from other sources. Accordingly, Treasury will continue to request this remaining data and information directly from insurers.

Treasury again proposes to use four different data collection templates (see 31 CFR 50.51(c)), depending upon the type of insurer involved. Insurers will fill out the template identified ''Insurer (Non-Small) Groups or Companies,'' unless the insurer meets the definition of a small insurer, captive insurer, or alien surplus lines insurer as set forth in 31 CFR 50.4. Such small insurers, captive insurers, and alien surplus lines insurers are required to complete separate tailored templates. Each template to be completed by each category of insurer contains multiple worksheets and is accompanied by separate instructions providing guidance on each data element requested in each worksheet.

There are two general categories of material changes [9] to the proposed reporting templates for 2022—one that applies solely to captive insurers, and the second that applies to the Cyber worksheet, which is contained in all templates and is to be completed by all participating insurers that write cyber insurance.

In the upcoming data call, Treasury plans to obtain more detailed information on the terrorism risk insurance issued by the captive insurers. First, Treasury is now seeking information that will allow FIO to determine whether the insurance coverage provided by the captive insurer to a policyholder encompasses the reimbursement of such policyholder's deductible that must be satisfied under a policy issued by another insurer. In prior data calls, Treasury has only requested separate information on the deductible reimbursement coverage for workers' compensation insurance (where it forms a significant percentage of all workers' compensation insurance issued by captive insurers). For other lines of insurance, Treasury has previously instructed captive insurers to combine the deductible reimbursement insurance to policyholders with other insurance written by the captive in the same line of insurance. The proposed changes request that the information be broken out by each TRIP-eligible line of insurance, which results in changes to both the Premium and Exposure Bases worksheets, where information is collected on a line-by-line basis. Second, in order to obtain a more complete view of the scope of the captive's operations, FIO is proposing two additional changes. The first proposed change will require captive insurers to provide the total amount of all other non-TRIP eligible direct earned premium of the captive insurer on the Premium worksheet. The second proposed change, on the Exposure Bases worksheet, requests information on whether coverage is being issued by the captive insurer that only provides coverage for nuclear, biological, chemical, and radiological (NBCR) exposures, in light of prior findings by FIO (and others) that the ability to obtain NBCR coverage in the conventional market is limited.[10]

The second area of material changes relates to the Cyber worksheet, which is completed by all participating insurers that write cyber insurance. In 2016, Treasury issued guidance confirming that cyber insurance written in a TRIP-eligible line of insurance is subject to the Program.[11] In 2018, Treasury began to collect cyber insurance information in the TRIP data call for the first time.[12] In 2021, Treasury finalized a rule change codifying its prior guidance that cyber insurance written in a TRIP-eligible line of insurance is subject to the Program.[13] The cyber insurance market continues to grow and evolve, and cyber-related losses (particularly with regard to ransomware) have increased significantly over the past few years.[14] In view of recent market developments and the important role of cyber insurance in the Program, Treasury would like to obtain more detailed information relating to the availability and affordability of such coverage in the market.

Interested parties should review the proposed Cyber worksheet contained within each proposed reporting template, along with the revised Instructions for that worksheet, for further details on the proposed changes.

The following paragraphs summarize the changes to the overall format of the worksheet:

(1) As Treasury recognized in its 2016 Cyber Guidance and in its final rule in 2021, not all cyber insurance is written in TRIP-eligible lines of insurance that would be subject to the Program. In order to assess the amount of cyber insurance that is not subject to the Program, and the potential implications for the Program, Treasury is now requesting premium and limits information for cyber coverages written in non-TRIP-eligible lines of insurance.[15]

(2) For cyber insurance written in both TRIP and Non-TRIP eligible lines, Treasury is now also requesting premium and policy count information broken out by size of policyholder. This information is separated into large, medium and small categories, as measured by the number of employees of the policyholder. This new data will assist Treasury in assessing the availability, affordability, and take up of cyber insurance for businesses in different size categories.

(3) Cyber extortion coverage (which may or may not extend coverage for ransomware payments) also can be an element of cyber insurance coverage. Ransomware has emerged as a significant risk exposure for United

[9] By material changes, Treasury means changes to the data call that require the provision of additional types of information, or information arrayed in a different fashion than previously requested. Non-material changes that have been incorporated include date changes to the reporting templates to reflect the different reporting year, and revisions to the Reinsurance worksheet to contain a new modeled loss question for insurers (excepting small insurers that do not respond to that question), in the same format as prior years.

[10] *See* Federal Insurance Office, *Report on the Effectiveness of the Terrorism Risk Insurance Program* (June 2020), 48 (''Because many insurers generally exclude NBCR risks under P&C policies (excepting workers' compensation, as discussed below), the amount of direct insurance coverage for such risks may be substantially limited.''), *https://home.treasury.gov/system/files/311/2020-TRIP-Effectiveness-Report.pdf;* U.S. General Accountability Office, *Terrorism Insurance: Status of Coverage Availability for Attacks Involving Nuclear, Biological, Chemical, or Radiological Weapons* (December 2008), 13 (''Commercial property/casualty insurers and reinsurers generally seek to exclude coverage for NBCR risks or place significant restrictions on such coverage.''), *https://www.gao.gov/assets/gao-09-39.pdf.*

[11] 81 FR 95312 (Dec. 27, 2016).

[12] 83 FR 14718, 14720 (April 5, 2018).

[13] 86 FR 30537, 30538 (June 9, 2021) (amending 31 CFR 50.4(w)(1)).

[14] *See generally* Federal Insurance Office, *Annual Report on the Insurance Industry* (September 2021), 74–80, *https://home.treasury.gov/system/files/311/FIO-2021-Annual-Report-Insurance-Industry.pdf.*

[15] As in past data calls, Treasury is not requesting insurers to provide information on premiums or exposures where a cyber loss may be found to be covered on a non-affirmative, or ''silent'' basis.

States businesses and for cyber insurers providing coverage for those exposures.[16] In order to better understand the scope of insurance coverage being provided for this risk and its potential implications for the Program, Treasury is now requesting more specific information on the cyber extortion coverages provided under cyber insurance policies.

(4) Given the significant increase in ransomware activity and reported substantial claims payments by insurers providing cyber insurance, Treasury is also requesting loss information regarding these ransomware exposures.

For the 2022 data call (requesting insurer data for calendar year 2021), an insurer will qualify as a small insurer if it had both *2020* policyholder surplus and *2020* direct earned premium in the TRIP-eligible lines of insurance of less than $1 billion.[17] Small insurers that had TRIP-eligible direct earned premium of less than $10 million in 2021 will be exempt from the 2022 consolidated TRIP data call.[18] Neither captive insurers nor alien surplus lines insurers are eligible for this reporting exemption. The only changes to the small insurer template are in connection with the global changes for cyber insurance identified above.

The non-small insurer template should be completed by insurance groups (or individual insurers not affiliated with a group) that had either a 2020 policyholder surplus or 2020 direct earned premium in the TRIP-eligible lines of insurance equal to or greater than $1 billion and are not otherwise subject to reporting as captive insurers or alien surplus lines insurers. The reporting template for non-small insurers does not contain changes, other than the global changes relating to cyber insurance described above.

Captive insurers are defined in 31 CFR 50.4(g) as insurers licensed under the captive insurance laws or regulations of any state. As in prior years, captive insurers that write policies in TRIP-eligible lines of insurance are required to report unless they do not provide their insureds with any terrorism risk insurance that is subject to the Program. As noted above, the captive insurer reporting template contains changes on the Premium and Exposure Bases worksheets,[19] as well as the global changes relating to cyber insurance described above.

Alien surplus lines insurers are defined in 31 CFR 50.4(o)(1)(i)(B) as insurers not licensed or admitted to engage in the business of providing primary or excess insurance in any state, but that are eligible surplus line insurers listed on the NAIC Quarterly Listing of Alien Insurers. Alien surplus lines insurers that are part of a larger group classified as a non-small insurer or as a small insurer should report as part of the group, using the appropriate template. Therefore, the alien surplus lines insurer template should only be used by an alien surplus lines insurer that is not part of a group that is subject to reporting on a different template. The reporting template for alien surplus lines insurers does not contain changes, other than the global changes relating to cyber insurance described above.

As in past consolidated data calls, state insurance regulators will provide their own guidance regarding the submission of reporting templates to the New York Portal, as well as in connection with any additional data that may be required for the state data call.

## III. Submission of Data

Following registration with the data aggregator, all insurers will be provided with the appropriate reporting templates for completion. Reporting insurers that wish to report in .csv format can obtain information from the data aggregator on how to do so. Insurers will be required to submit the completed reporting templates through a secure web portal provided by the data aggregator. Submission of reports to the New York Portal does not satisfy the obligation to report to Treasury in the TRIP data call. All data must be provided no later than May 15, 2022, which will also be the reporting deadline for state insurance regulators. Treasury intends to provide training and additional resources throughout the data collection period to facilitate the proper completion of reporting templates.

Reporting under the 2022 data call will be mandatory for all commercial property and casualty insurers writing insurance in lines subject to TRIA, unless the insurer falls within the exceptions for certain small insurers and captive insurers described above.

## IV. Request for Comments

To ensure efficient and accurate completion of the forms, Treasury is requesting public feedback on the content of the 2022 data call reporting templates outlined in this Request for Comments and on associated matters. In particular, Treasury requests comments on the following issues:

(1) Please comment upon the proposed material changes to the existing data collection forms as respects captive insurers and cyber insurance.

(2) Are there other publicly available information sources that bear upon the identified issues concerning captive insurers and insurers writing cyber coverage that Treasury should consider in connection with the information identified in this Request for Comments?

(3) Is there any additional information that Treasury should collect given the proposed changes regarding captive insurers, in light of the matters identified in this Request for Comments?

(4) Is there any additional information that Treasury should collect given the proposed changes regarding insurers writing cyber coverage, in light of the matters identified in this Request for Comments?

The proposed forms are available for review at *https://home.treasury.gov/policy-issues/financial-markets-financial-institutions-and-fiscal-service/federal-insurance-office/terrorism-risk-insurance-program/annual-data-collection.*

## V. Procedural Requirements

*Paperwork Reduction Act.* The collection of information contained in this Request for Comments will be submitted to the Office of Management and Budget (OMB) for review as a revision to OMB Control Number 1505–0257 under the requirements of the Paperwork Reduction Act, 44 U.S.C. 3507(d). Comments should be sent to Treasury in the form discussed in the **ADDRESSES** section of this Request for Comments. Comments on the collection of information should be received by January 18, 2022.

[16] *See, e.g.,* U.S. Treasury, Financial Crimes Enforcement Network, Financial Trend Analysis, Ransomware Trends in Bank Secrecy Act Data Between January 2021 and June 2021, *https://www.fincen.gov/sites/default/files/2021-10/Financial%20Trend%20Analysis_Ransomware%20508%20FINAL.pdf.*

[17] Small insurers are defined in 31 CFR 50.4(z) as insurers (or an affiliated group of insurers) with policyholder surplus for the immediately preceding year less than five times the Program Trigger for the current year, and TRIP-eligible lines direct earned premium for the previous year that is also five times less than the Program Trigger. Accordingly, an insurer qualifies as a small insurer if its 2020 policyholder surplus and 2020 direct earned premium are less than five times the 2021 Program Trigger of $200 million.

[18] To the extent an insurer with less than this level of TRIP-eligible lines direct earned premium is part of a larger group that is required to report, the insurer must report as part of the group as a whole, even if it is under the $10,000,000 direct earned premium threshold on an individual basis. Individual company information for such entities must also be reported to state insurance regulators.

[19] In addition, on the Affiliations worksheet for captive insurers, there is now an additional drop-down option for Type of Insurer for affiliated companies, adding Alien Surplus Lines Insurer to the listing, based upon an inquiry received during the 2021 data call.

Comments are being sought with respect to the collection of information in the proposed Terrorism Risk Insurance Program 2022 data call. *Treasury specifically invites comments on:* (a) Whether the proposed collection is responsive to the statutory requirement; (b) the accuracy of the estimate of the burden of the collections of information (*see below*); (c) ways to enhance the quality, utility, and clarity of the information collection; (d) ways to use automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to maintain the information.

Treasury previously analyzed the potential burdens associated with the 2021 data call. See 85 FR 41676, 41677–78 (July 10, 2020). The information sought by Treasury comprises data elements that insurers currently collect or generate, although not necessarily grouped together the way in which insurers currently collect and evaluate the data. Based upon insurer submissions in the 2021 data call, Treasury estimates that for purposes of the 2022 data call, approximately 100 Program participants will be required to submit the ''Insurer (Non-Small) Groups or Companies'' data collection form, 225 Program participants will be required to submit the ''Small Insurer'' form, 575 Program participants will be required to submit the ''Captive Insurer'' form, and 100 Program participants will be required to submit the ''Alien Surplus Lines Insurers'' form.

Each set of reporting templates is expected to incur a different level of burden. At the time of the 2020 estimate, the average burden estimate for Non-Small Insurers was 82 hours; for Small Insurers, 28 hours; for Captive Insurers, 51 hours, and for Alien Surplus Lines Insurers, 51 hours.[20] When Treasury added a Cyber worksheet to the reporting templates in 2018, it did not estimate any additional material burden at that time associated with incremental addition of requiring some limited cyber insurance reporting.[21]

The changes to the proposed data reporting elements in 2022 are not anticipated to have a significant impact on Treasury's prior burden estimates with respect to the additional requested information specific to captive insurers, as the additional information is largely the same information that has been previously collected, with the additional requirement that such information be divided between deductible reimbursement policies versus other policies in the same line of insurance. Given the relatively small number of policies issued by captive insurers, the additional effort to make this separation (assuming the captive insurer issues policies in both categories) should not be significant. Treasury does anticipate that the additional information collection concerning cyber insurance (which is sought from each category of participating insurer) will have an impact upon the existing burden estimates.

Although the amount of information requested concerning cyber insurance is more than has been requested in the past, it is in generally in the same format, with the exception that some information is now requested to be provided by size of policyholder. FIO anticipates that this will require some further manipulation of the data by participating insurers than in prior years. In addition, the templates now request claims-related information. Accordingly, for those insurers required to respond to the Cyber (Nationwide) worksheet, Treasury anticipates an additional 10 hours of burden, based upon its own evaluation and engagement with its data aggregator. That estimate, however, should be reduced by the percentage of insurers in each respective category that complete the Cyber worksheet. Based upon the results of the 2021 data call, 80 percent of Non-Small Insurers, 33 percent of Small Insurers, 10 percent of Captive Insurers, and 60 percent of Alien Surplus Lines Insurers provided information in connection with this worksheet. Accordingly, Treasury estimates the incremental additional burden for each group as 8 hours for Non-Small Insurers, for 90 hours total; 4 hours for Small Insurers, or 32 hours total; 1 hour for Captive Insurers, or 52 hours total; and 6 hours for Alien Surplus Lines Insurers, or 57 hours total.

Assuming this breakdown, and when applied to the number of reporting insurers anticipated in light of the experience of the 2021 data call, the estimated annual burden would be 51,800 hours ((100 insurers × 90 hours) + (225 insurers × 32 hours) + (575 insurers × 52 hours) + (100 insurers × 57 hours)). At a blended, fully loaded hourly rate of $52.25,[22] the anticipated labor cost would be $2,706,550 across the industry as a whole, or $4,703 per Non-Small Insurer, $1,672 per small insurer, $2,717 per Captive Insurer, and $2,978 per Alien Surplus Lines Insurer.

Dated: November 15, 2021.

**Steven E. Seitz,**

*Director, Federal Insurance Office.*

[FR Doc. 2021–25181 Filed 11–17–21; 8:45 am]

BILLING CODE 4810–AK–P

[20] 85 FR 41676, 41677–78 (July 10, 2020).

[21] 82 FR 56328, 56331 (Nov. 28, 2017).

[22] Based on data from the Bureau of Labor Statistics, for Insurance Carriers and Related Activities, *https://www.bls.gov/iag/tgs/iag524.htm.* The average wage rate for all insurance employees was $39.02 in July 2021, and the total benefit compensation in the 2nd Quarter of 2021 was 33.9%, which is a benefit multiplier of 1.339. Therefore, a fully-loaded wage rate for insurance employees is $52.25, or $39.02 × 1.339.

## DEPARTMENT OF VETERANS AFFAIRS

**[OMB Control No. 2900–0021]**

## Agency Information Collection Activity: VA Loan Electronic Reporting Interface (VALERI) System

**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, 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. 2900–0021.

**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. 2900–0021'' in any correspondence.

**SUPPLEMENTARY INFORMATION:**

*Authority:* 38 CFR 36.4338(a)

*Title:* VA LOAN ELECTRONIC REPORTING INTERFACE (VALERI) SYSTEM.

*OMB Control Number:* 2900–0021.

*Type of Review:* Extension of approved information collection.

*Abstract:* VA is submitting a regular extension for an already approved collection. VA provides the authority for VA-guaranteed mortgage servicers to assist Veteran borrowers and their families experiencing financial difficulty. VA then provides oversight of the servicers' actions by collecting specific documentation and data. In today's environment, this collection is done via the VALERI application.

VA submitted an emergency information collection request, which was approved to January 31, 2022, to account for data collection requirements associated with the COVID–19 Refund Modification. Much like VA's temporary COVID–19 Veterans Assistance Partial Claim Payment program (COVID–VAPCP), servicers who offer the COVID–19 Refund Modification are required to report information related to selecting this home retention option to VA electronically.

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 51226 on September 14, 2021, pages 51226 and 51227.

*Affected Public:* Individuals or Households.

*Estimated Annual Burden:* 70 hours.

*Estimated Average Burden per Respondent:* 1 minute.

*Frequency of Response:* One time.

*Estimated Number of Respondents:* 967.

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. 2021–25197 Filed 11–17–21; 8:45 am]

**BILLING CODE 8320–01–P**

# FEDERAL REGISTER

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Part II

## Department of Commerce

Bureau of Industry and Security

Publication of a Report on the Effect of Imports of Transformers and Transformer Components on the National Security: An Investigation Conducted Under Section 232 of the Trade Expansion Act of 1962, as Amended; Notice

## DEPARTMENT OF COMMERCE

### Bureau of Industry and Security

**RIN 0694–XC085**

### Publication of a Report on the Effect of Imports of Transformers and Transformer Components on the National Security: An Investigation Conducted Under Section 232 of the Trade Expansion Act of 1962, as Amended

**AGENCY:** Bureau of Industry and Security, Commerce.

**ACTION:** Publication of a report.

**SUMMARY:** The Bureau of Industry and Security (BIS) in this notice is publishing a report that summarizes the findings of an investigation conducted by the U.S. Department of Commerce (the ''Department'') pursuant to Section 232 of the Trade Expansion Act of 1962, as amended (''Section 232''), into the effect of imports of transformers and transformer components on the national security of the United States. This report was completed on October 15, 2020 and posted on the BIS website in July 2021. BIS has not published the appendices to the report in this notification of report findings, but they are available online at the BIS website, along with the rest of the report (*see* the **ADDRESSES** section).

**DATES:** The report was completed on October 15, 2020. The report was posted on the BIS website in July 2021.

**ADDRESSES:** The full report, including the appendices to the report, are available online at *https://www.bis.doc.gov/index.php/documents/section-232-investigations/2790-redacted-goes-report-20210723-ab-redacted/file.*

**FOR FURTHER INFORMATION CONTACT:** Kevin Coyne, Industrial Studies Division, Bureau of Industry and Security, U.S. Department of Commerce (202) 482–4952, *ESproducts232@bis.doc.gov.* For more information about the Section 232 program, including the regulations and the text of previous investigations, please see *www.bis.doc.gov/232.*

**SUPPLEMENTARY INFORMATION:**

### The Effect of Imports of Transformers and Transformer Components on the National Security

*U.S. Department of Commerce, Bureau of Industry and Security, Office of Technology Evaluation*

Final Report

October 15, 2020

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### I. Executive Summary

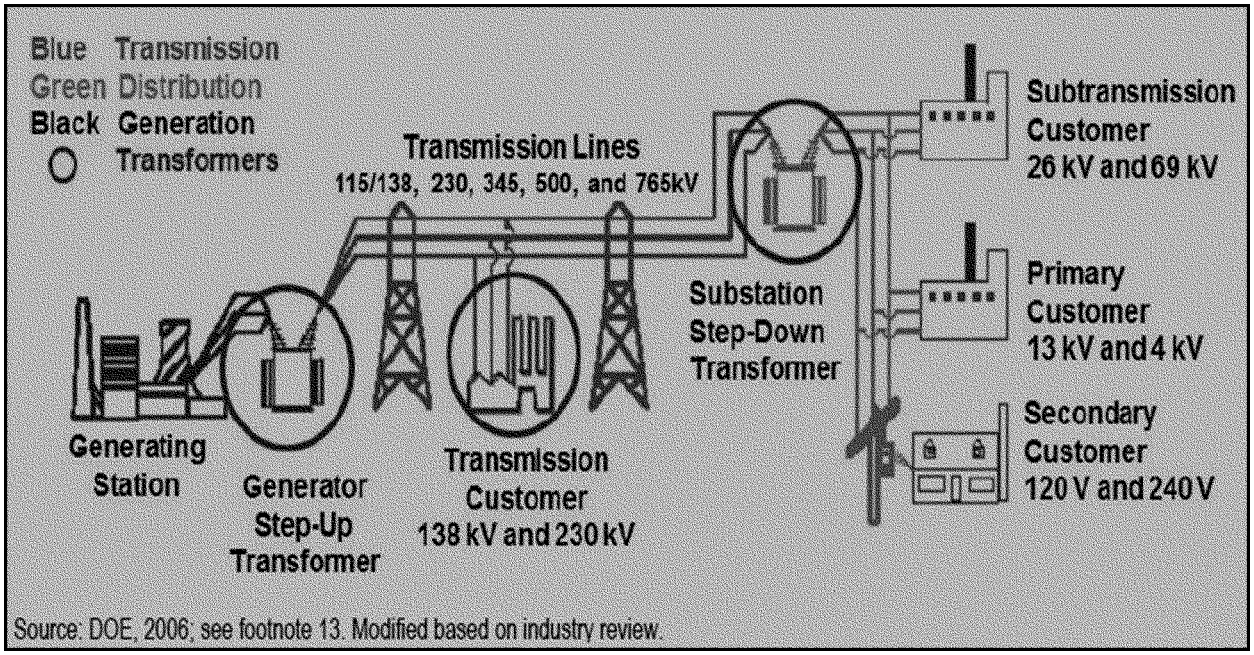
On May 4, 2020, U.S. Secretary of Commerce Wilbur Ross announced he would initiate an investigation into whether laminations for stacked cores for incorporation into transformers, stacked and wound cores for incorporation into transformers, electrical transformers, and transformer regulators are being imported into the United States in such quantities or under such circumstances as to threaten to impair the national security. Secretary Ross officially initiated this investigation on May 11, 2020, in response to inquiries and requests from multiple Members of Congress, a grain-oriented steel manufacturer, and producers of power and distribution transformers.

On May 19, 2020, the Department of Commerce (Department) published a **Federal Register** Notice (*See* Appendix C—**Federal Register,** 85 FR 29926) announcing the initiation of the investigation and inviting interested parties to submit written comments, opinions, data, information, or advice relevant to the investigation. The Department received 79 public comments and 30 rebuttal comments from a wide range of interested parties, including industry participants, representatives of state and local governments, foreign governments, and trade associations. A summary of the public comments received is included in Appendix D.

In addition, the Department surveyed (*See* Appendix E) 87 U.S. companies identified as participating in production or distribution of electrical steel, laminations and stacked and wound cores for transformers, power and distribution transformers, and voltage regulators. Survey responses provided the Department with detailed industry information that is otherwise not publicly available and was necessary to conduct a thorough analysis for this investigation.

The Department consulted with the Department of Defense (including the Office of Industrial Policy and Defense Logistics Agency) regarding methodological and policy questions that arose during the investigation. Given the vital role that these products play in the energy sector and the critical infrastructure of the country, the Department also consulted with the Departments of Energy (Office of Electricity) and Homeland Security. In addition, the Department consulted with the Office of the United States Trade Representative, given the trade implications of any actions taken with regard to imports of these products.

The products subject to this investigation are essential inputs to the manufacture and functioning of transformers, as well as the finished transformers themselves. In particular, this investigation focuses on *transformers and transformer components (i.e., laminations and cores) for which the crucial input is grain-oriented electrical steel (GOES).* Transformers are critical assets used to step-up and step-down power voltages throughout the electrical grid. As such, they are fundamental to the efficient transmission and distribution of electricity across the bulk-power system of the United States. The U.S. electricity grid supplies residential, commercial, and industrial customers, as well as the power required to support military and defense installations, including bases, arsenals, and laboratories. A simplified schematic of the role of transformers in the electrical grid is presented below.




In addition to transmission and distribution, transformers are used widely in major industrial sectors such as mining, manufacturing, and chemical processing. Large commercial users of transformers include hospitals, hotels, office buildings, and airports. Sophisticated military equipment, such as fighter jets and naval vessels, relies on transformers of various types and capacities to provide the correct voltage within subsystems. Due to its importance for certain defense applications, the Defense Logistics Agency has included GOES among its requests for inclusion in the National Defense Stockpile.

Large Power Transformers (LPTs) are among the most critical elements of the United States Bulk-Power System (BPS), which was the subject of an emergency declaration issued by President Trump on May 1, 2020. Executive Order 13920 (E.O. 13920 or Bulk Power Executive Order), titled ''Securing the United States Bulk-Power System,'' noted that as the backbone of our Nation's energy infrastructure, the BPS is fundamental to national security, emergency services, critical infrastructure, and the economy.[1] The President determined that the unrestricted foreign supply of electrical equipment constitutes an unusual and extraordinary threat to the national security, foreign policy, and economy of the United States. The President also determined that the evolving threats facing our critical infrastructure have highlighted supply chain risks and the need to ensure the availability of secure components from American companies and other trusted sources.[2]

The global transformer industry is dominated by large multinational companies that offer a wide product range and benefit from economies of scale. In addition to these large global players, in the United States there are also a number of smaller domestic companies that manufacture transformers of various power-handling capacities. Many manufacturers have established production facilities in locations that allow them to take advantage of lower labor costs and environmental standards. Mexico, in particular, has become a significant player in transformer manufacturing.

*A. GOES*

Grain-oriented electrical steel (GOES) is a critical material essential to the performance of transformers and accounts for a significant portion of the cost of transformer production (about 25 percent based on responses to the Department survey). AK Steel, Inc., a subsidiary of Cleveland Cliffs Inc., is the sole U.S. domestic producer of GOES, which it manufactures at facilities in Zanesville, Ohio, and Butler, Pennsylvania. While still a leader in the domestic market, AK Steel's electrical steel operations are not profitable, in part due to years of pressure from lower cost imports.[3] The CEO of Cleveland Cliffs, Inc., has stated that it may shut down the two unprofitable plants at which GOES is manufactured. If AK Steel's GOES operations were to close, the United States would lack the ability to produce transformers of any power handling capacity without relying on foreign sources for the key material that is essential to their operation and efficiency.

The threat to national security posed by imports of GOES (among other steel products) was addressed by a Section 232 investigation conducted in 2017, which resulted in the 2018 imposition of 25 percent tariffs on imports of steel products from most countries. As a result, imports of GOES in 2019 were dramatically lower than in 2018 (down 56 percent). [TEXT REDACTED]

[TEXT REDACTED].[4] Moreover, many transformer companies, in public comments or survey responses, indicated concern over AK Steel's capabilities and capacity to supply a full range of GOES products, especially the higher grades that are increasingly in demand due to current DOE energy standards for distribution transformers as well as general market trends toward energy efficiency.

1. Transformer Components (Laminations and Cores)

This investigation sought to evaluate the status of domestic production and the impact of imports for key subcomponents of transformers, namely laminations for stacked cores for

[1] *https://www.whitehouse.gov/presidential-actions/executive-order-securing-united-states-bulk-power-system/.*

[2] *https://www.energy.gov/articles/president-trump-signs-executive-order-securing-united-states-bulk-power-system.*

[3] AK Steel Public Comments.

[4] Department of Commerce, Section 232 Investigation into Impact of Steel Imports on National Security, 2018.

incorporation into transformers, stacked cores for incorporation into transformers, and wound cores for incorporation into transformers.

Arguably the most important part of a transformer is its core, which is made up of thin layers of laminations, usually made of GOES. Cores may have varying designs and specifications, but their function is generally to facilitate the magnetic field necessary for the induction of voltages between the two windings (*i.e.,* in order to ''step-up'' or ''step-down'' the power voltage). The layered composition helps reduce the core's energy losses. Transformer lamination and core producers make up the primary customer base for GOES suppliers such as AK Steel.

However, over the past few years, there has been a marked decline in the domestic manufacturing of laminations and cores (both in-house by transformer companies and by independent producers), and a movement of production offshore (especially to Canada and Mexico). The United States has become highly dependent on foreign sources for these critical transformer components.

A corollary to the movement of lamination and core manufacturing out of the United States is the decline of the domestic market for AK Steel's GOES. Although not the only factor, the tariffs imposed on imports of electrical steel under Section 232 have raised material costs for lamination and core manufacturers, affecting their ability to compete, because electrical steel accounts for a large percentage of the cost of these items [TEXT REDACTED].

In 2019, laminations with a total value of $40.2 million were sourced by surveyed companies. Of this $40.2 million, less than 12 percent came from domestic suppliers. This implies an import penetration level of 88% for laminations. In the years immediately prior, there was a dramatic increase in imports of these products—from $18 million in 2017 to $33 million in 2019—which displaced U.S. production. Over 95 percent of these imports came from Canada (68 percent) and Mexico (29 percent).

A similar situation exists with regard to stacked and wound cores. Based on survey data, imports account for about 75 percent of wound core purchases by surveyed transformer companies in 2019. With regard to stacked cores, imports accounted for 54 percent of purchases by respondents. [TEXT REDACTED]. However, this firm reported that it shut down core production in February 2020 due to its inability to compete with imports. [TEXT REDACTED]. With the exit of the leading domestic non-captive supplier, future imports of stacked cores will also likely exceed 80 percent of purchases, with China serving as a major source.

Imports of transformer cores (stacked and wound) rose from $22 million in 2015 to $167 million in 2019—a 650 percent increase—again with Canada (52 percent) and Mexico (45 percent) accounting for more than 95 percent of the total. Since domestic demand for laminations and cores has not increased in parallel with the increase in imports, the surge in imports represents displaced domestic production. Moreover, neither Mexico nor Canada has indigenous production capability for GOES. While Japan is the leading source of GOES for these countries, they also import some of this material from China and Russia.

*B. Transformers*

This investigation evaluated the status of the domestic transformer industry in several categories: Liquid-filled distribution transformers and small power transformers, medium power transformers, LPT, dry-type transformers, and voltage regulators.

Distribution transformers (both liquid-dielectric as well as dry-type), and small and medium power transformers are used extensively in the U.S. electrical grid—millions are installed and operating. This investigation found that domestic industrial production and capabilities in these sectors is generally adequate. In the liquid-dielectric categories, imports account for less than a quarter of apparent consumption, and companies in this sector are largely financially sound and competitive in the market, based on responses to the BIS industry survey. While import penetration is currently relatively low, survey participants indicated competitiveness challenges, especially from Mexico and China. Survey respondents also mentioned workforce issues, such as difficulty finding and attracting qualified labor, as a concern.

Imports play a major role in the dry-type transformer sector, and leading U.S.-based producers also have overseas production facilities. Countries with low cost labor—including China, Indonesia, and Mexico—are major sources of imported dry-type transformers. Despite relatively strong domestic production capabilities, an in-depth analysis of suppliers found a heavy dependence on foreign sources among domestic manufacturers in all transformer categories for critical components including laminations and cores and the GOES from which they are made, as described above.

This investigation found shortcomings with regard to domestic production of LPTs that are critical elements of the United States BPS. Because they serve the greatest number of customers, the failure or destruction of just a single unit can have a large impact on U.S. economic, public health, and security interests. Moreover, long procurement lead times and limited availability of spare LPT and parts have serious implications for the resiliency of critical infrastructure.

Domestic production capability falls far short of demand for the LPT segment of the industry, with imports accounting for over 80 percent of consumption. This lack of domestic production capability and the accompanying extreme dependence on imports has persisted for at least a decade, creating a critical infrastructure vulnerability, which has been raised in previous Department of Energy assessments.[5]

Only six companies currently manufacture LPTs in the United States; [TEXT REDACTED]. The largest domestic producer is Korean-owned Hyundai, which has publicly noted that its Alabama facility will be utilized ''in maneuvering U.S. imposed anti-dumping tariff [sic] and its protectionist policies.''[6]

[TEXT REDACTED].[7] Compounding the issue, domestic LPT producers are highly dependent on foreign sources for GOES, laminations, and cores.

*C. Findings*

[TEXT REDACTED]. While still a leader in the domestic market, the market has eroded due to the migration of production of transformer components (and finished transformers) out of the United States. If this manufacturer were to shut down GOES production, the United States would be completely dependent on foreign sources for material critical to the manufacture of transformers.

There is insufficient or no domestic production capability for certain grades and qualities of GOES that are increasingly in demand to meet efficiency standards for distribution transformers as well as general market trends toward more efficient transformers using higher grades of GOES.

The United States lacks sufficient capacity to produce transformer cores

[5] ''Large Power Transformers in U.S. Electric Grid'', Department of Energy, Office of Electricity and Energy Reliability, June 2012 *https://www.energy.gov/sites/prod/files/Large%20Power%20Transformer%20Study%20-%20June%202012_0.pdf.*

[6] *http://hhiamerica.com/about/sub04.htm.*

[7] [TEXT REDACTED].

and laminations, which are the key components in transformers. Transformer manufacturers in the United States rely on foreign sources (especially Canada and Mexico) for these critical components to meet over 75 percent of (non-captive) demand.

The United States is also highly dependent on foreign-sourced transformers, most significantly for the LPTs that form the backbone of the BPS.

Based on the overwhelming dependence of domestic transformer manufacturers on foreign sources, the Secretary finds that transformer laminations, stacked cores and wound cores are being imported into the United States in such quantities and under such circumstances as to threaten to impair the national security. In addition, LPTs are being imported into the United States in such quantities and under such circumstances as to threaten to impair national security. This dependence on imports leaves the United States with insufficient production capability for LPTs to meet the needs of the critical energy infrastructure of the United States.

## II. Legal Framework

### *A. Section 232 Requirements*

Section 232 of the Trade Expansion Act of 1962, as amended, provides the Secretary with the authority to conduct investigations to determine the effect on the national security of the United States of imports of any article. It authorizes the Secretary to conduct an investigation if requested by the head of any department or agency, upon application of an interested party, or upon his own motion. *See* 19 U.S.C. 1862(b)(1)(A).

Section 232 directs the Secretary to submit to the President a report with recommendations for ''action or inaction under this section'' and requires the Secretary to advise the President if any article ''is being imported into the United States in such quantities or under such circumstances as to threaten to impair the national security.'' *See* 19 U.S.C. 1862(b)(3)(A).

Section 232(d) directs the Secretary and the President to consider, in light of the requirements of national security and without excluding other relevant factors, the domestic production needed for projected national defense requirements and the capacity of the United States to meet national security requirements. *See* 19 U.S.C. 1862(d).

Section 232(d) also directs the Secretary and the President to ''recognize the close relation of the economic welfare of the Nation to our national security, and . . . take into consideration the impact of foreign competition on the economic welfare of individual domestic industries'' by examining whether any substantial unemployment, decrease in revenues of government, loss of skills or investment, or other serious effects resulting from the displacement of any domestic products by excessive imports, or other factors, results in a ''weakening of our internal economy'' that may impair the national security.[8] *See* 19 U.S.C. 1862(d).

Once an investigation has been initiated, Section 232 mandates that the Secretary provide notice to the Secretary of Defense that such an investigation has commenced. Section 232 also requires the Secretary to do the following:

(1) ''Consult with the Secretary of Defense regarding the methodological and policy questions raised in [the] investigation;''

(2) ''Seek information and advice from, and consult with, appropriate officers of the United States;'' and

(3) ''If it is appropriate and after reasonable notice, hold public hearings or otherwise afford interested parties an opportunity to present information and advice relevant to such investigation.''[9] *See* 19 U.S.C. 1862(b)(2)(A)(i)–(iii).

As detailed in the report, all of the requirements set forth above have been satisfied.

In conducting the investigation, Section 232 permits the Secretary to request that the Secretary of Defense provide an assessment of the defense requirements of the article that is the subject of the investigation. *See* 19 U.S.C. 1862(b)(2)(B). Upon completion of a Section 232 investigation, the Secretary is required to submit a report to the President no later than 270 days after the date on which the investigation was initiated. *See* 19 U.S.C. 1862(b)(3)(A). The report must:

(1) Set forth ''the findings of such investigation with respect to the effect of the importation of such article in such quantities or under such circumstances upon the national security;''

(2) Set forth, ''based on such findings, the recommendations of the Secretary for action or inaction under this section;'' and

(3) ''If the Secretary finds that such article is being imported into the United States in such quantities or under such circumstances as to threaten to impair the national security . . . so advise the President.'' *See* 19 U.S.C. 1862(b)(3)(A).

All unclassified and non-proprietary portions of the report submitted by the Secretary to the President must be published. *See* 19 U.S.C. 1862(b)(3)(B).

Within 90 days after receiving a report in which the Secretary finds that an article is being imported into the United States in such quantities or under such circumstances as to threaten to impair the national security, the President shall:

(1) ''Determine whether the President concurs with the finding of the Secretary;'' and

(2) ''If the President concurs, determine the nature and duration of the action that, in the judgment of the President, must be taken to adjust the imports of the article and its derivatives so that such imports will not threaten to impair the national security'' *See* 19 U.S.C. 1862(c)(1)(A).

### *B. Discussion*

While Section 232 does not specifically define ''national security,'' both Section 232 and the implementing regulations at 15 CFR part 705 contain non-exclusive lists of factors that the Secretary must consider in evaluating the effect of imports on the national security. Congress, in Section 232, explicitly determined that ''national security'' includes, but is not limited to, ''national defense'' requirements. *See* 19 U.S.C. 1862(d).

The Department has determined that ''national defense'' includes both the defense of the United States directly and the U.S. ''ability to project U.S. military capabilities globally.''[10] The Department also concluded that ''[i]n addition to the satisfaction of national defense requirements, the term 'national security' can be interpreted more broadly to include the general security and welfare of certain industries, beyond those necessary to satisfy national defense requirements, which are critical to the minimum operations of the economy and government.''[11] The Department deemed these certain industries as ''critical industries.''[12] This report applies these interpretations of the terms ''national defense'' and ''national security,'' in defining ''critical industries.'' In doing so, this report considers 16 critical infrastructure sectors identified in Presidential Policy

[8] An investigation under Section 232 looks at whether imports threaten to impair the national security, rather than looking at unfair trade practices as in an antidumping investigation.

[9] Department regulations (i) set forth additional authority and specific procedures for such input from interested parties, *see* 15 CFR 705.7 and 705.8, and (ii) provide that the Secretary may vary or dispense with those procedures ''in emergency situations, or when in the judgment of the Department, national security interests require it.'' *Id.*, § 705.9.

[10] Department of Commerce, Bureau of Export Administration; *The Effect of Imports of Iron Ore and Semi-Finished Steel on the National Security;* Oct. 2001 (''2001 Report'').

[11] *Id.*

[12] *Id.*

Directive 21.[13] Section 232 directs the Secretary to determine whether imports of any article are being made ''in such quantities'' or ''under such circumstances'' that those imports ''threaten to impair the national security.'' *See* 19 U.S.C. 1862(b)(3)(A). Accordingly, either the quantities or the circumstances, standing alone, may be sufficient to support an affirmative finding.

The statute does not prescribe a threshold or a standard for when ''such quantities'' of imports are sufficient to threaten to impair the national security, nor does it define the ''circumstances'' that might qualify.

Likewise, the statute does not require a finding that the quantities or circumstances are impairing the national security. Instead, the threshold question under Section 232 is whether those quantities or circumstances ''threaten to impair the national security.'' *See* 19 U.S.C. 1862(b)(3)(A). This demonstrates that Section 232 may be used to prevent a threatened impairment to the national security from occurring before the national security is actually impaired.

Section 232(d) contains a list of factors for the Secretary to consider in determining if imports ''threaten to impair the national security''[14] of the United States, and this list is mirrored in the implementing regulations. *See* 19 U.S.C. 1862(d) and 15 CFR 705.4. While the list provided by Congress in Section 232 provides mandatory factors for the Secretary to consider, it is not exhaustive.[15] Congress' illustrative list is focused on the ability of the United States to maintain the domestic capacity to provide the articles in question as needed to maintain the national security of the United States.[16] Congress split the list of factors into two equal parts using two separate sentences. The first sentence focuses directly on ''national defense'' requirements, thus making clear that ''national defense'' is a subset of the broader term ''national security.'' The second sentence focuses on the broader economy and expressly directs that the Secretary and the President ''shall recognize the close relation of the economic welfare of the Nation to our national security.''[17] *See* 19 U.S.C. 1862(d).

In addition to ''national defense'' requirements, two of the factors listed in the second sentence of Section 232(d) are particularly relevant in this investigation. Both are directed at how ''such quantities'' of imports threaten to impair national security. *See* 19 U.S.C. 1862(b)(3)(A). In administering Section 232 to ''[determine] whether such weakening of our internal economy may impair the national security,'' the Secretary and the President are required to ''take into consideration the impact of foreign competition on the economic welfare of individual domestic industries,'' as well as to and analyze whether there exist ''serious effects resulting from the displacement of any domestic products by excessive imports.'' *See* 19 U.S.C. 1862(d). In certain key product categories, imports of transformers and transformer components accounted for over 80 percent of U.S. consumption in 2019. In the case of transformer cores and laminations, imports have substantially displaced domestic production of these items. Because these products are the primary market for GOES, the displacement of domestic production by imports also threatens threaten the financial viability of the only remaining domestic producer of GOES.

Two other factors included in the statute that are also particularly relevant to this investigation are ''loss of skills'' and ''loss of investment.'' *See* 19 U.S.C. 1862(d). As imports of GOES have increased, losses of U.S. GOES production capacity have caused a decline in the skilled workforce needed for the GOES manufacturing process. Additionally, as a result of their impact on the revenues of U.S. producers, these imports have mitigated investment in U.S. GOES production facilities, precluding future sustainable development of domestic GOES production. Similarly, these imports also create a disincentive for needed investment in U.S. GOES production facilities; without this investment, future production of domestic GOES is not sustainable. These factors are illustrative of a ''weakening of the internal economy [that] may impair the national security'' as defined in Section 232.

## III. Investigation Process

### *A. Initiation of Investigation*

On May 4, 2020, the Secretary of Commerce announced that he would initiate an investigation into whether laminations for stacked cores for incorporation into transformers, stacked and wound cores for incorporation into transformers, electrical transformers, and transformer regulators are being imported into the United States in such quantities or under such circumstances as to threaten to impair the national security.[18] Laminations and cores made of GOES are critical transformer components, and transformers are a key element for distribution of all types of energy—including solar, nuclear, wind, coal, and natural gas—across the country. The decision to launch an investigation under Section 232 of the Trade Expansion Act of 1962, as amended (19 U.S.C. 1862), followed inquiries and requests from multiple Members of Congress, a GOES manufacturer, and producers of power and distribution transformers.

On May 11, 2020, the Department officially initiated the investigation. Pursuant to Section 232(b)(1)(b), the Department notified Secretary of Defense Mark T. Esper of the investigation and requested Department of Defense participation as it relates to methodology, policy questions, and national defense requirements for these products. Additionally, given that the products subject to this investigation are used extensively in the electrical grid and critical infrastructure of the United States, the Department also notified Secretary of Energy Dan R. Brouillette and Acting Secretary of Homeland Security Chad F. Wolf. Finally, the Secretary notified United States Trade Representative Robert E. Lighthizer,

[13] Presidential Policy Directive 21, *Critical Infrastructure Security and Resilience* (Feb. 12, 2013) (''PPD–21'').

[14] 19 U.S.C. 1862(b)(3)(A).

[15] *See* 19 U.S.C. 1862(d) (''the Secretary and the President shall, in light of the requirements of national security and without excluding other relevant factors . . .'' and ''serious effects resulting from the displacement of any domestic products by excessive imports shall be considered, without excluding other factors . . .'').

[16] This reading is supported by Congressional findings in other statutes. *See, e.g.,* 15 U.S.C. 271(a)(1) (''The future well-being of the United States economy depends on a strong manufacturing base . . .'') and 50 U.S.C. 4502(a) (''Congress finds that—(1) the security of the United States is dependent on the ability of the domestic industrial base to supply materials and services . . . (2)(C) to provide for the protection and restoration of domestic critical infrastructure operations under emergency conditions . . . (3) . . . the national defense preparedness effort of the United States government requires—(C) the development of domestic productive capacity to meet—(ii) unique technological requirements . . . (7) much of the industrial capacity that is relied upon by the United States Government for military production and other national defense purposes is deeply and directly influenced by—(A) the overall competitiveness of the industrial economy of the United States; and (B) the ability of industries in the United States, in general, to produce internationally competitive products and operate profitably while maintaining adequate research and development to preserve competitiveness with respect to military and civilian production; and (8) the inability of industries in the United States, especially smaller subcontractors and suppliers, to provide vital parts and components and other materials would impair the ability to sustain the Armed Forces of the United States in combat for longer than a short period.'').

[17] *Accord* 50 U.S.C. 4502(a).

[18] Department of Commerce Press Release, May 4, 2020.

noting that Department staff will consult with counterparts in the Office of the United States Trade Representative regarding methodological and policy questions that arise during the investigation. (See Appendix A).

On May 19, 2020, the Department published a **Federal Register** Notice (*See* Appendix C—**Federal Register**, 85 FR 29926) announcing the initiation of the investigation to determine the effect of imports of Laminations for Stacked Cores for Incorporation into Transformers, Stacked Cores for Incorporation into Transformers, Wound Cores for Incorporation into Transformers, Electrical Transformers, and Transformer Regulators on the national security. The notice also announced the opening of the public comment period.

*B. Public Comments*

In the **Federal Register** Notice announcing the investigation, the Department invited interested parties to submit written comments, opinions, data, information, and advice relevant to the criteria listed in Section 705.4 of the National Security Industrial Base Regulations (15 CFR 705.4) as it affects the requirements of national security, including the following:

(a) Quantity of the articles subject to the investigation and other circumstances related to the importation of such articles;

(b) Domestic production capacity needed for these articles to meet projected national defense requirements;

(c) The capacity of domestic industries to meet projected national defense requirements;

(d) Existing and anticipated availability of human resources, products, raw materials, production equipment, facilities, and other supplies and services essential to the national defense;

(e) Growth requirements of domestic industries needed to meet national defense requirements and the supplies and services, including the investment, exploration, and development, necessary to assure such growth;

(f) The impact of foreign competition on the economic welfare of any domestic industry essential to our national security;

(g) The displacement of any domestic products causing substantial unemployment, decrease in the revenues of government, loss of investment or specialized skills, and productive capacity, or other serious effects;

(h) Relevant factors that are causing or will cause a weakening of our national economy; and

(i) Any other relevant factors, including the use and importance of the Products in critical infrastructure sectors identified in Presidential Policy Directive 21 (Feb. 12, 2013) (for a listing of those sectors see *https://www.dhs.gov/cisa/critical-infrastructure-sectors*).

At the request of several parties, and in light of the global pandemic, the initial public comment period, as well as the rebuttal period, were extended ten additional days. The department provided an additional 24 days to submit public comments, with an additional time period provided for the submission of rebuttals to such comments as well. The final deadline for the submission of rebuttals to the public comments July 24, 2020.

The Department received 82 written comments concerning this investigation, 79 of which were responsive on *Regulations.gov* for public review. Parties that submitted comments included members of industry, representatives of state and local governments, foreign governments, and other concerned groups.

All 79 comments were available for response during the rebuttal period. Thirty-four rebuttal comments from industry participants and other stakeholders were received and 30 were responsive and were posted on *Regulations.gov* for public review. All of the appropriate comments and rebuttals were reviewed and factored into the investigative process. These responsive public comments received are summarized in Appendix D, along with a link to the *Regulations.gov* docket (BIS–2020–0015), where comments can be viewed in full.

*C. Information Gathering and Data Collection Activities*

Because this investigation commenced during a pandemic during which, many public and private sector organizations were shut down or operating under limited conditions, the Department decided not to hold a public hearing for this investigation. In lieu of a public hearing, the Department issued mandatory surveys (*See* Appendix E) to 87 companies or divisions of companies identified as participating in the production or distribution of electrical steel, laminations and stacked and wound cores for transformers, and power and distribution transformers. Survey responses were received from most of the major participants in the domestic transformer supply chain. The surveys collected both qualitative and quantitative information.

These mandatory surveys were conducted pursuant to Section 705 of the Defense Production Act (DPA) of 1950, as amended (50 U.S.C. 4555), and collected data on imports, exports, production, capacity utilization, employment, operating status, global competition, and financial information. The resulting aggregate data provided the Department with detailed industry information that is otherwise not publicly available, which was necessary to conduct a thorough analysis for this investigation.

Information furnished in the survey responses is deemed confidential and will not be published or disclosed except in accordance with Section 705 of the DPA.[19]

*D. Interagency Consultation*

The Department consulted with the Department of Defense (including the Office of Industrial Policy and Defense Logistics Agency) regarding methodological and policy questions that arose during the investigation. Given the vital role that these products play in the energy sector and the critical infrastructure of the country, the Department also consulted with the Departments of Energy (Office of Electricity) and Homeland Security. In addition, the Department consulted with the Office of the United States Trade Representative, given the trade implications of any actions with regard to imports of these products.

The Department also consulted with other U.S. government agencies with expertise and information regarding the domestic and global transformer and GOES industries, including the Department's International Trade Administration and the U.S. International Trade Commission.

*E. Product Scope of the Investigation*

The scope of this investigation includes laminations for incorporation into stacked cores, stacked cores for incorporation into transformers, wound cores for incorporation into transformers, electrical transformers, and transformer regulators. While GOES is not the direct subject of this investigation, because it is the primary material used in laminations, stacked cores, and wound cores, it is included in the scope of products addressed in this report. Products were examined in accordance with the Harmonized Tariff Schedule of the United States (HTS) up to the ten-digit level. The products and their associated HTS code are provided in Figure 1 below.

[19] Section 705 of the DPA prohibits the publication or disclosure of this information unless the President determines that withholding such information is contrary to the interest of the national defense. Unless or until such a determination is made, information will not be shared with any non-government entity in other than aggregate form.

FIGURE III–1—PRODUCT SCOPE OF THE INVESTIGATION

| 10 digit HTS | Product description |
|---|---|
| 7226.19.1000 | Non-Oriented Electrical Steel (NOES) (300–600mm). |
| 7226.19.9000 | Non-Oriented Electrical Steel (NOES) (<300mm). |
| 7225.11.0000 | Grain-Oriented Electrical Steel (GOES) (>600mm width). |
| 7226.11.1000 | Grain-Oriented Electrical Steel (GOES) (300–600mm). |
| 7226.11.9030 | Grain-Oriented Electrical Steel (GOES) (<300mm; <.25mm thick). |
| 7226.11.9060 | Grain-Oriented Electrical Steel (GOES) (<300mm; >.25mm thick). |
| 8504.90.9634 (Post 2016), 8504.90.9534 (2015) | Transformer Laminations (Stacked). |
| 8504.90.9638 (Post 2016), 8504.90.9538 (2015) | Transformer Cores (Stacked). |
| 8504.90.9642 (Post 2016), 8504.90.9542 (2015) | Transformer Cores (Wound). |
| 8504.21.0020 | Liquid-Dielectric Transformer Under 50KVA. |
| 8504.21.0040 | Liquid-Dielectric Transformer 50–100KVA. |
| 8504.21.0060 | Liquid-Dielectric Transformer 100–500KVA. |
| 8504.21.0080 | Liquid-Dielectric Transformer 500–650KVA. |
| 8504.22.0040 | Liquid-Dielectric Transformer 650–2,500KVA. |
| 8504.22.0080 | Liquid-Dielectric Transformer 2,500–10,000KVA. |
| 8504.23.0041 | Liquid-Dielectric Transformer 10,000–60,000KVA. |
| 8504.23.0045 | Liquid-Dielectric Transformer 60,000KVA–100,000KVA. |
| 8504.23.0080 | Liquid-Dielectric Transformer Over 100,000KVA. |
| 8504.32.0000 | Dry-Type/Other Transformer 1–16KVA. |
| 8504.33.0020 | Dry-Type/Other Transformer 16–50KVA. |
| 8504.33.0040 | Dry-Type/Other Transformer 50–500KVA. |
| 8504.34.0000 | Dry-Type/Other Transformer Over 500KVA. |
| 9032.89.4000 | Voltage Regulators. |

Source: United States International Trade Commission and U.S. Department of Commerce, Bureau of Industry and Security.

## IV. Description of the Products Subject to the Investigation

The products subject to this investigation are those that are critical to the manufacture and functioning of transformers, as well as the transformers themselves. In particular, this investigation focuses on *transformers and transformer components for which the crucial input is GOES*.

*Transformers* are passive devices that change (or transform) the voltage or electrical current level using a magnetic circuit. They are used to either increase (step-up) or decrease (step-down) voltage to ensure the correct voltage for a specific electricity use application. Transformers are available with a wide range of power-handling capabilities, typically measured in kilo-volt-amperes (kVA), from less than one kVA, to more than 100,000 kVA (which can also be expressed as 100 mega-volt-amperes where 1 MVA = 1,000 kVA). LPTs can be several stories tall and weigh hundreds of tons, while transformers for consumer products may be small enough to fit in your hand. No matter the size, the basic purpose of any transformer is to transform electrical power from one voltage to another.

There are many ways in which transformers can be categorized. Common industry terminology may classify by specific type (autotransformer, instrument transformer), current type (direct or alternating), function (step-up, step-down), core type (shell-form or core-form), or type of installation (pole-mounted, pad-mounted, underground). The size of a transformer can be measured by the input voltage (in kilovolts), the output voltage (in kilovolts), or the load capacity (measured by kilovolt amperes). This report will generally classify transformers based on their power load handling capacity (in kVA) as well as their type of dielectric insulation (liquid or dry). These categorizations were chosen because they correspond with the way in which the U.S. Census Bureau collects information on imports of these items. Transformers of most power-handling capacities are subject to this investigation. The exception is very small transformers (under 1 kVA), such as those typically used in conjunction with power cables for consumer electronics including laptops and cell phones, as these generally do not use electrical steel cores.

The most ubiquitous use of transformers is in the electrical grid, where they are used by electric utilities and power producers for the transmission and distribution of electricity from power generation plants to residential, commercial, and industrial customers. In addition to the electrical grid, large industrial users such as mines and major manufacturing, and chemical plants, as well as large commercial users including hospitals, hotels, office buildings, and airports may connect directly to the transmission grid and utilize their own transformers to take advantage of lower marginal costs.

Transformers are crucial equipment used throughout the electrical grid. Power leaves the generator and enters a transmission substation located at the power plant. This transmission substation uses LPTs to ''step-up'' the generator's voltage to extremely high voltages (155 kV to 765 kV volts) for efficient transmission over long distances (up to 300 miles). For the electricity to be used by commercial, industrial, or residential users, it must be ''stepped-down'' by transformers to distribution voltages (less than 10 kV; a standard line voltage is 7.2 kV at a substation). From there, the electricity is distributed locally via overhead or sunk power lines before it is further stepped-down by smaller transformers (such as pole mounted units) to the 240 volts that is standard household electrical service. Additionally, as noted above, some large commercial and industrial users may connect directly at substation transmission levels. The diagram below presents a simplified depiction of the use of transformers in the electrical grid.

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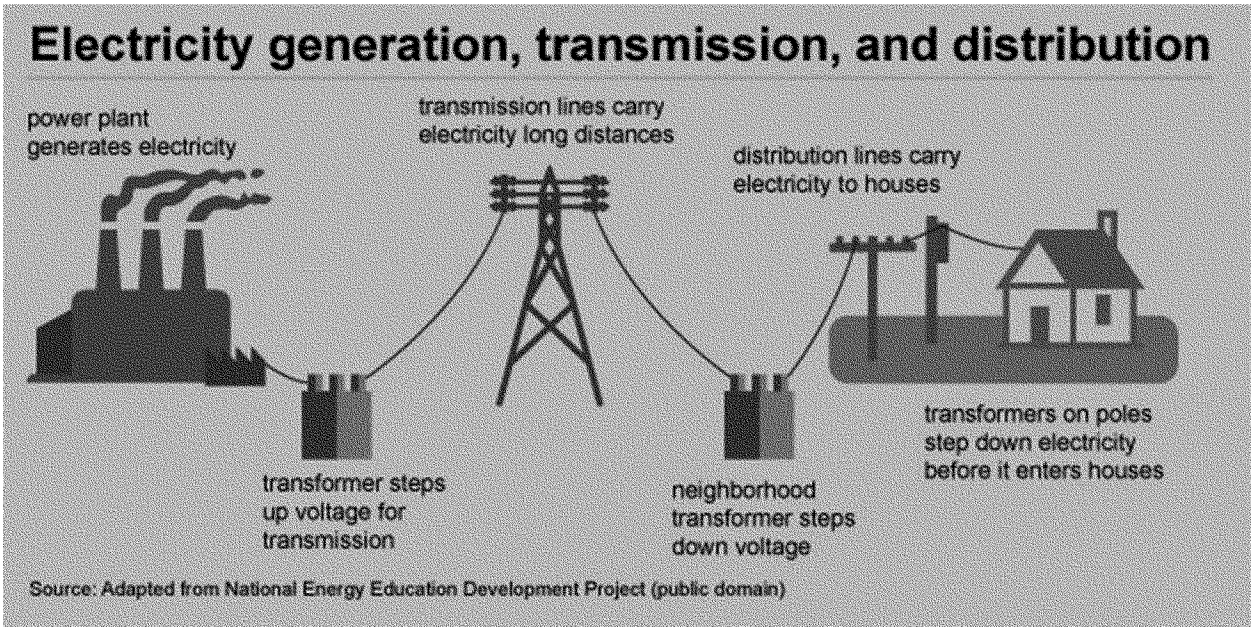
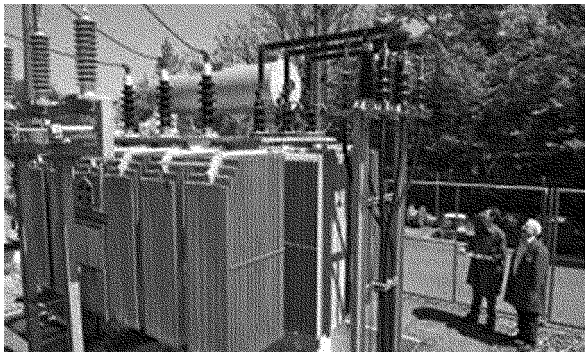



*A. Types of Transformers*

LPTs generally have power-handling capacities above 100,000 kVA (100 MVA) and are used to step-up the voltage up to extremely high levels at power generation sites for efficient transmission over long distances. They are used again at substations to step-down the voltage for more local distribution. LPT are also used by manufacturing sectors that require high voltages in their production processes, such as steel mills.



*Small and medium power transformers,* which generally have power handling capacities from 5,000 kVA to 100,000 kVA, are also used extensively throughout the electrical grid. They are available in a wide range of voltage ratings and power handling capacities, to meet the specific needs of consumers. For example, they are used at substations and at industrial facilities.

*Distribution transformers* (up to 5,000 kVA) are used to further step-down the voltage at substations to deliver electricity to customers. Distribution transformers provide the final voltage transformation in the electrical grid. While they are energized for 24 hours a day, their load fluctuates throughout the day with changing energy demands.

Also located along the electric grid are banks of *voltage regulators,* which are used to compensate for voltage fluctuation during power distribution. Voltage regulators play an important role in light of the increasing use of distributed energy resources such as solar and wind, which are intermittent.

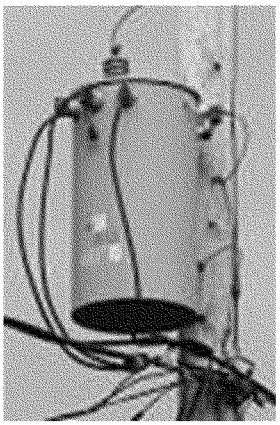
Transformers can be classified by the material used in core-insulation (*e.g.,* ''Liquid-dielectric'' or ''Dry-Type''). Cooling is important because transformers generate heat and pose potential fire or explosion hazards.

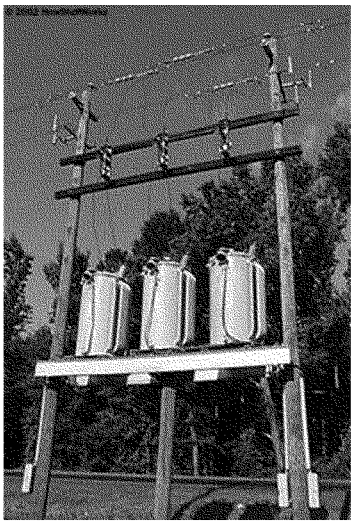
*Liquid-dielectric transformers* consist of the transformer core placed in a metal sealed container filled with mineral oil, which serves as a coolant and insulator.

*Dry-type transformers* have a metal housing for insulation but are cooled by air convection or fans, or may be encased in resin. Oil-filled liquid transformers are generally more efficient than dry-type, which are more limited in their power-handling capacity and size. However, oil-filled transformers require more maintenance, and because the liquid may be flammable or toxic, dry-type may be more preferable in public spaces.

Pole Mounted

Distribution Transformer





Transformer Regulators

Dry-type transformers are commonly used in light industrial and commercial applications; some are used indoors or underground. They are often used in cases in which liquid-dielectric transformers present unacceptable environmental, explosion, or fire hazards.

Specialized transformers perform specific functions in the electric grid. For example, *instrument transformers* step-down currents and voltages for accurate and reliable measurement by secondary equipment such as meters, protection relays, and other devices. Another specialized type of transformer is the *autotransformer,* which is used in power transmission systems to interconnect systems operating at different voltage; this type of transformer can also be used as a voltage regulators.

Transformers have been in use for over 100 years (Westinghouse built the first reliable commercial transformer in 1886) and are becoming more complex as they evolve to become part of the growing interconnected ''smart grid.'' [20] The smart grid is an automated network with a two-way flow of energy and information that is capable of monitoring and controlling energy metrics between the power plant and the end user, as well as at the many points in between. To function as part of the smart grid, transformers must be able to communicate in real time, be capable of extensive customer interaction, feature remote digital monitoring, and have the ability to self-diagnose and repair malfunctions.

*B. Transformer Construction*

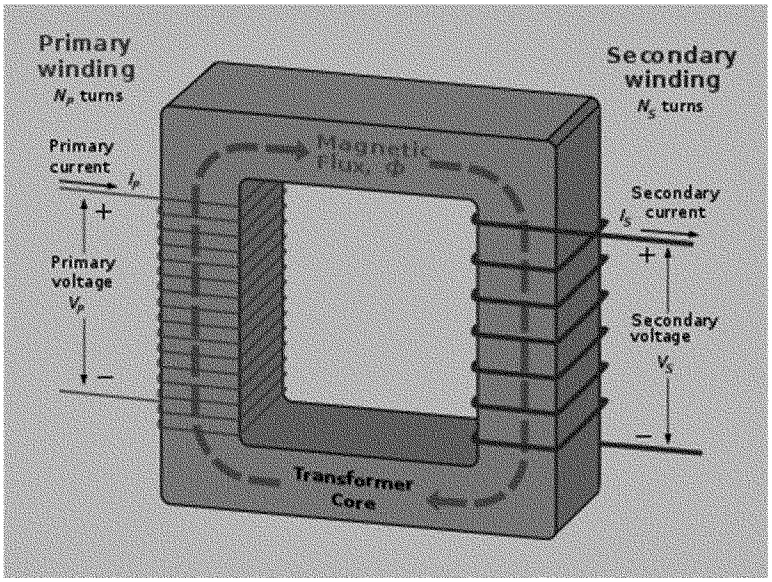
Regardless of their size or application, all transformers work through electromagnetic induction, a process in which a coil of wire magnetically induces a voltage into another coil of wire in close proximity to it. The basic structure of a transformer is two coils of copper wire: The ''primary winding'' and the ''secondary winding.'' The primary winding takes the power into the transformer, and the secondary winding delivers the power from the transformer. The difference in voltage between the primary and secondary windings is achieved by differences in the number of coil turns in each winding.[21]

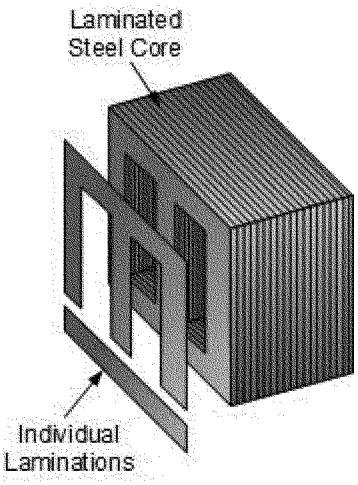
The two windings are not in direct contact with one another, but rather are each wound around a closed magnetic circuit that forms the *core* of the transformer. The core is not solid, but is made up of thin layers, or *laminations,* usually made of GOES. This layered composition helps reduce energy losses (eddy flow and hysteresis) within the core. Core laminations are the main material input in an electrical transformer and can account for up to 50 percent of a transformer's cost.[22]

[20] *https://global.abb/group/en/about/history/heritage-brands/westinghouse.*

[21] *https://circuitdigest.com/tutorial/transformer-basics.*

[22] *https://www.worldofsteel.com/Types%20of%20CRGO.html.*




Electrical transformers are typically produced with either *stacked or wound cores.* Stacked cores are most often used in larger distribution and power transformers, while wound cores are used in small and medium distribution transformers that step-down the voltage from the transmission line and provide power. In either case, GOES is the most common material used.

When used in *stacked cores,* GOES is sheared or stamped into individual laminations, which are then stacked together to form the core. Stacked laminations often resemble letters of the alphabet, including C, E, L, U, and I shapes. Commonly used core shapes include E–I, E–E, L, and U–I. When used in *wound cores,* a continuous length of GOES is wound around a mandrel multiple times to form the core. Copper windings (electricity conductors) are wrapped around both stacked and wound cores.

Transformers can be produced in ''single-phase'' or ''three-phase'' models. A single-phase transformer has one primary and one secondary set of windings, while a three-phase transformer has three primary and secondary windings around three core limbs. Most commercial electric power applications use three-phase transformers, while lower voltage and distribution level transmissions use single-phase transformers.

There are two typical configurations for the core and windings of a transformer: *Core-form* and *shell-form.* In core-form, the windings are in a cylindrical shape around the legs of the core. In shell-form, the windings are wrapped around the center of the core. Core-form transformers are the most widely used because they are generally simpler in design and less expensive than shell-form transformers. Shell form transformers typically use more electrical steel and are more resistant to short circuit offering an advantage for extra high voltage applications. For this reason, they are often used in industrial applications, such as steel mills, where short circuits are common.

*C. Electrical Steel* [23]

As noted in the above description of transformer construction, the key material used in the core of most transformers is GOES; this application accounts for the majority of GOES consumption. The magnetic properties of electrical steel are integral to the primary function of transformers, *i.e.,* converting voltage from one level to another.

Electrical steel is a flat-rolled silicon alloy. The benefits of adding silicon to steel include increased electrical resistivity, high permeability, and low hysteresis loss. There are two types of electrical steel: GOES, also known as Cold-Rolled Grain Oriented Steel (abbreviated CRGO), and non-grain-oriented electrical steel (NOES), also known as Cold-Rolled Non-Grain Oriented Steel (abbreviated CRNGO).

GOES is the most energy efficient type of electrical steel used to transport and transform mechanical energy to electrical energy. Its primary application is in transformers where energy or core loss is critical (particularly large and medium-sized electrical power and distribution transformers. In contrast, NOES is more commonly used in electric motors and generators, as well as in some smaller transformers.

GOES is milled to yield exceptionally good magnetic properties. It can be sold in sheets or strips in fully processed form (annealed by the manufacturer) or semi-processed (requiring further heat treatment by purchaser). GOES, which typically contains approximately 3.2 percent by weight of silicon, is manufactured using specialized rolling and annealing (heat treatment) processes, which produces grain structures uniformly oriented in the rolling (lengthwise) direction of the steel sheet. Compared with NOES, this uniformly oriented grain structure permits the GOES steel sheets to conduct a magnetic field with a higher degree of efficiency in the direction of rolling.

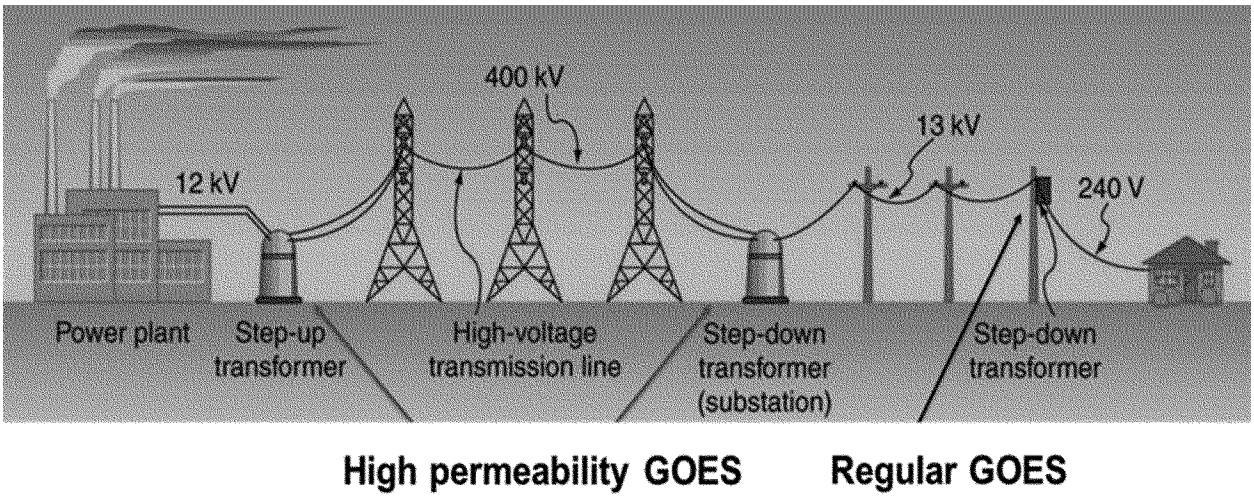
1. Types of GOES

GOES is produced in compliance with specifications issued by standards organizations and various proprietary specifications. For example, *conventional GOES* is available in standard gauges (thicknesses), ranging from 0.007 inch (0.18 mm) through 0.0138 inch (0.35 mm), and *high-permeability GOES* is found in two standard thicknesses (0.23 mm and 0.27mm). Conventional products in the standard thicknesses are often referred to as U.S. or American Iron and Steel Institute grades M2 through M6. Thinner gauge GOES is often preferred

[23] This section draws from USITC's report, Grain-Oriented Electrical Steel From the People's Republic of China, the Czech Republic, Germany, Japan, the Republic of Korea, Poland, and the Russian Federation: Initiation of Antidumping Duty Investigations, 78 FR 65283 (October 31, 2013).

because thinner laminations yield lower core losses in transformers, despite the added cost for both the steel and the manufacturing of the transformer core. Within each type of GOES, magnetic characteristics may vary, with producers manufacturing the same product with differing average core losses.

In addition to differences in thickness, GOES is produced with varying levels of magnetic permeability, distinguished by the size and orientation precision of the grains within the steel. Conventional GOES has smaller but less precisely oriented grains, while high-permeability GOES has more precisely oriented but larger grains. High-permeability products allow a transformer to operate at a higher level of flux (flow) density than conventional products, thus permitting a transformer to be smaller and have lower energy operating losses.




High permeability GOES is also produced as a domain-refined (surface-treated) type that has even lower core loss at high flux density. Domain refinement occurs by using laser scribing, mechanical scribing or electrolytic etching to scribe thin lines onto the surface of the steel, which subdivides larger-oriented grains into smaller ones to produce ''domain-refined GOES'' (DR–GOES). GOES that undergoes laser scribing does not retain its enhanced magnetic characteristics when it is annealed (heat treated) to relieve internal stresses. As a result, laser-scribed GOES (or ''non-heat-proof GOES'') is not suitable for producing wound-core transformers, which require superior core-loss properties but must undergo heat treatment to relieve internal stresses (which increase core losses) accumulated from the manufacturing process. By contrast, domain-refined GOES produced by mechanical scribing or electrolytic etching (''heat-proof'' or ''permanent'' DR–GOES'') retains its enhanced magnetic characteristics, even though stress-relief treatment. There is no known production of mechanically scribed or electrolytically-etched heat-proof GOES in the United States.

2. Amorphous Metal

Amorphous metal transformer cores are an alternative to traditional cores made from GOES. Amorphous metal, called metglas, is an alloy of iron that includes boron, silicon, and phosphorous in the form of thin foil. Produced using rapid solidification of molten alloy (at a rate of about one million degrees Celsius per second), it differs from GOES in that it has a random rather than a crystalline structure. While more expensive than GOES on a per kilogram basis and more labor intensive to form into cores, the material has the potential to reduce costs in the long run for utilities over the life of the transformer. Compared to cores made from GOES, core losses from eddy currents can be 70–80 percent lower in transformers with amorphous metal cores, reducing their operating costs and improving their energy efficiency. Amorphous metal is most often used in industrial and distribution transformers with power handling capacities in the 50 to 1000 kVA range.

*D. Transformer Construction*

The typical transformer manufacturing process consists of the following steps:

*1. Engineering and design:* Design is complex, balancing the costs of raw materials (copper, steel, and cooling oil), electrical losses, manufacturing labor hours, plant capability constraints, and shipping constraints.

*2. Core building:* The core is the most critical component of a transformer, and it requires both a highly trained and skilled workforce and a supply of GOES.

*3. Windings production and assembly of the core and windings:* Windings are predominantly copper and have an insulating material.

*4. Drying operations:* Excess moisture must be removed from the core and windings because moisture can degrade the dielectric strength of the insulation.

*5. Tank production:* A tank must be completed before the winding and core assembly finish the drying phase so that the core and windings do not reabsorb moisture.

*6. Final assembly:* The final assembly must be done in a clean environment; even a tiny amount of dust or moisture can deteriorate the performance of a transformer.

*7. Testing:* Testing is performed to ensure the accuracy of voltage ratios, verify power ratings, and determine electrical impedances.

**V. Importance for Critical Infrastructure and National Security**

*A. Critical Energy Infrastructure*

The Cybersecurity and Infrastructure Security Agency (CISA) has identified 16 critical infrastructure sectors whose assets, systems, and networks, whether physical or virtual, are considered so vital to the United States that their incapacitation or destruction would have a debilitating effect on security, national economic security, national public health or safety, or any combination thereof.[24] One of these 16 sectors is the Energy Sector. CISA has

[24] *https://www.cisa.gov/critical-infrastructure-sectors.*

determined that the U.S. energy infrastructure fuels the economy of the 21st century. Without a stable energy supply, health and welfare are threatened, and the U.S. economy cannot function. In fact, CISA notes that, among the sixteen sectors, the Energy Sector is *uniquely* critical because it provides an ''enabling function'' across all critical infrastructure sectors. The energy infrastructure is divided into three interrelated segments: Electricity, oil, and natural gas. Items subject to this investigation form the backbone of the electricity segment.

The U.S. electricity segment contains more than 9,700 power plants with 1,200 gigawatts capacity, sourced by coal, petroleum, natural gas, nuclear, hydroelectric, and renewable energy sources such as wind and solar.[25] The number of power plants has increased significantly in recent years, due primarily to the expansion of solar and wind power generation. The electricity generated by the plants is processed along hundreds of thousands of miles of high voltage transmission lines and millions of miles of local distribution lines through transformers subject to this investigation. In addition to plant-generated power, there is an evolution of sorts where distributed energy resources are allowing energy resources such as solar, wind, and energy storage, to be owned and operated at the customer level. However, the vast majority of electric power is in plant-generated and delivered via traditional means to consumers.

In its Energy-Sector Specific Plan, CISA notes that the failure of U.S. power infrastructure, and specifically LPTs, could present a vulnerability to the electric grid. CISA further expresses concern that the United States heavily depends on overseas manufacturers to meet its demand for LPTs and that the supply and procurement of LPTs can be challenging because it can take more than 12 months to replace an LPT due to its long and complex procurement process and the uniqueness in construction for the specific voltages and currents at the intended substation.[26]

While the electrical grid, especially at the BPS level,[27] has operated at a high-level of reliability, there is a growing concern that the ever-expanding list of threats, which could be physical and/or cyber-related in nature, further increases the grid's vulnerability and the need for enhanced security. In addition to their long manufacturing and acquisition lead time, LPTs pose unique vulnerabilities because of transformer's susceptibility to the serious and evolving threats and hazards. Single or multiple failures of LPTs are becoming a significantly greater concern to grid reliability.

As a result of these concerns, several efforts by the federal government and electric utility industry have been initiated and are underway. For example, the North American Electric Reliability Corporation (NERC) issued the NERC–CIP–14 Standard in 2015, requiring transmission asset owners to apply risk assessments to identify and protect transmission stations and substations, as well as their associated primary control centers. Instability, uncontrolled separation, or cascading failure within an interconnected transmission system could result if these assets were rendered inoperable or damaged as a result of a physical attack.

In addition, the Fixing America's Surface Transportation Act [Pub. L. No. 114–94 (FAST Act)], signed into law in December 2015, requiring the DOE to establish a plan for a Strategic Transformer Reserve that could be tapped in the event of a major disruption to the electric grid.[28] DOE's responsive recommendation is that a voluntary industry-based approach would be more feasible and effective than a national, Government-owned stockpile of transformers. The DOE report, however, noted the lack of domestic capacity to produce LPT and the extreme dependence on foreign suppliers, especially for high-voltage transmission (>345 kV).[29]

President Trump signed Executive Order 13920 (E.O. 13920), titled ''Securing the United States Bulk-Power System,'' on May 1, 2020.[30] The President determined that the unrestricted foreign supply of BPS electric equipment constitutes an unusual and extraordinary threat to the national security, foreign policy, and economy of the United States.

In this Executive Order, the President declared that threats to the BPS by foreign adversaries constitute a national emergency. He also found that as it serves as the backbone of our Nation's energy infrastructure, the BPS is fundamental to national security, emergency services, critical infrastructure, and the economy. Transformers subject to E.O. 13920 include substation transformers, substation voltage regulators, and instrument transformers, which are key elements of the BPS. The E.O. notes that the BPS is a target of those seeking to commit malicious acts against the United States and its people, including malicious cyber activities, because a successful attack on the U.S. BPS would present significant risks to the economy and human health and safety and would render the United States less capable of acting in defense of itself and its allies.

While BPS electric equipment supplied by potential adversaries raises immediate concerns, the Secretary of Energy has also noted that evolving threats facing our critical infrastructure have only served to highlight the supply chain risks and the need to ensure the availability of secure components from American companies and other trusted sources.[31] DOE is currently undertaking a rulemaking effort, in consultation with other agencies, to implement the authorities delegated to the Secretary of Energy in E.O. 13920. E.O. 13920 authorizes the Secretary of Energy to (1) prohibit any acquisition, importation, transfer, or installation of BPS electric equipment by any person or with respect to any property to which a foreign adversary or an associated national thereof has any interest, that poses an undue risk to the BPS, the security or resiliency of U.S. critical infrastructure or the economy, or U.S. national security; (2) establish and publicize criteria for recognizing particular equipment and vendors in the BPS electric equipment market as ''pre-qualified'' for future transactions and to apply these criteria to establish and publish a list of pre-qualified equipment and vendors; (3) in consultation with heads of other agencies, to identify existing BPS electric equipment in which a foreign adversary or associated national thereof has an interest that poses an undue risk to the BPS, the security or resiliency of U.S. critical infrastructure or the U.S. economy, or U.S. national security, and develop recommendations to identify, isolate, monitor, or replace this equipment as appropriate; and (4) establish a Task Force on Federal Energy Infrastructure Procurement Policies Related to National Security, which will focus on the coordination of Federal Government

[25] EIA, Electric Power Annual, Table 4.1.

[26] *https://www.cisa.gov/sites/default/files/publications/nipp-ssp-energy-2015-508.pdf.*

[27] The North American Electric Reliability Corporation defines the bulk-power system to consist of all generation components and transmission system elements generally operating at 100 KV or higher. See: *https://www.nerc.com/pa/Stand/Project%20201017%20Proposed%20Definition%20of%20Bulk%20Electri/bes_phase2_reference_document_20140124_llh.pdf.*

[28] *https://www.congress.gov/114/plaws/publ94/PLAW-114publ94.pdf.*

[29] DOE Transformer Reserve Study, 2017.

[30] *https://www.federalregister.gov/documents/2020/05/04/2020-09695/securing-the-united-states-bulk-power-system.*

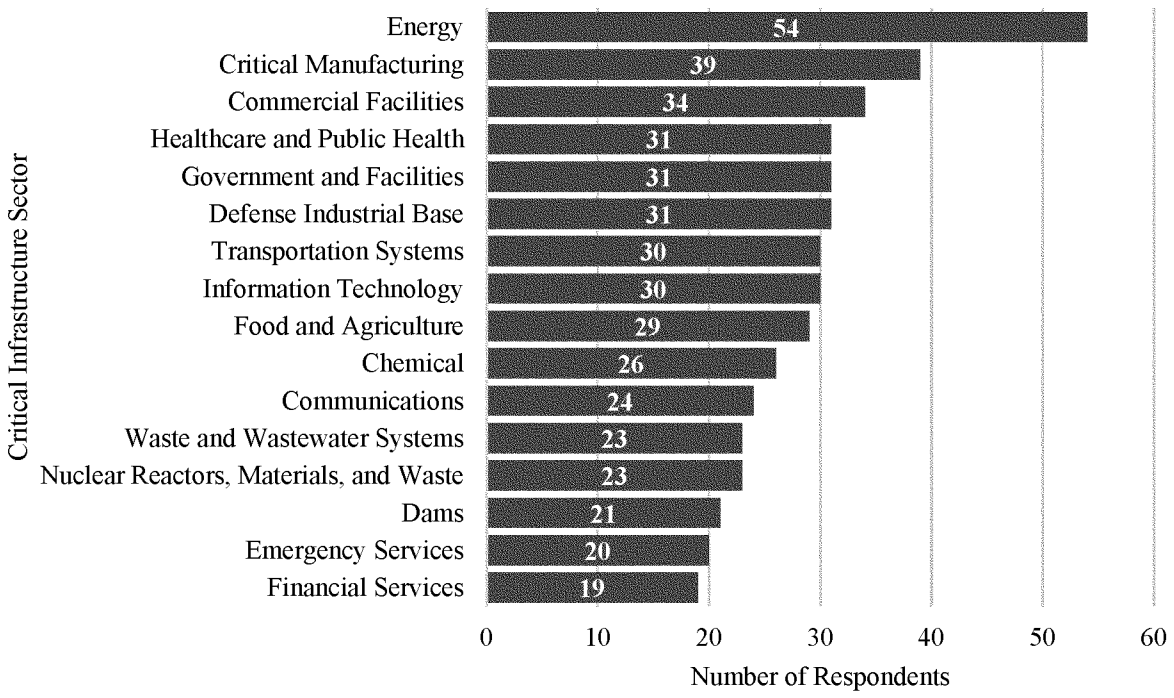
[31] *https://www.energy.gov/articles/president-trump-signs-executive-order-securing-united-states-bulk-power-system.*

procurement of energy infrastructure, the sharing of risk information and risk management practices, and the development of recommendations for implementation to the Federal Acquisition Regulatory Council (FAR Council). DOE and the Department will coordinate efforts to ensure consistency of rules and supporting program activities.

1. Role of Transformer Manufacturers in Critical Infrastructure

As part of its survey of industry conducted for this investigation, the Department requested survey recipients to provide information on which of the 16 critical infrastructure sectors their products support. Respondents indicated support for all 16 sectors, with the Energy Sector (not surprisingly) indicated most frequently. As mentioned above, the Energy Sector is unique among the 16 sectors because it provides an ''enabling function'' across all critical infrastructure sectors, and survey responses validated this fact. Other critical infrastructure sectors that received numerous mentions by survey respondents were critical manufacturing, commercial facilities, Government facilities, information technology, chemical sector, defense industrial base, and food and agriculture (see Figure V–1).

**Figure V-1. Top Critical Infrastructure Sectors by Supported by Respondents**

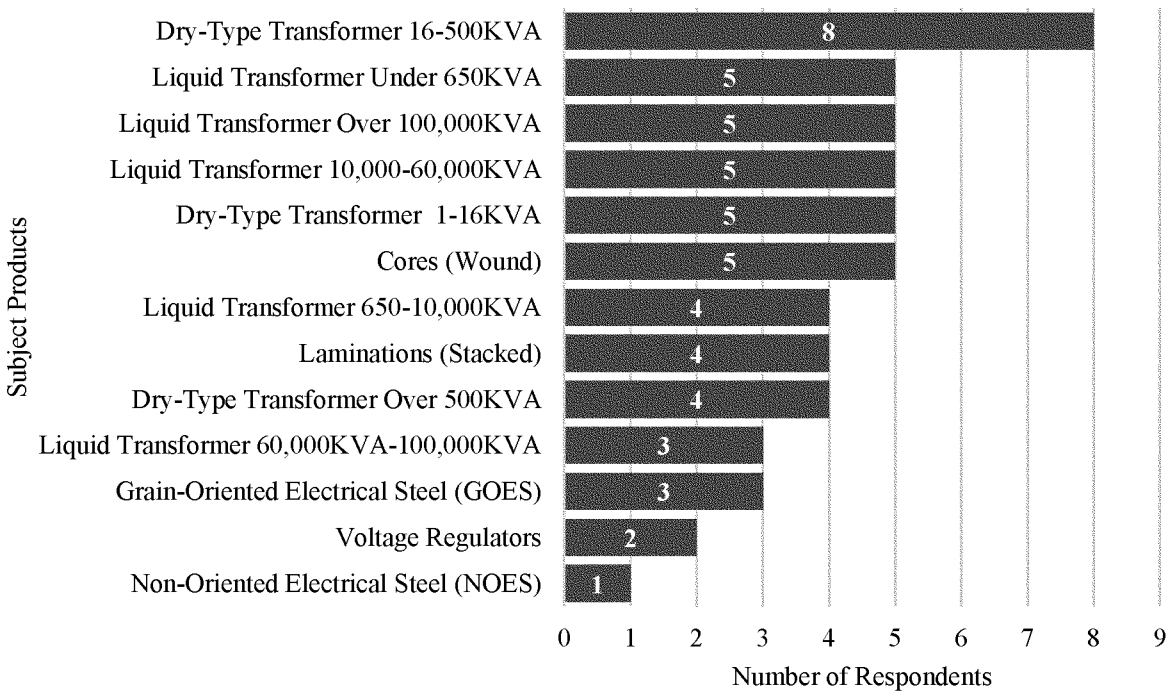



Source: U.S. Department of Commerce, Bureau of Industry and Security, Electrical Steel and Transformer-Related Products Survey, Q9, A

*87 Respondents*

By product, all categories were again cited as providing support to critical technology sectors (see Figure V–2). Most frequently mentioned were dry-type transformers 16–500 kVA, followed by liquid-dielectric transformers 60–100 MVA, and liquid-dielectric transformers under 650 kVA.

**Figure V-2. Energy Sector – Top Electrical Steel and Transformer-related Products by Respondent Support**




Source: U.S. Department of Commerce, Bureau of Industry and Security, Electrical Steel and Transformer-Related Products Survey, Q9, A

*54 Respondents*

*B. National Security/Defense Requirements*

In today's technology-dependent environment, energy requirements are inseparable from the Department of Defense's (DOD) mission requirements, whether discussing weapons platforms or the installations and systems that support those capabilities around the globe. As such, energy resilience, which enables the capabilities of weapons platforms, facilities, and equipment, is a critical investment that must be part of the DOD's research, acquisition, operations, and sustainment conversations.[32]

DOD is the largest single energy-consuming entity in the United States, both within the Federal Government and as compared to any single private-sector entity. DOD operational and installation energy consumption represents approximately 80 percent of total Federal energy consumption, more than sixteen times the total energy consumption of the next closest Federal agency (the United States Postal Service).[33] In FY 2018, DOD spent approximately $3.49 billion on installation energy, of which $2.5 billion was for electricity used to power, heat, and cool buildings.

The U.S. electrical grid, primarily under the ownership and control of private organizations, supplies the power required to support DOD installations, including military bases, arsenals, and laboratories. This supply is a key part of the ''Defense Critical Electric Infrastructure,'' which is defined as any electrical infrastructure in the 48 contiguous States or the District of Columbia that serves a facility designated by the Secretary of Energy as critical to the defense of the United States and vulnerable to a disruption of the supply of electric energy provided to such a facility by an external provider, but that is not owned or operated by the owner or operator of such facility.[34] In 1998, with the issuance of Defense Reform Initiative #49, the military services were directed to privatize their utility systems. The Department of Defense's Defense Logistics Agency Energy acts as the procurement agency for contracting with utilities for this purpose.[35]

The Department of Defense operates 500 installations worldwide, with nearly 300,000 buildings covering 1.9 billion square feet. Energy needed to power these fixed installations accounts for nearly 30 percent of DoD's total energy use, and the installations rely extensively on transformers of various power handling capacities to distribute electricity at the appropriate voltage level.[36]

As noted above, DOD relies primarily on commercial power to support its installations. Commercial power supplies can be threatened by a variety of events, ranging from natural hazards and physical attacks on infrastructure (including transformers), to cyber-attacks on networks and Supervisory Control and Data Acquisition (SCADA) systems. Disruption of power could affect critical DOD missions involving power projection, defense of the

[32] Department of Defense Annual Energy Management and Resilience Report (AEMRR) for Fiscal Year 2018, *https://www.acq.osd.mil/eie/Downloads/IE/FY%202018%20AEMR.pdf.*

[33] Id, p. 32.

[34] *https://www.federalregister.gov/documents/2018/10/29/2018-23459/critical-electric-infrastructure-information-new-administrative-procedures.*

[35] *https://archive.defense.gov/dodreform/drids/drid49.html.*

[36] DOD AEMMR.

homeland, or operations conducted at installations in the United States directly supporting warfighting missions overseas.

DOD's efforts to improve the energy resilience of its installations mainly focuses on backup power *generation* to compensate when the commercial grid experiences a disruption. However, emergency power generation assets are ineffective if the surrounding *distribution* system is unable to convey power between the generation asset and final point of use. Therefore, DOD may also pursue upgrading distribution system equipment, including transformers and power lines, as a standalone solution if backup generation is already adequate or as an integrated solution when new backup power generation assets are implemented.

In addition to their vital role in the electricity grid to supply power to military installations, transformers also play an essential role in supporting military operations. Sophisticated military equipment, such as missiles, fighter jets, and naval vessels, rely on transformers of various types and capacities to provide the correct voltage within subsystems. Additional military applications include tactical displays and field operations equipment such as mobile power supplies and reconnaissance equipment. In addition to reliability and durability, military transformers must meet defense specifications (Mil Spec) and often must be designed and manufactured to withstand extreme environmental conditions, such as high humidity, salt spray, sand, high altitude, shock, and vibration. Military transformers may be specially encapsulated to withstand these types of harsh conditions.

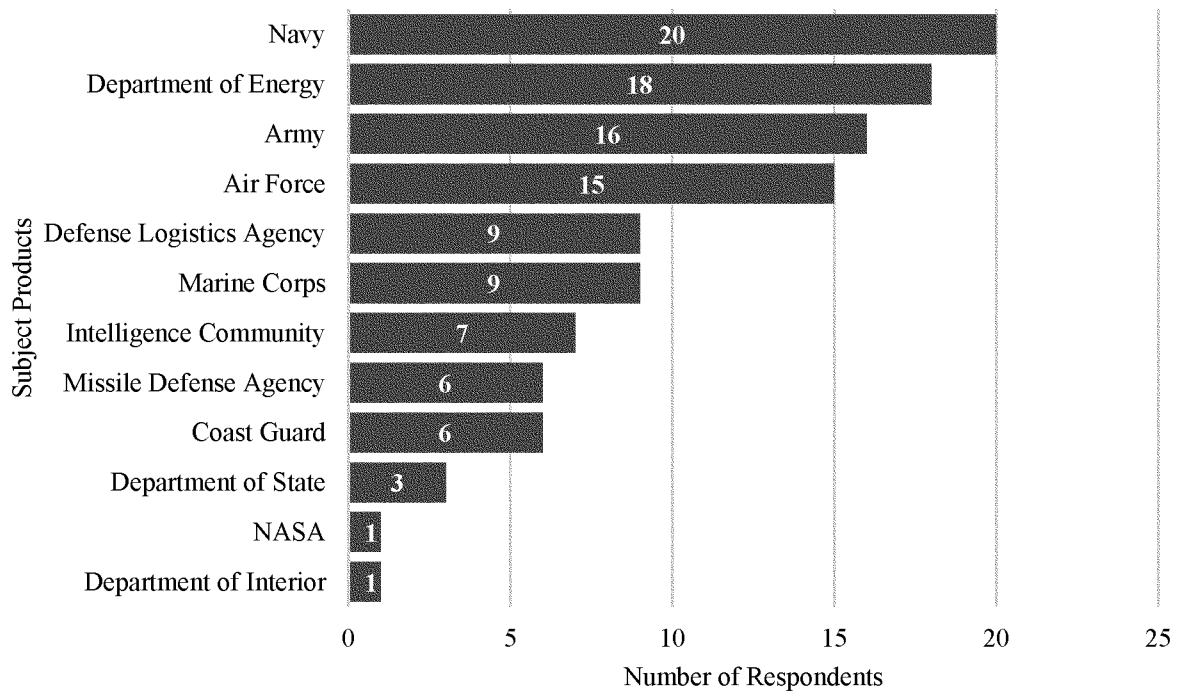
[TEXT REDACTED].

Due to its importance for certain defense applications, the Defense Logistics Agency (DLA) has included GOES among its requests for inclusion in the National Defense Stockpile. In their Fiscal Year 2019 Report to Congress on Stockpile Requirements, DLA Strategic Materials identified a potential shortfall for GOES of approximately [TEXT REDACTED]. Per the Strategic and Critical Materials Stock Piling Act (50 U.S.C. 98 *et seq.* Sec 14 (b)), shortfalls are estimated under national emergency planning assumptions consisting of ''a military conflict scenario consistent with the scenario used by the Secretary of Defense in budgeting and defense planning purposes.'' In other words, shortfall amounts are calculated based on surge requirements for the military engaging in conflict, taking into consideration weapons and munitions lost and expended during the conflict in an environment of reduced foreign availability of supplies of strategic and critical materials. If United States' sole domestic source of GOES were to cease production, DLA's estimated shortfalls would be larger. DLA Strategic Materials recommended a [TEXT REDACTED]. The stockpile recommendation is lower than the estimated requirement due to competing stockpile needs and budget constraints.

In the industry survey conducted as part of this investigation, the Department queried participants as to whether their products were provided, directly or indirectly, for U.S. defense systems, installations, or known defense end-uses. The majority of survey respondents were unable to provide specific information in this regard because most defense-related sales are indirect; instead, respondents noted that their products (especially liquid-dielectric transformers) are used to provide power in the national grid that supplies power to military bases. Most of those that responded to the question with specifics reported that only a small percentage of sales, about 1–3 percent, involved defense-related uses. Moreover, in most cases, this was just an estimate, as survey respondents typically did not have insight into the ultimate end use of their products.

However, some survey respondents were able to provide precise information on defense and military uses for their products. These respondents supported every branch of the military, as well as the Department of Energy/National Labs, the DLA, the State Department, NASA, the Department of Defense's Missile Defense Agency, and the U.S. Intelligence Community.

**Figure V-3. National Defense – Top USG Agencies by Respondent Support**
*****Note: Respondents may support more than one USG agency**

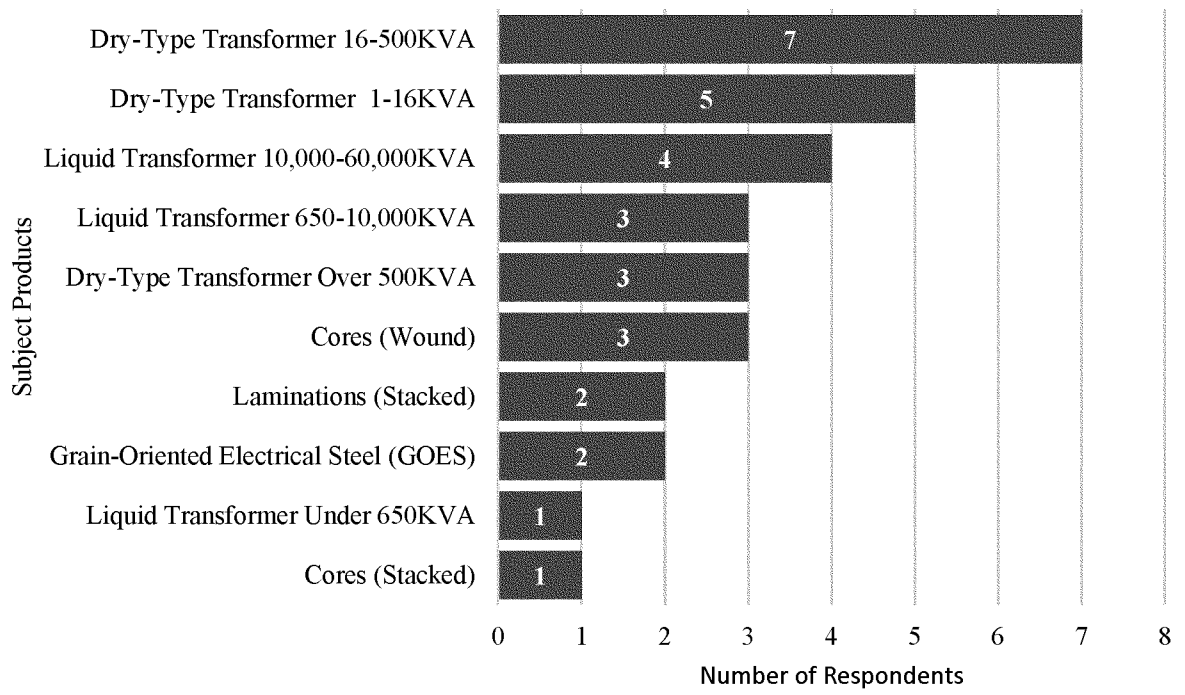



Source: U.S. Department of Commerce, Bureau of Industry and Security, Electrical Steel and Transformer-Related Products Survey, Q8, B

*22 Respondents*

Based on survey responses, dry-type transformers (particularly of higher power handling capacities) are suitable for inside installations and thus play an important role in direct defense applications such as onboard radars, missiles, ships, and aircraft.

**Figure V-4. Defense Industrial Base Sector – Top Electrical Steel and Transformer-related Products by Respondent Support**




Source: U.S. Department of Commerce, Bureau of Industry and Security, Electrical Steel and Transformer-Related Products Survey, Q9, A

*31 Respondents*

No respondent attributed sales of voltage regulators, non-oriented electrical steel, liquid-dielectric transformer 60,000–100,000 kVA, or liquid-dielectric transformer over 100,000 kVA to direct defense industrial base support.

[TEXT REDACTED].

[TEXT REDACTED].[37] [TEXT REDACTED].

## VI. United States' and Global Markets for GOES, Transformers and Transformer Components

### *A. GOES Market*

The market for GOES is dominated by transformers, particularly LPTs, which can weigh over 400 tons, and GOES constitutes a significant portion of this weight. Although large transformers by sheer size incorporate more GOES by weight, the market for them is small in terms of units. In contrast, smaller transformers, such as distribution transformers, utilize less GOES by weight, but they are sold in much greater volumes and so also provide a significant market for GOES.

A recent report by a market research firm estimated that the global market for GOES will reach $20.8 billion by 2025, with a compounded annual growth rate (CAGR) of 5.8 percent. The average annual growth rate in the United States is estimated to be 4.6 percent over the next five years (adjusted downward from 5.7 percent due to the impacts of COVID–19); the market in China will grow at 9.5 percent.[38]

AK Steel is the sole remaining U.S. supplier of GOES. Another domestic producer, Allegheny Technologies, Inc. (ATI) stopped production of GOES in 2016. However, industry reports indicate that Big River Steel (Osceola, AR), a manufacturer of non-grain oriented steel, intends to produce high quality GOES in the future, including high permeability grades (such as Hi-B).[39]

Outside of the United States, there are 13 manufacturers of GOES, as listed in Figure VI–1.

[37] *https://new.abb.com/news/detail/64657/abb-completes-divestment-of-power-grids-to-hitachi.*

[38] *https://www.reportlinker.com/p05798466/Global-Electrical-Steel-Industry.html?utm_source=GNW.*

[39] *https://bigriversteel.com/products/electrical/.*

| Figure VI-1. Manufacturers of GOES Outside the United States | |
|---|---|
| **Company Name** | **Country of Manufacture** |
| Baowu Iron & Steel Co., Ltd | China |
| Anshan Iron & Steel Group Corp. | China |
| Hebei Shougang Iron & Steel Co., Ltd. | China |
| TISCO | China |
| JFE Steel Corporation | Japan |
| Nippon Steel & Sumitomo Metal Corp. (NSSMC) | Japan |
| ThyssenKrupp Electrical Steel GmbH | France/Germany |
| ThyssenKrupp | India |
| StalProdukt | Poland |
| GO Steel Frydek Mistek A.S.<br>(Purchased by StalProdukt from Arcelor Mittal in 2018)[40] | Czech Republic |
| Novolipetsk Steel (NLMK) | Russia |
| Aperam | Brazil |
| POSCO | South Korea |
| Source: DLA Report | |

[TEXT REDACTED].[41]

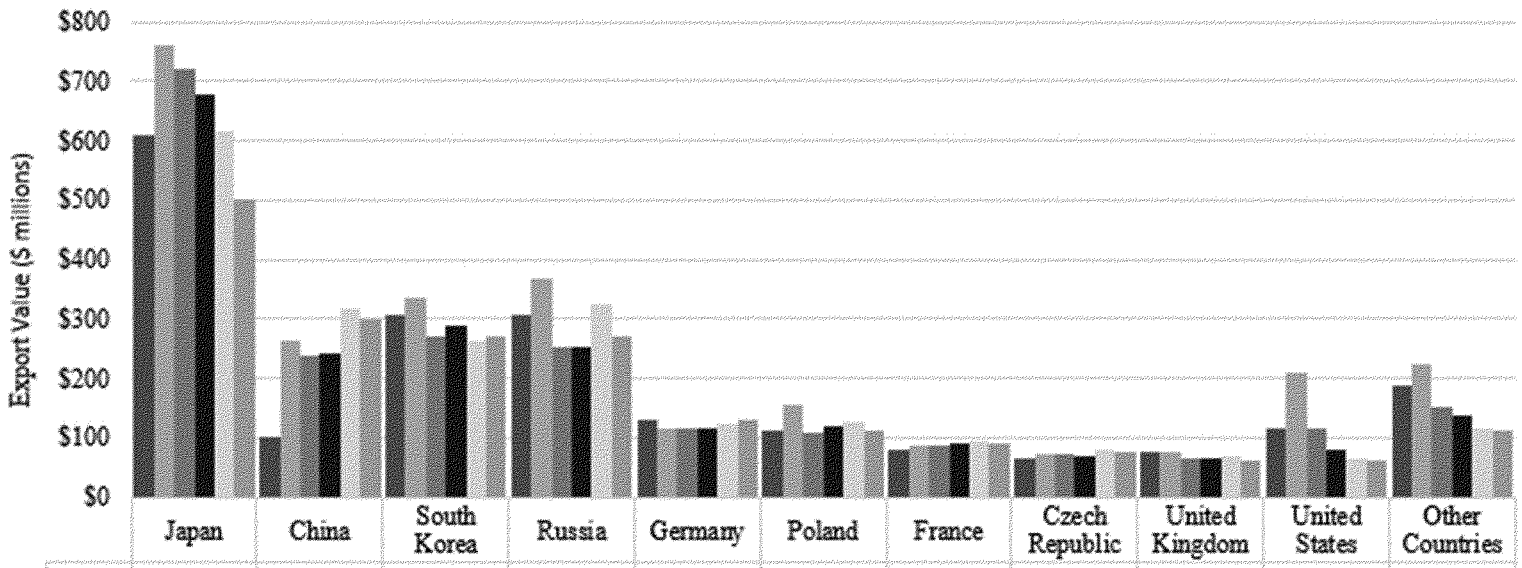
A limited number of these global suppliers, such as those from Japan and South Korea, are capable of producing the high permeability GOES that the market is demanding in response to current DOE standards. China is the world's largest producer of GOES but much of its production is consumed internally, and Chinese firms have not dominated export markets.

[TEXT REDACTED]

[40] *http://www.corpin.cz/en/arcelorgosteel.html.*

[41] [TEXT REDACTED]

**Figure VI-2. 2014-2019 Export Statistics of HTSD Code 7225.11 – Flat-Rolled Silicon Electrical Steel 600 Mm or More Wide, Grain-Oriented**

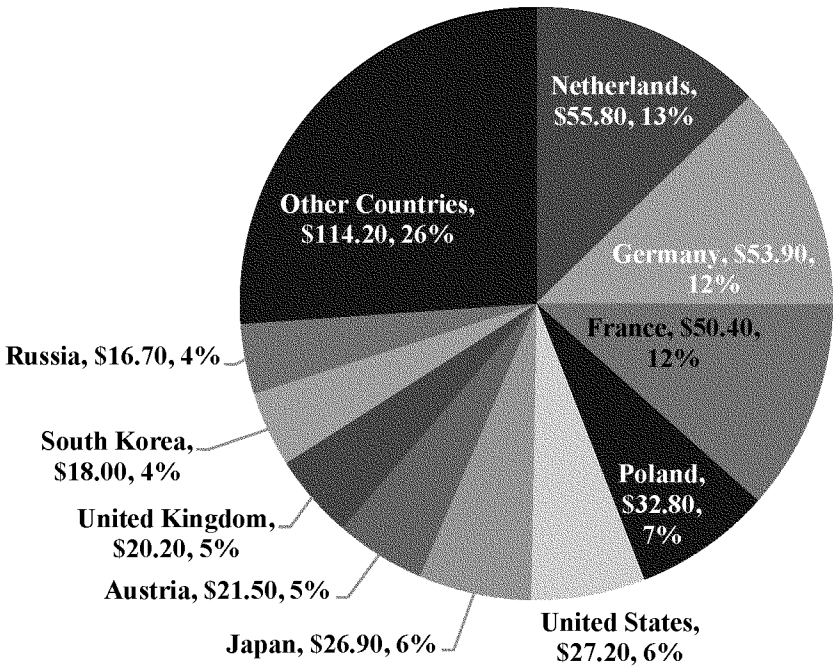



| | Japan | China | South Korea | Russia | Germany | Poland | France | Czech Republic | United Kingdom | United States | Other Countries |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 2014 | $611 | $102 | $308 | $305 | $129 | $112 | $80 | $65 | $77 | $116 | $188 |
| 2015 | $759 | $262 | $336 | $369 | $116 | $154 | $88 | $71 | $75 | $208 | $223 |
| 2016 | $722 | $238 | $271 | $254 | $116 | $108 | $87 | $72 | $64 | $115 | $152 |
| 2017 | $676 | $241 | $290 | $252 | $116 | $118 | $90 | $69 | $65 | $80 | $136 |
| 2018 | $615 | $317 | $262 | $324 | $122 | $128 | $93 | $79 | $68 | $65 | $114 |
| 2019 | $501 | $300 | $270 | $270 | $129 | $110 | $90 | $75 | $63 | $63 | $113 |

Source: Global Trade Atlas, retrieved on July 6, 2020

For GOES <600 Mm in width, the total trade in 2019 was $437.6 million, much smaller than GOES ≥600 Mm in width, and the major players were mainly Europen countries.

**Figure VI-3 2019 Export Statistics of HTS Code 7226.11 – Grain-Oriented Electrical Steel Under 600 Mm Wide (millions of $)**




Source: Global Trade Atlas, retrieved on July 6, 2020

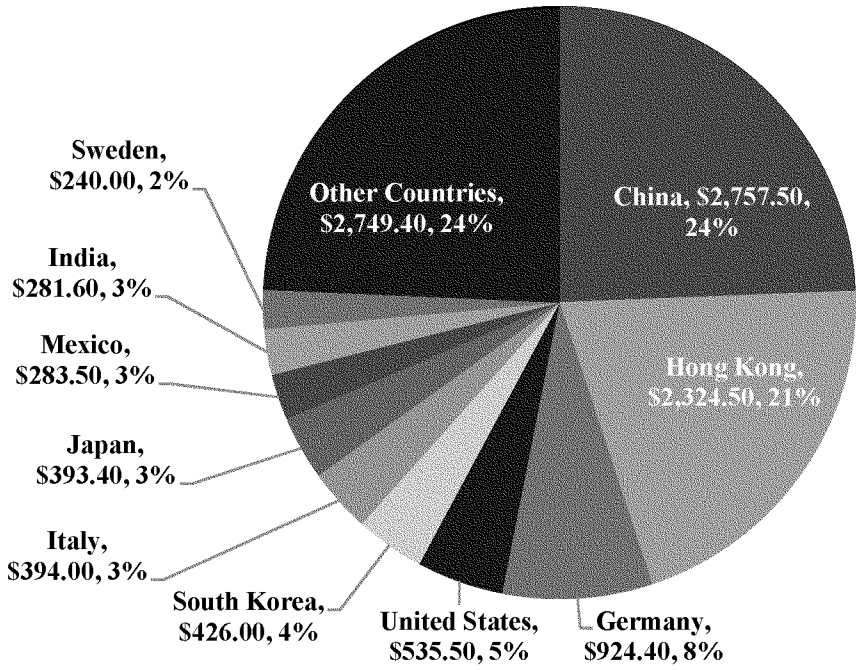
*B. Transformer Laminations and Cores*

Most of the major global transformer companies produce laminations and cores for internal consumption, although manufacture of these items does not necessarily occur in the same facility in which they are consumed. However, there are also companies that manufacture these products for transformer producers. Lamination and core manufacturers tend to be small companies that produce specialized products, and there is little information available on them as a distinct industry sector.

Based on data available from GTAA, the biggest players in the world export market for the category including transformer parts (laminations and cores but also products not subject to this investigation) [42] is China, including Hong Kong. In 2019, of the total $11.3 billion of trade of transformer parts, China exported $2.8 billion and Hong Kong exported $2.3 billion; together, China and Hong Kong accounted for 44.9 percent of the total trade. Germany was second, with exports of $924.4 million. Although Canada and Mexico are the main sources for U.S. imports of transformer cores and laminations, neither country is significant actors in global exports: Mexico ranked 8th with $283.5 million and Canada ranked 12th with $184.0 million.

[42] Note: At the 6 digit HTS level for which global trade data are available, this category (8504.90) includes parts and components unrelated to transformers (*e.g.,* parts of static converters and inductors). There is no way to determine how much of this trade is transformer laminations and cores. Therefore, this information should be considered indicative of general trading patterns only.

**Figure VI-4. 2019 Top 10 Exporters for HTS Code 8504.90 – Parts of Electrical Transformers (millions of $)**




Source: Global Trade Atlas, retrieved on July 6, 2020

The leading destination for China's exports of transformer parts was the United States with $282.4 million total imports in 2019, followed by India with $256.9 million. The leading destination for Hong Kong's exports of transformer parts during the same year was also the United States with $152.6 million, followed by Germany with $77.9 million.

*C. Global and U.S. Transformers Market*

[TEXT REDACTED]. Typical customers are companies in electricity generation, transmission, and distribution industries. End-use customers also include energy-intensive industries such as mining, chemical manufacturing, and steel and pulp/paper mills, as well as large commercial facilities.

The global transformer industry has undergone numerous mergers, acquisitions, consolidations over the past several decades, resulting in fewer, larger players that offer a wider product range and are able to benefit from economies of scale. During the consolidation process, many manufacturers moved their production offshore (*e.g.,* Mexico, India, Colombia), taking advantage of lower labor costs, lower labor and environmental standards, and access to local markets with rapidly increasing demands for electricity.[43] Mexico, in particular, has become a significant player in transformer manufacturing; among the global transformer manufacturers with production facilities in Mexico [TEXT REDACTED].

In addition to these large global players, in the United States there are a number of smaller companies that manufacture transformers of various power-handling capacities. These include [TEXT REDACTED].

In its most recent market assessment, Global Market Insights estimated the global transformer market to reach $80 billion by 2024, assuming a CAGR of 6.5 percent. Key markets for transformers are those with rising electricity demands and investments in power distribution infrastructure—namely, the Asia/Pacific region, Africa, and the Middle East. The greatest market potential is in emerging markets such as these; 15 percent of the world's population does not yet have access to electricity.[44]

In contrast, the U.S. market is mature, and demand for transformers is largely based on upgrades and replacements of aging infrastructure, including efforts to install smart grids to increase energy efficiency. The average transformer in the United States is 38 years old, with 70 percent of U.S. transformers older than 25 years.[45] New transformers are also needed to distribute electricity from the growing number of renewable energy generation plants. With over 9,000 power plants, 1.2 terawatts of power generating capacity, and 360,000 miles of high voltage transmission lines, the United States remains one of the largest markets for transformers.

Trade data available through GTA show the major players by country in export markets for transformers of various power handling capacities. While only available at broad (6 digit HTS) product categories, these data are useful to show the relative global export market sizes and which countries dominate exports in each broad segment.

Among all transformer categories, the product with the greatest value of world exports is the liquid-dielectric transformers with a handling capacity of

[43] Large Power Transformers and the U.S. Electric Grid, DOE, 2014.

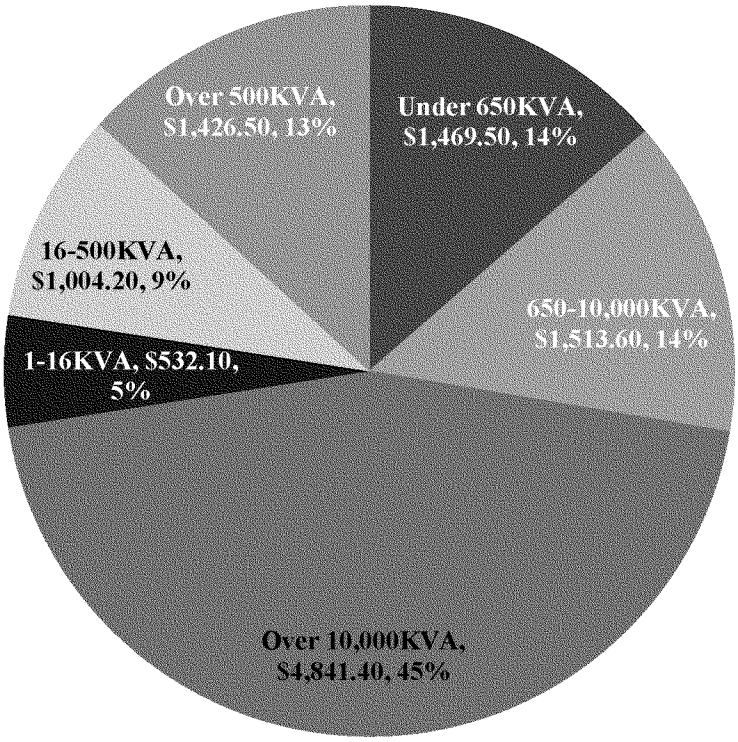
[44] Draws from *http://www.firstresearch.com/industry-research/Transformer-Manufacturing.html* (Dun & Bradstreet).

[45] DOE LPT Study, 2014 update.

more than 10,000 kVA (HTS 8504.23). This category includes large power transformers, as well as medium sized power transformers and larger distribution transformers. It accounted for nearly 45 percent of total world trade in transformers, based on average annual value of global exports over the 2014–2019 period. In this category, China is the top exporter with an average annual export value of $893.9 million, followed by South Korea with $635.9 million, and Germany with $371.8 million.

For liquid-dielectric transformers with smaller power handling capacities (distribution transformers, HTS 8504.21 and 8504.22), as well as mid-sized dry-type transformers (HTS 8504.32 and 8504.33), Mexico is a major exporter. Virtually all of Mexico's transformer exports are destined for the United States.

**Figure VI-5. Transformer World Trade Average Export Value by Power Handling Capacity, 2014-2019 (millions of $)**




Source: Global Trade Atlas, retrieved on July 29, 2020

| Figure VI-6. Top Five Exporters for Dry-Type/Other Transformers by HTS Code, 2014-2019 | | | |
|---|---|---|---|
| HTS Code | Power Handling Capacity | Country | Average Annual Export Value, 2014-2019 ($ millions) |
| 8504.32 | 1-16KVA | United States | $70.6 |
| | | China | $68.4 |
| | | Hong Kong | $66.2 |
| | | Germany | $53.5 |
| | | Mexico | $49.0 |
| | | | |
| 8504.33 | 16-500KVA | Mexico | $255.6 |
| | | United States | $132.3 |
| | | China | $71.6 |
| | | Italy | $57.3 |
| | | Germany | $56.3 |
| | | | |
| 8504.34 | Over 500KVA | Germany | $214.9 |
| | | China | $186.7 |
| | | Italy | $147.7 |
| | | Denmark | $137.3 |
| | | Spain | $93.5 |
| Source: Global Trade Atlas, retrieved on July 29, 2020 | | | |

| Figure VI-7. Top Five Exporters for Liquid-Dielectric Transformers by HTS Code, 2014-2019 | | | |
|---|---|---|---|
| HTS Code | Power Handling Capacity | Country | Average Annual Export Value, 2014-2019 ($ millions) |
| 8504.21 | Under 650KVA | Mexico | $198.3 |
| | | United States | $110.5 |
| | | India | $102.4 |
| | | China | $99.6 |
| | | Turkey | $79.4 |
| | | | |
| 8504.22 | 650-10,000KVA | China | $150.5 |
| | | Mexico | $133.8 |
| | | Turkey | $104.6 |
| | | Switzerland | $96.3 |
| | | Austria | $92.6 |
| | | | |
| 8504.23 | Over 10,000KVA | China | $893.9 |
| | | South Korea | $635.9 |
| | | Germany | $371.8 |
| | | Turkey | $321.8 |
| | | Italy | $298.7 |
| Source: Global Trade Atlas, retrieved on July 29, 2020 | | | |

*D. United States Transformers Market*

In the United States, there are about 250 establishments involved in transformer manufacturing (including units of companies with multiple locations), with a combined annual revenue of about $5 billion according to Global Market Insights. The National Electrical Equipment Manufacturers Association (NEMA) is the major sector-specific trade association that represents companies in this industry. NEMA states that there are over two dozen companies and over 15,000 employees involved in transformer manufacturing in the United States.[46]

[46] NEMA Public Comments.

Transformer manufacturing is most highly concentrated in Mississippi, Wisconsin, Virginia, North Carolina, and California. The industry is highly regulated by local, state, and federal agencies for environmental protection reasons, as well as to ensure workplace safety. DOE sets energy efficiency standards for distribution transformers,

with the standards last increased to achieve stricter efficiency in 2016.[47]

The industry is made up of large companies, such as GE (headquartered in the United States but with most transformer manufacturing facilities abroad) and ABB (now called Hitachi ABB Power Grids), which offer a variety of transformer products to utilities and industrial customers. In addition, there are numerous small companies that manufacture specialty transformers and niche products to industrial and consumer products customers. However, the 50 largest companies account for 90 percent of industry revenue.[48]

According to the Census Bureau, in 2018 (the most recent year for which data are available), the U.S. power, distribution, and specialty transformer manufacturing industry employed 19,227 people, operated in 285 locations, and totaled $6.15 billion in revenue. The Census Bureau classifies data using the North American Industry Classification System (NAICS) codes. Because the NAICS code representing power, distribution, and specialty transformer manufacturing is broader and more inclusive than the scope of this investigation, the data below should be interpreted to represent industry trends.

**Figure VI-8. Employment for Power, Distribution, and Specialty Transformer Manufacturing Industry (2012-2018)**

| Year | Number of Locations | Number of Employees |
|---|---|---|
| 2012 | 253 | 18,678 |
| 2013 | 253 | 19,603 |
| 2014 | 256 | 18,873 |
| 2015 | 246 | 19,289 |
| 2016 | 246 | 18,803 |
| 2017 | 242 | 18,502 |
| 2018 | 284 | 19,227 |
| Source: United States Census Bureau | | |

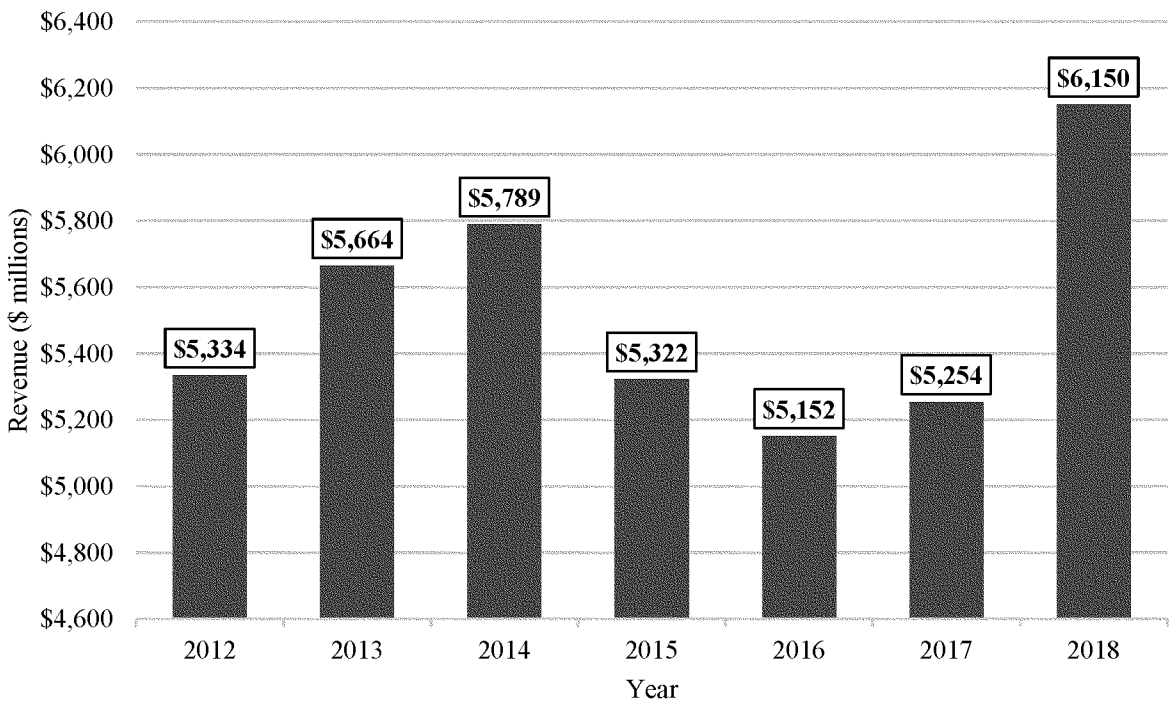
**Figure VI-9. Employment Distribution by Location Size 2018**

| Location Size | Number of Locations | Number of Employees |
|---|---|---|
| < 5 employees | 100 | 189 |
| 5 ≤ 9 employees | 32 | 203 |
| 10 ≤ 19 employees | 34 | 471 |
| 20 ≤ 49 employees | 43 | 1,402 |
| 50 ≤ 99 employees | 26 | 1,784 |
| 100 ≤ 249 employees | 30 | 4,573 |
| 250 ≤ 499 employees | 16 | 5,854 |
| 500 ≤ 999 employees | 3 | 2,141 |
| Source: United States Census Bureau | | |

[47] *https://www.researchandmarkets.com/reports/4376152/transformer-manufacturing.*

[48] *https://www.researchandmarkets.com/reports/4376152/transformer-manufacturing.*

**Figure VI-10. Power, Distribution, and Specialty Transformer Annual Revenue, 2012-2018**

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Imports account for about 35 percent of the U.S. market for transformers (of all power handling capacities combined); primary sources of imports are Mexico, Canada, South Korea, and China. About 10 percent of U.S. production is exported, mainly to Mexico and Canada.

With regard to specific subsectors of the transformer industry, there are few companies worldwide that manufacture LPTs; in the United States, as previously discussed, there are six manufacturers but their capability is limited. Distribution transformers are produced by a greater number of companies, including U.S. manufacturers.

DOE has gathered extensive information about the distribution transformer market as a result of the energy conservation standards that the Energy Efficiency and Renewable Energy (EERE) Office is required to set under the Energy Conservation and Policy Act of 1975, as amended. DOE determined that there is significant domestic manufacturing of these products, finding that 75 percent of the employees who work for manufacturers that provide medium-voltage dry-type transformers are located domestically.[49]

The Edison Electric Institute (EEI), which represents investor-owned electric companies that provide power to about 220 million Americans, estimates that its members have procured about four million transformers, at a total cost of more than $20 billion, over the last five years. The vast majority of these were distribution transformers. EEI estimates that investments in the grid will continue at similar levels in the coming years. EEI members also reported that transformers were sourced both domestically and internationally, with a majority of the reported distribution transformer purchases sourced domestically.[50]

## VII. U.S. Production Capabilities, Industry Health and Competitiveness, and the Impact of Imports on National Security for Transformer Component Manufacturers

### *A. Introduction*

This chapter evaluates the state of U.S. production capabilities, industry health and competitiveness, and the impact of imports on national security for GOES, transformer lamination, and transformer core manufacturers. In particular, it presents data on U.S. GOES production, as well as production of key transformer components primarily composed of GOES: Transformer laminations, stacked cores, and wound cores.

### *B. Grain-Oriented Electrical Steel*

GOES is a highly specialized, technically challenging product that requires dedicated equipment, advanced manufacturing process know-how, and well-trained, experienced employees. This product is absolutely critical to the performance of transformers, as it is the key material used in transformer cores, which constitutes the primary market for GOES.

AK Steel is the only domestic producer of GOES.[51] The company, then known as Armco Steel, invented and introduced GOES products to the

[49] DOE, EERE, Technical Support Document (TSD), Ch. 12, Manufacturer Impact Analysis, filed in Docket No. ERE–2010–BT–STD–0048 (Apr. 2013), at 12–48.

[50] EEI et al. Public Comments.

[51] Paul J. Bough, ''ATI to Permanently Close Midland, Bagdad Metal Plants,'' *Pittsburgh Business Times*, October 25, 2016, *https://www.bizjournals.com/pittsburgh/news/2016/10/25/ati-to-permanently-close-midland-bagdad-metals.html*. Another U.S. company, Big River Inc. (Osceola, Arkansas) has indicated an intention to enter the GOES market. The company currently produces a wide variety of non-grain oriented steels for motor laminations. It has invested in plant equipment and infrastructure to expand production to include high permeability grain-oriented electrical steels. It also has expressed interest in utilizing the facility at which Orb Steel formerly manufactured grain oriented electrical steel in the United Kingdom (owned by Tata of India, which is attempting to sell the plant). However, the company's production capacity and product range is unknown at this time so cannot be counted as domestic production capability.

market in 1926.[52] Another manufacturer, Allegheny Ludlum, a subsidiary of Allegheny Technologies, Inc. (ATI), ceased manufacturing of GOES in 2016, with a loss of 350 jobs. [TEXT REDACTED] [53]

AK Steel melts, rolls, and finishes electrical steel at its Butler Works facility in Butler, Pennsylvania (which employs about 1,300 employees; this plant also processes other rolled steel products including Non-Grain Oriented Electrical Steel) and finishes electrical steel at its Zanesville Works plant in Zanesville, Ohio (which employs about 100 employees). However, electrical steel represents only a small percentage of AK Steel's business, accounting for [TEXT REDACTED] of revenues (the automotive industry is AK Steel's primary customer). AK Steel was acquired by Cleveland Cliffs Inc., the nation's largest producer of iron ore pellets, in March 2020.[54]

While still a leader in the domestic market, AK Steel's electrical steel operations are in poor financial condition, in part due to years of pressure from lower-cost foreign imports. In his testimony before the Congressional Steel Caucus in March 2020, Lourenco Goncalves, the President & CEO of Cleveland Cliffs, warned that the company would be forced to close the Butler and Zanesville facilities, both of which are unprofitable, unless the U.S. Government were to take action to limit imports of GOES in the form of transformer laminations and cores.[55] If AK Steel's GOES operations were to close, the United States would lack the ability to produce transformers of any power handling capacity without relying on foreign sources for the key material that is essential to their operation and efficiency.

The charts below present the current status of AK Steel specific to several important industry measures.

| [TEXT REDACTED] | | |
|---|---|---|
| [TEXT REDACTED].[56] | [TEXT REDACTED] [57] | [TEXT REDACTED] |
| [TEXT REDACTED] | | |
| [TEXT REDACTED].[58] | | |
| [TEXT REDACTED] | | |
| [TEXT REDACTED] | | |

[TEXT REDACTED].[59] [60] [TEXT REDACTED] [61] [TEXT REDACTED].[62] [TEXT REDACTED].

[TEXT REDACTED]. As a result of its inadequate investment, AK Steel says it will not be able to innovate in order to keep pace with the latest production technology or be able to meet increasingly stringent DOE efficiency standards. AK Steel states (and transformer companies validate) that the company can make high-permeability GOES products that have very low losses and are highly efficient. However, if the DOE increases its efficiency standards to require more high-permeability GOES, AK Steel would likely need to invest in more capacity to meet U.S. demand. Under current market conditions and pricing, AK Steel claims it cannot justify investments to achieve such additional capacity.[63]

[TEXT REDACTED]

[TEXT REDACTED]

1. U.S. GOES Production, Consumption and Import Penetration

[TEXT REDACTED].

[TEXT REDACTED]

The United States imported about 27,000 metric tons of GOES in 2019, for which Japan and Korea were the main sources. Imports of GOES in 2019 were dramatically lower than in 2018 (down 56 percent), a result of 25 percent tariffs imposed on imported GOES from most locations (Steel 232 tariffs). However, the steel tariffs did not achieve the intended result of increased production and consumption of domestic GOES.

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[52] *https://www.aksteel.com/our-products/electrical-steel/grain-oriented-electrical-steels.*

[53] [TEXT REDACTED].

[54] *http://www.clevelandcliffs.com/English/news-center/news-releases/news-releases-details/2020/Cleveland-Cliffs-Completes-Acquisition-of-AK-Steel/default.aspx.*

[55] *http://www.butlereagle.com/article/20200306/NEWS12/200309971.*

[56] [TEXT REDACTED].

[57] [TEXT REDACTED].

[58] [TEXT REDACTED].

[59] U.S. Department of Commerce, Bureau of Industry and Security, Section 232 Investigation on Impact on National Security of Imports of Steel, 2017.

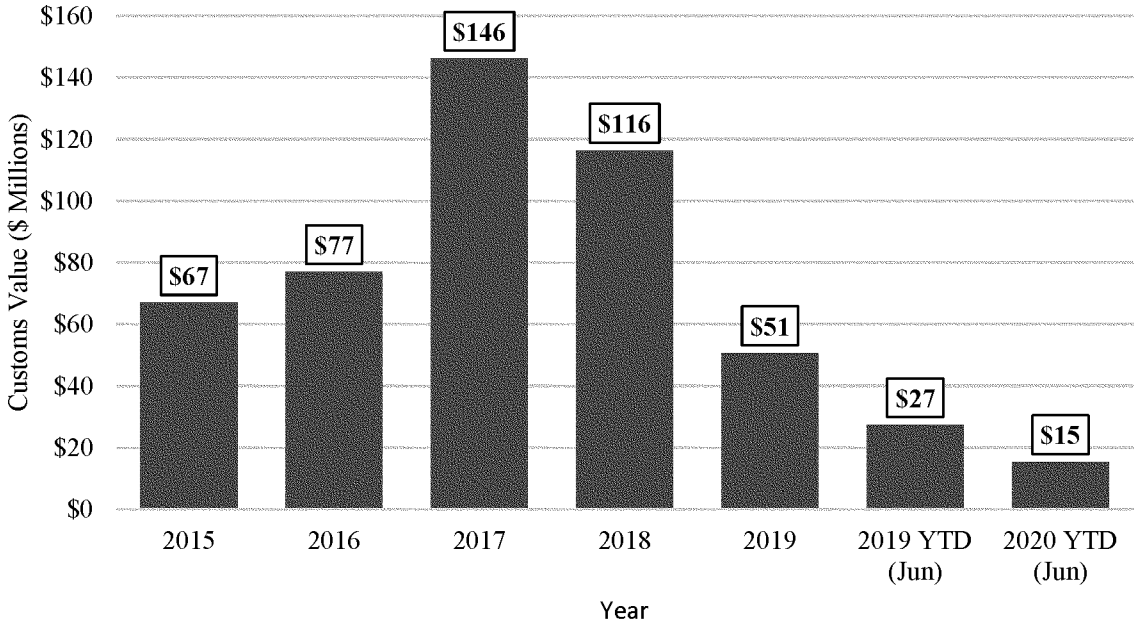
[60] [TEXT REDACTED].

[61] Ibid.

[62] Ibid.

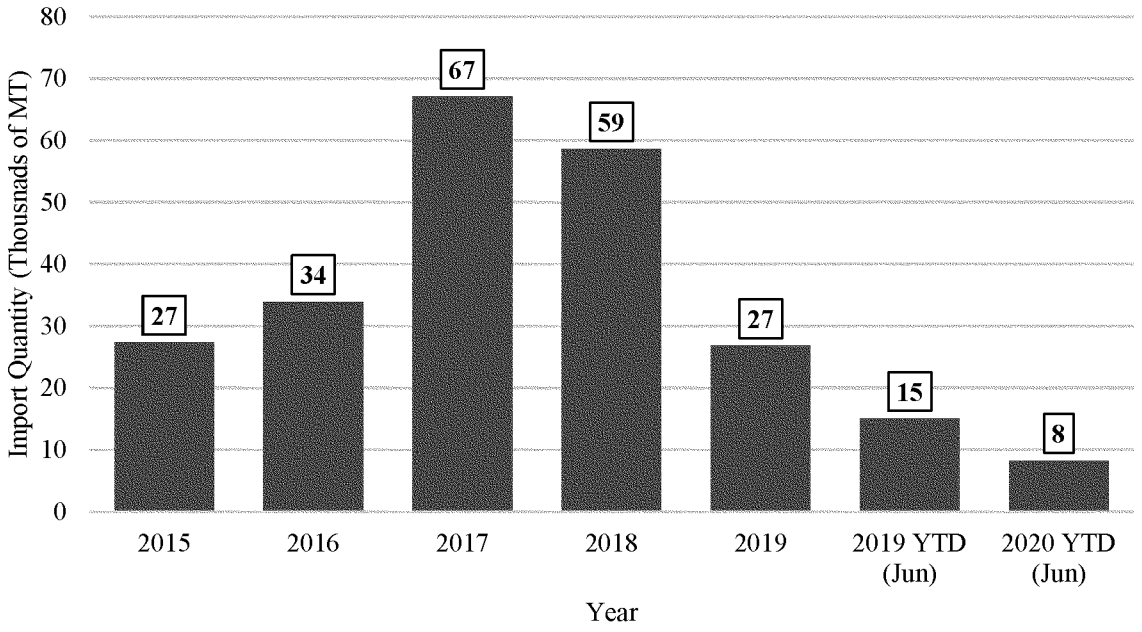
[63] AK Steel Public Comments.

**Figure VII-8. GOES Import Customs Value (2015-2020 YTD Jun)**




Source: United States International Trade Commission, U.S. Department of Commerce, Bureau of Industry and Security

**Figure VII-9. GOES Import Customs Quantity (2015-2020 YTD Jun)**




Source: United States International Trade Commission, U.S. Department of Commerce, Bureau of Industry and Security

**Figure VII-10. GOES Import Quantities by Top 10 Countries (MT, 2015-2020 YTD Jun)**

| Country | 2015 | 2016 | 2017 | 2018 | 2019 | 2019 YTD (Jun) | 2020 YTD (Jun) | Total* 2015-2019 |
|---|---|---|---|---|---|---|---|---|
| **Japan** | 9,705 | 10,397 | 25,543 | 17,251 | 6,581 | 4,506 | 1,711 | **71,188** |
| **South Korea** | 4,122 | 5,270 | 18,868 | 22,794 | 11,915 | 4,770 | 4,402 | **67,372** |
| **China** | 455 | 3,262 | 9,061 | 4,608 | 1,045 | 571 | 493 | **18,924** |
| **Russia** | 3,777 | 5,701 | 4,132 | 2,475 | 639 | 397 | 822 | **17,546** |
| **Czech Republic** | 2,760 | 3,704 | 4,299 | 916 | 374 | 374 | 13 | **12,065** |
| **United Kingdom** | 1,990 | 2,128 | 2,262 | 2,835 | 79 | 57 | 35 | **9,329** |
| **Brazil** | 1,539 | 2,575 | 1,120 | 1,416 | 2,170 | 1,113 | 424 | **9,245** |
| **Thailand** | - | - | - | 4,110 | 2,738 | 2,543 | - | **6,848** |
| **Poland** | 140 | 184 | 1,016 | 1,652 | 920 | 641 | 240 | **4,151** |
| **Canada** | 1,006 | 186 | 62 | 338 | 30 | 23 | 60 | **1,682** |

Source: United States International Trade Commission, U.S. Department of Commerce, Bureau of Industry and Security
*Excludes 2019 YTD (Jun) Data

| Figure VII-11. GOES Import Penetration by Weight | | | | | |
|---|---|---|---|---|---|
| Year | 2015 | 2016 | 2017 | 2018 | 2019 |
| [TEXT REDACTED] | | | | | |
| Imports For Consumption | 27,311,498 | 33,893,810 | 67,082,534 | 58,572,133 | 26,764,624 |
| Domestic Exports | 96,669,121 | 57,014,300 | 42,772,205 | 41,523,736 | 34,786,151 |
| [TEXT REDACTED] | | | | | |
| Import Penetration | 21% | 22% | 37% | 31% | 18% |
| [TEXT REDACTED] | | | | | |

| Figure VII-12. GOES Import Penetration by Value | | | | | |
|---|---|---|---|---|---|
| Year | 2015 | 2016 | 2017 | 2018 | 2019 |
| [TEXT REDACTED] | | | | | |
| Imports For Consumption | $66,915,489 | $76,976,977 | $146,193,243 | $116,343,595 | $50,658,381 |
| Domestic Exports | $230,523,114 | $138,029,576 | $90,527,328 | $87,625,426 | $69,715,767 |
| [TEXT REDACTED] | | | | | |
| Import Penetration | 19% | 20% | 31% | 24% | 13% |
| (Table excludes domestic production for 2015/2016 by Allegheny Ludlum) | | | | | |

Thus, based on production and trade data for GOES (presented in Table VII–11), imports accounted for less than 20 percent of domestic consumption (on a tonnage basis) in 2019. This is down from a high of 37 percent in 2017, prior to imposition of the steel tariffs. On a value basis, penetration is even lower, at 13 percent. These simple calculations do not present an accurate picture of the dependence of the domestic transformer industry on imported GOES, however, as will be discussed in the section analyzing suppliers to U.S. transformer manufacturers provided in the BIS industry survey.

2. Analysis of BIS Survey Supplier Data: GOES

The Department's industry survey provided additional data and insight on domestic consumption of GOES. Thirty-nine survey respondents reported that they directly sourced GOES and provided details on their suppliers and purchases. The aggregated amount of GOES that they procured on an annual basis was relatively stable between 2015 and 2019, [TEXT REDACTED]. This figure is roughly consistent with estimates for domestic GOES demand. Moreover, the total amount supplied by AK Steel as reported by survey respondents is consistent with that company's GOES production data. This data indicates that the Department's survey accurately captured most of the market.

The survey respondents reported obtaining GOES from a wide variety of global suppliers. Purchases were made from suppliers in Japan, China, Mexico, Germany, Russia, Canada, France, Brazil, Poland, and South Korea, as well as the United States. In addition to the steel mills that produce GOES sheets in coils, some respondents included in their responses information on purchases from suppliers that provide GOES in slightly more processed forms. These suppliers typically start their production with electrical steel sourced from a steel mill producing electrical steel and perform additional processing such as cutting, slitting, stamping, and/or coating. In this regard, the line between GOES and transformer laminations is seemingly quite indistinct, as other survey recipients recorded purchases from these same suppliers under the ''laminations'' category.

[TEXT REDACTED]

Four GOES suppliers accounted for 93 percent of purchases by the survey population in 2019. [TEXT REDACTED]. The remainder of the market shifted considerably among other players, with the most significant development the exit of ATI (Allegheny Ludlum) from the market in 2016. [TEXT REDACTED].

[TEXT REDACTED]

[TEXT REDACTED].
[TEXT REDACTED].
[TEXT REDACTED].
[TEXT REDACTED].

3. Sufficient Quantity and Quality of Domestic GOES

A number of transformer companies have indicated, through their public comments, through the Section 232 steel tariff exclusion process, and through survey responses, that the sole domestic source of GOES (AK Steel) lacks the capacity to meet the domestic demand for the full range of GOES products. U.S. consumption of GOES is estimated at approximately 220,000 metric tons per year, [TEXT REDACTED].[64] However, AK Steel's stated capacity does not take into consideration the production of variable grades of GOES. For example, much of the company's production is of conventional grades of GOES (M class); its production capacity for higher grades is limited.

In its public comments, the Core Coalition noted that although AK Steel is widely recognized in the industry as a supplier of high-quality GOES. However, it is a high-cost supplier compared to foreign sources, which the Core Coalition attributes to the company's lack of capital investment and its continued use of obsolete production equipment and processes. AK Steel notes that the Department's

[64] Core Coalition Public Comments.

antidumping investigations have found that foreign GOES manufacturers sell at unfair prices (dumping) or are subsidized by their governments. The European Union has found AK Steel practices dumping.

In addition, AK Steel does not manufacture or offer an intermediate grade of GOES, called MOH, which is widely available from suppliers in South Korea, Japan, and China. While AK offers a higher grade GOES that can be used instead of MOH, it is more expensive and is not optimal for use in certain standard-issue transformers where GOES price weighs more heavily than energy efficiency in sourcing decisions.

Another concern expressed by domestic transformer manufacturers is the maximum width of AK's Steel's product. The company does not produce steel wide enough (>932mm) to form the laminations and cores of larger transformers. According to the technical specifications on AK Steel's website, the maximum width of its domain-refined products (TRAN–COR) is 920mm.[65] While two pieces of steel can be patched together, this process leads to increased production costs and loss of efficiencies in the core.[66]

Many transformer companies submitting public comments during the investigation indicated that AK Steel's lack of capital investment over many years has affected the company's ability to supply the highest grades of steel grades that steel transformer manufacturers prefer to use in the cores of distribution transformers subject to DOE energy standards. In addition, in general, utility companies are increasingly seeking to install transformers with high efficiency/lower losses (that tend to require higher grades of GOES) that reduce costs and are environmentally friendly. For example, European and Asian manufacturers offer a high permeability GOES called HI–B (originally developed by Nippon Steel of Japan but licensed the technology to other companies).[67]

A summarized list of concerns with AK Steel's capabilities and capacity expressed through the public comments process is provided in the table below.

[65] *https://www.aksteel.eu/files/downloads/TRAN-COR_H_%20Grain_Oriented_Electrical_Steel.pdf.*

[66] Public comments of Domestic Transformer Producers.

[67] Public comments of Domestic Transformer Producers.

| Figure VII-15. Analysis of Negative Comments Aimed Toward AK Steel | |
|---|---|
| **Public Commenter** | **Nature of Comment** |
| Central Moloney Inc. | • Passing the proposal will create a monopoly for AK Steel, allowing them to control price and determine who is successful in the transformer industry<br>• AK Steel does not have capacity to keep up with the demand, Central Moloney has been put on allocation several times due to capacity issues<br>• AK does not have the ability to make the same quality of steel (Permanent Domain Refined core steel) which meets current efficiency levels set by the Department of Energy |
| Southwest Electric Company | • There is only one domestic provider and they have not invested and adapted enough to stay competitive with global players<br>• Additionally they would not be able to provide the volumes in specific quality/performance graded needed to support the U.S. market alone |
| WEG Transformers USA | • Foreign competition is not a significant issue related to GOES<br>• AK Steel already has a 70% market share of the current industry and they are not able to support significant growth and changes to the electrical grid that renewable energy is driving |
| Tempel Steel Co | • AK Steel's outdated technology and antiquated equipment limits the quantity and quality of grades it offers and inflates the cost structure<br>• A transformer has a life expectancy of 25 years and the average transformer at AK Steel is dated 38 years |
| JFE Shoji Steel America Inc. | • AK Steel individually does not have the capacity to supply the domestic demand for transformers and transformer parts<br>• AK Steel is not capable today of manufacturing some of the best available and required materials in the world<br>• AK Steel's process capability does not enable them to produce their best published grades in large quantities<br>• All GOES and NOES is not interchangeable. To the extent that AK Steel cannot or will not quickly be able to meet those specifications and obtain certification, those customers will be the most negatively impacted |
| U.S. Chamber of Commerce | • U.S. production of GOES, including cores and laminations, is insufficient to supply the needs of the entire U.S. transformer manufacturing base<br>• Some specific high-grade silicon electrical steels used in some transformer manufacturers' current designs to meet mandatory U.S. Department of Energy conservation standards for transformers are either not available or are not available in sufficient quantities from domestic producers and therefore must be imported |
| ABB Enterprise Software, Inc. | • Tariffs on imported transformer components will undermine the industry's ability to supply the U.S. market. Domestic producers are not able to manufacture all of the laminations and cores used in their transformers or secure those components from U.S. sources |
| Cogent Power Inc. | • AK Steel is also not capable today of manufacturing some of the best available and required materials in the world<br>•Not only will there be restrictions on total capacity output from AK Steel to the US market, there will be restrictions on the best available grades |

| | |
|---|---|
| Hyosung Heavy Industries Corporation | • Currently, there is limited availability of domestically-produced GOES from the single U.S. supplier, AK Steel<br>• Forcing entire U.S. transformer industry to rely on a single U.S. GOES supplier with limited capacity raises serious concerns. Indeed, U.S. transformer manufacturers continue to submit product exclusion requests for GOES under the existing Section 232 measures on steel imports, citing a persistent lack of domestic availability |
| Eaton Corporation | • The domestic manufacturer of GOES still does not meet the specifications needed to manufacture our specific transformers in the United States |
| National Foreign Trade Council | • Foreign-produced electrical steel is imported precisely because U.S. electrical steel manufacturing capacity is insufficient to meet domestic demand. The one GOES producer in the United States cannot meet all of the domestic demand and will not be able to do so for the foreseeable future |
| Domestic Transformer Manufacturers | • These are high-value materials that cannot be replicated by the domestic steel industry (Delta Star, Inc.; SPX Transformer Solutions, Inc.; Pennsylvania Transformer Technology; and Niagara Transformer Corp) |
| The Core Coalition | • AK Steel, the only current producer of GOES in North America, prices GOES well above all other global competitors—the current 25 percent tariffs still do not make AK price competitive<br>• This gap in prices has persisted for years before tariff protection for all steel products under Section 232<br>• The main reason for high AK prices is an aberrational cost structure, higher than global competition. This disparity stems from AK's failure to modernize its production methods to keep pace with global competition<br>• The US does not have the production capacity to support total production requirements for inputs for production of Power transformers |
| Source: Public Comments Submitted to *Federal Register* | |

[TEXT REDACTED].[68]

A number of transformer manufacturers indicated that the sole domestic source of GOES does not offer the full range of efficient GOES, with the result that the manufacturers must seek foreign suppliers. For example, transformer manufacturers indicated that they are unable to obtain permanent, heat resistant domain-refined grain oriented steel (PDR GOES) from the sole domestic manufacturer.[69] DOE energy efficiency standards for distribution transformers that came into effect in 2016 have reduced demand for lower-permeability, conventional grades of GOES, and increased the demand for high grades, such as PDR–GOES. PDR–GOES is capable of being annealed after core production while retaining its domain-refined properties, which is important for use in wound cores often used in distribution transformers.[70] Nippon Steel of Japan is recognized as the primary source of this product.

[TEXT REDACTED]. However, while there is some degree of interchangeability among different grades of GOES in transformer core construction, doing so could result in higher core losses/decreased efficiencies and/or require a larger size transformer. As a result, using non-permanent DR–GOES in lieu of PDR–GOES could affect the competitive position of the transformer manufacturer when bidding for contracts.[71]

This apparent deficiency in U.S. production capabilities for GOES with superior magnetic qualities helps explain continued imports of GOES (especially from Japan) despite the additional cost due imposition of tariffs. In fact, the Department has granted some requests for exclusion from the 25 percent tariffs on imported steel due to lack of domestic capability of the particular product grade. Additionally, some imports of GOES from South Korea and Brazil continue to be economical because the Section 232 remedy resulted in a quota, rather than tariffs for steel from those countries.

While just a rough estimate, the average unit value by country (based on value imports divided by unit imports) is broadly illustrative of the varying grades of GOES from different suppliers. Other than the United Kingdom, which is not a major source of GOES imports, GOES imported from Japan has an average unit value significantly higher than from other sources. This suggests that Japan is the source of the highest grades GOES imported into the United States.

[68] Joe Paladino Technical Advisor, DOE Office of Electricity, in written comments to BIS submitted on 9/21/202.

[69] For example, in its public comments, Central Moloney, a domestic manufacturer of distribution transformers, expressed concern over the quality of AK Steel's GOES. They said that the company's manufacturing equipment and processes are antiquated, and it lacks the capability to produce electrical steel that it prefers to use to meet DOE efficiency standards for distribution transformers—namely Permanent Domain-Refined GOES (PDR). In addition, tariff exclusion requests from Sumitomo, ABB, Eaton/Cooper, and SPX cited lack of domestic capabilities.

[70] *https://Agmetalminer.com/tag/grain-oriented-electrical-steel/.*

[71] See, *e.g.,* SPX Exclusion Request.

| Figure VII-16. GOES Customs Value Imports AUV by Top 10 Countries ($/Kg, 2015-2020 YTD Jun) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Country** | **2015** | **2016** | **2017** | **2018** | **2019** | **2019 YTD (Jun)** | **2020 YTD (Jun)** | **Average* 2015-2019** |
| **United Kingdom** | $2.64 | $2.64 | $2.88 | $2.28 | $2.68 | $2.83 | $2.41 | **$2.59** |
| **Japan** | $2.66 | $2.61 | $2.58 | $2.42 | $2.12 | $2.05 | $2.10 | **$2.41** |
| **Canada** | $2.48 | $2.64 | $2.62 | $2.26 | $2.22 | $0.34 | $1.50 | **$2.29** |
| **Russia** | $2.52 | $2.31 | $2.75 | $2.04 | $2.19 | $2.04 | $1.60 | **$2.24** |
| **South Korea** | $2.16 | $2.21 | $1.80 | $1.90 | $1.97 | $1.64 | $1.89 | **$1.99** |
| **Poland** | $2.25 | $1.99 | $2.00 | $1.90 | $1.73 | $1.90 | $1.67 | **$1.92** |
| **China** | $2.23 | $1.93 | $1.73 | $1.67 | $2.15 | $2.25 | $1.58 | **$1.88** |
| **Czech Republic** | $2.17 | $1.82 | $1.66 | $1.71 | $1.62 | $0.67 | $1.77 | **$1.79** |
| **Brazil** | $1.92 | $1.79 | $1.51 | $1.73 | $1.83 | $1.94 | $1.61 | **$1.73** |
| **Thailand** | - | - | - | $0.93 | $0.91 | $0.72 | - | **$0.92** |
| Source: United States International Trade Commission, U.S. Department of Commerce, Bureau of Industry and Security<br>*Weighted Average by Quantity. Excludes 2019 YTD (Jun) Data | | | | | | | | |

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*C. Laminations and Cores*

Transformer lamination and core producers make up the primary customer base for GOES suppliers. There are very few companies in the United States that manufacture only transformer laminations and cores; some major transformer companies produce laminations and cores for in-house use in their transformers. Manufacture of these critical transformer components requires expensive, specialized equipment which can only produce laminations within a specific size range. This limits the ability of independent companies to offer laminations in the varied sizes required across transformer product categories. Over the past few years, there has been a marked decline in domestic manufacturing of laminations and cores (by both transformer companies and independent producers), and a movement of production offshore (especially to Canada and Mexico). A corollary to the movement of lamination and core manufacture out of the United States is the loss of a potential domestic market for AK Steel's GOES.

Because electrical steel accounts for such a large percentage of the cost of transformer laminations and cores (averaging about 60 percent for the surveyed companies), the 25 percent import tariff raised material costs and decreased transformer manufacturers' ability to compete. The CEO of one of the remaining domestic producers of these items, Orchid Monroe LLC (Wisconsin), stated that imported laminations and cores often cost less than the price at which its company can procure domestic electrical steel, without any processing or manufacturing costs included.[72]

Global transformer companies with multiple facilities have adapted to changes in raw material prices by shifting their lamination and/or core production or sourcing offshore in order to continue to utilize foreign-origin GOES without the price premium for domestically produced GOES. Smaller companies that specialize in these products either moved their operations offshore or ceased production.

The trend toward moving lamination production offshore occurred prior to the Section 232 steel tariffs, but the situation worsened after their imposition. The expansion of core-making capacity in Canada and Mexico began in the mid-2010s, at which time the United States had initiated antidumping investigations on GOES from many foreign sources. In the antidumping investigations conducted by the Department, many foreign suppliers of GOES were found to be selling at less than fair value, or in the case of China, with the benefit of government subsidies. However, the International Trade Commission did not find material injury to U.S. industry was not found, no duties were imposed.[73] Despite this, partly to avoid potential duties, transformer and transformer component manufacturers began to shift production offshore where they are able to use foreign origin GOES without the risk of increasing costs due to the imposition of duties.

Another factor in the movement of core and lamination toward offshore outsourcing was the new DOE energy efficiency standards for distribution transformers that were implemented in 2016. To meet these standards, transformer companies had to redesign their products, including the choice of electrical steel and core construction. [TEXT REDACTED].[74] [TEXT REDACTED].[75]

As a result, there are very few remaining domestic producers of laminations and cores. The Department's survey included responses from 10 small businesses in the United States that reported production of laminations, stacked core, and/or wound cores using GOES. The table below presents the state of transformer lamination and core manufacturing in the United States by these non-captive producers.

[TEXT REDACTED]

[TEXT REDACTED]. Moreover, analysis of these companies' financial reports reveals additional weaknesses.

[72] Public Comments from Gordon Bibby, Orchid Monroe LLC.

[73] *See Grain-Oriented Electrical Steel from Germany, Japan, and Poland,* Inv. Nos. 731–TA–1233, 1234, and 1236, USITC Pub. 4491 (Sep. 2014), at 2.

[74] [TEXT REDACTED].

[75] [TEXT REDACTED].

Respondents were assigned a comprehensive financial risk score by the Department, which incorporated yearly scores and trends in financial health. Based on this scorecard, respondents were categorized as low/neutral risk, moderate/elevated risk, or high/severe risk.[76]

[TEXT REDACTED]

All of the companies noted in their survey responses that they face serious negative impacts from foreign competition. Three of the 10 have shut down their domestic operations in recent years [TEXT REDACTED]. A fifth company has reduced its capacity in an attempt to return to profitability. The five companies remaining have had to increasingly rely on niche markets, including aerospace and defense, to counter the loss of demand from other customers (which have either shifted sourcing or are themselves impacted by foreign competition).

Among the domestic laminations and core manufacturers that have been negatively affected is [TEXT REDACTED].

[TEXT REDACTED].

[TEXT REDACTED].

As mentioned above, in addition to these specialized manufacturers, several transformer companies produce laminations and/or cores in the United States for their own internal consumption. [TEXT REDACTED]. These captive producers, too, have changed production and sources for laminations and cores, either completely or partially outsourcing. [TEXT REDACTED].

[TEXT REDACTED]. The new company (80 percent owned by Hitachi and 20 percent by ABB) is called Hitachi ABB Power Grids.[77] Although Hitachi's long-term plans for the facility are unknown, the sale may impact domestic production of laminations and cores.

1. Lamination Suppliers

The lack of domestic production capability is validated by the lamination and core supplier data provided by survey recipients. Twenty-two survey participants reported sourcing *stacked laminations for use in transformer cores.* They sourced laminations from suppliers in a variety of countries, including the United States, South Korea, Mexico, Canada, Turkey, Italy, and India.

In 2019, laminations with a total value of $40.2 million were sourced by surveyed companies.[78] Of this $40.2 million, less than 12 percent came from domestic suppliers, while 88 percent were from foreign sources. [TEXT REDACTED].

[TEXT REDACTED]

[TEXT REDACTED].[79] [TEXT REDACTED]. In addition to these two companies, survey respondents reported several other suppliers from Mexico along with minor suppliers located in South Korea, Italy, Turkey, India, and China.

It is clear from respondents' replies to the supplier question that there is an ambiguity between what is considered GOES and what is considered a lamination; data from the survey show that 60 percent of the value of laminations is accounted for by the cost of GOES. Among the suppliers listed, as noted earlier, there is overlap between the two categories. [TEXT REDACTED].

2. Stacked Core Suppliers

Outside of captive production by several transformer manufacturers, 16 transformer companies participating in the Department's survey procured a total of $114.7 million worth of *stacked cores* in 2019. Their suppliers were located in Canada, Mexico, Italy, and China, as well as the United States. Of the $114.7 million total, [TEXT REDACTED]. The other leading core suppliers were [TEXT REDACTED]. As with the lamination sector, this would mean that foreign fabricated cores could account for over 80 percent of the future market.

[TEXT REDACTED]

As noted above, Cogent Power was recently purchased by JFE Shoji. This Japanese steel trading company also acquired an unspecified interest in another leading source of stacked cores, [TEXT REDACTED].

[TEXT REDACTED], several Chinese companies were minor suppliers of stacked cores.

3. Wound Core Suppliers

Twenty-nine respondents to the Department's survey indicated that they procured *wound cores* for use in manufacturing transformers during the 2015–2019 period. The total value of the wound cores that these companies purchased increased markedly in the last three years of the time period, from $132 million in 2017 to $410 million in 2019. The increase may be because wound cores are often used in distribution transformers that are subject to the DOE energy efficiency standards. PDR–GOES, which is not produced in the United States, is desirable for use in wound cores because it is capable of withstanding the annealing process.

By far the leading source of wound cores for the survey sample was [TEXT REDACTED].

[TEXT REDACTED] mentioned that make up the other 25 percent of consumption are domestic companies that have shut down their U.S. facilities since 2019.

4. U.S. Imports of Laminations and Cores

U.S. import statistics affirm the Department's survey data with regard to the dominant role that foreign sources play in the United States domestic transformer market. The dramatic increase in imports of these products, particularly from Canada has resulted in the displacement of U.S. production of transformer components.

BILLING CODE 3510–33–P

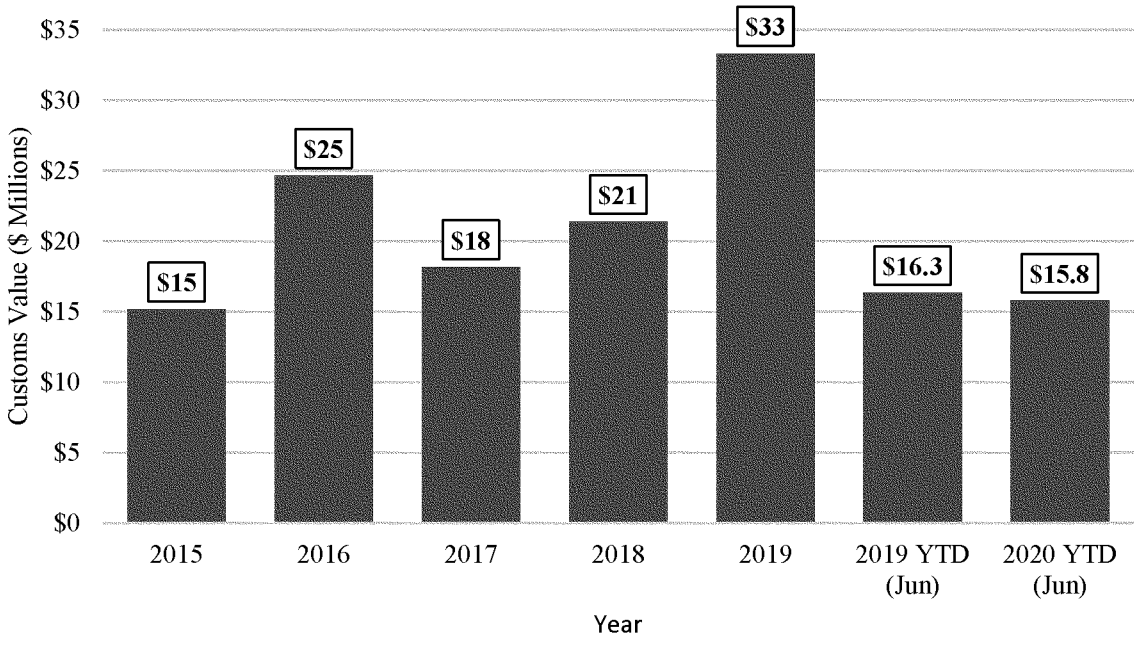
[76] For how BIS assessed financial health, see note [45], *infra.*

[77] *http://www.hitachi.com/New/cnews/month/2020/07/f_200701.pdf.*

[78] This figure exceeds the value of imports of laminations (HTS 8504.90.9634) according U.S. Census trade statistics, which was $33 million in 2019; purchases in an annual period and export shipments in an annual period do not necessarily match.

[79] *https://magneticsmag.com/jfe-gains-foothold-in-na-with-acquisition-of-cogent-power-from-tata-steel/.*

**Figure VII-21. Lamination Import Customs Value (2015-2020 YTD Jun)**



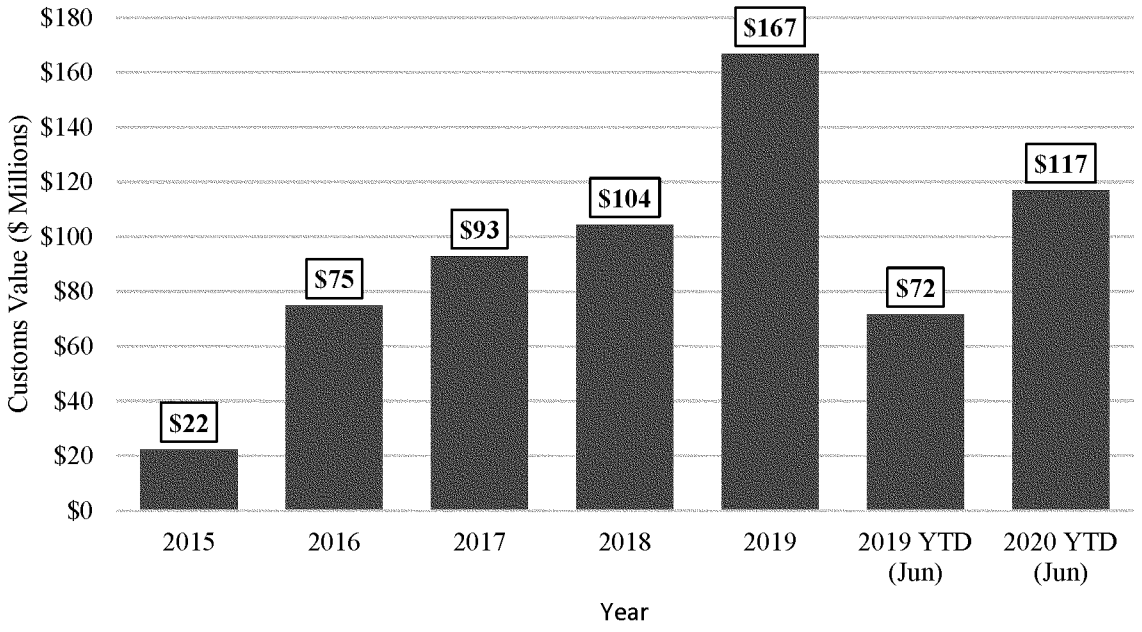

Source: United States International Trade Commission, U.S. Department of Commerce, Bureau of Industry and Security

**Figure VII-21. Lamination Import Customs Value by Top 10 Countries ($ Millions, 2015-2020 YTD Jun)**

| Country | 2015 | 2016 | 2017 | 2018 | 2019 | 2019 YTD (Jun) | 2020 YTD (Jun) | SUM* |
|---|---|---|---|---|---|---|---|---|
| **Canada** | $0.16 | $8.04 | $8.92 | $15.36 | $22.61 | $11.32 | $10.29 | **$65.39** |
| **Mexico** | $13.87 | $15.21 | $8.10 | $5.61 | $9.55 | $4.69 | $5.02 | **$57.36** |
| **Italy** | $0.31 | $0.56 | $0.08 | - | $0.84 | $0.20 | $0.32 | **$2.11** |
| **South Korea** | $0.73 | $0.70 | $0.29 | $0.17 | $0.13 | $0.03 | $0.02 | **$2.05** |
| **Germany** | $0.00 | $0.02 | $0.29 | $0.05 | $0.11 | $0.06 | $0.05 | **$0.53** |
| **China** | $0.03 | $0.03 | $0.11 | $0.14 | $0.04 | $0.01 | $0.04 | **$0.39** |
| **Japan** | - | $0.01 | $0.16 | - | - | - | - | **$0.17** |
| **Czech Republic** | - | - | $0.08 | - | - | - | - | **$0.08** |
| **Taiwan** | $0.01 | $0.02 | $0.05 | - | - | - | - | **$0.07** |
| **Philippines** | - | - | $0.01 | - | - | - | $0.04 | **$0.04** |

Source: United States International Trade Commission, U.S. Department of Commerce, Bureau of Industry and Security
*Excludes 2019 YTD (Jun) Data

**Figure VII-22. Stacked & Wound Core Import Customs Value (2015-2020 YTD Jun)**




Source: United States International Trade Commission, U.S. Department of Commerce, Bureau of Industry and Security

**Figure VII-23. Stacked & Wound Core Import Customs Value by Top 10 Countries ($ Millions, 2015-2020 YTD Jun)**

| Country | 2015 | 2016 | 2017 | 2018 | 2019 | 2019 YTD (Jun) | 2020 YTD (Jun) | SUM* |
|---|---|---|---|---|---|---|---|---|
| **Canada** | $1.20 | $54.41 | $69.71 | $70.84 | $86.65 | $42.49 | $58.30 | **$341.1** |
| **Mexico** | $17.79 | $17.34 | $17.00 | $28.48 | $74.60 | $26.67 | $55.76 | **$211.0** |
| **China** | $1.65 | $1.55 | $1.85 | $0.78 | $0.46 | $0.27 | $0.32 | **$6.61** |
| **Bulgaria** | $0.00 | $0.01 | $0.11 | $1.45 | $1.85 | $0.89 | $0.76 | **$4.18** |
| **Japan** | $0.43 | $0.44 | $0.36 | $0.53 | $1.05 | $0.46 | $0.54 | **$3.36** |
| **South Korea** | $0.00 | $0.01 | $0.89 | $0.71 | $0.00 | $0.00 | $0.68 | **$2.29** |
| **India** | $0.16 | $0.08 | $0.52 | $0.42 | $0.63 | $0.21 | $0.05 | **$1.86** |
| **Turkey** | $0.23 | $0.19 | $0.45 | $0.37 | $0.40 | $0.18 | $0.19 | **$1.83** |
| **Italy** | $0.02 | $0.01 | $0.50 | $0.17 | $0.27 | $0.00 | $0.04 | **$1.01** |
| **Thailand** | $0.11 | $0.26 | $0.17 | $0.14 | $0.07 | $0.05 | $0.02 | **$0.76** |

Source: United States International Trade Commission, U.S. Department of Commerce, Bureau of Industry and Security
*Excludes 2019 YTD (Jun) Data

U.S. imports of transformer laminations rose from $18 million in 2017 to $33 million in 2019, with most of the increase due to imports from Canada. For stacked and wound transformer cores, imports rose from $22 million in 2015 to $167 million in 2019—a 650 percent increase—with Canada and Mexico accounting for more than 95 percent of the total imported. Data for the first six months of 2020 indicate that the trend toward increased imports is continuing. As domestic demand for laminations and cores has not increased, this surge in imports represents displaced domestic production.

The United States-Mexico-Canada Agreement (USMCA) establishes a country of origin (COO) rule for transformers and transformer components, including laminations and cores. These rules of origin, which will come into force in five years (2025), will consider transformer laminations and cores as derived from the country in

which the electrical steel from which they are made was produced, based on the high percentage of these products' value that is accounted for by the electrical steel. As Canada and Mexico have no electrical steel production, those cores will not be considered products of either Mexico or Canada when full implementation of USMCA is achieved.[80] However, even when this new requirement for preferential treatment comes into effect, it will likely not discourage the production of these items in Canada or Mexico (using foreign GOES) for export to the United States, because that the general, most-favored-nation U.S. tariff rate on imports of these items is zero.

5. Consumption of GOES Contained in Transformer Cores

Due to the movement offshore of lamination and core production, U.S. imports of these products must also be considered as part of U.S. GOES consumption that is not captured in the trade statistics for GOES. In 2019, the United States imported an estimated 68,000 metric tons of GOES in the form of transformer laminations and cores.[81]

[TEXT REDACTED]. Based on these figures, the import penetration for GOES was approximately 44 percent in 2019. (Note: this number could include double counting from U.S. exports of GOES that is then imported into the United States in the form of cores, but this is likely minimal because Canada was not a major destination for U.S. GOES exports or a major source of Canadian imports).

A public comment by the Core Coalition estimates that total U.S. core imports, in kilograms, will be much higher in 2020 than in 2019 (due primarily to an anticipated increase in imports of wound cores; trade data from the first half of 2020 validates this). Based on the Coalition's estimate of 2020 core imports of 96,000 metric tons, and assuming steady U.S. GOES production and export and import levels, import penetration is estimated to reach over 50 percent this year.

6. Dominance of Suppliers for Laminations and Cores

As discussed, Canada and Mexico are by far the leading suppliers of components for U.S. transformer manufacturers. [TEXT REDACTED].

[TEXT REDACTED]. Until 2019, Cogent was owned by Tata of India, which also owned Orb Steel, which may explain why Orb was a major supplier to Cogent. Now that Cogent is owned by JFE Shoji, it is likely that JFE Steel will emerge as one of its major suppliers.

[TEXT REDACTED].

7. Consumption of GOES Imported in Finished Transformers

Despite the grim results that the inclusion of the GOES-derivative products discussed above presents, the complete picture with regard to the true dependency of the U.S. electricity grid on foreign sources for GOES, laminations, and cores remains incomplete until the impact of finished transformers is included. Given that transformers have a high percentage value of GOES, domestic GOES production (and transformer production) is adversely impacted by imports of complete transformers. The vast majority of imported transformers contain cores composed of foreign-origin GOES. In 2019, the United States imported a total $2.56 billion worth of transformers (of all power handling capacities), representing about 35 percent of the market (per Global Insights/D&B). For LPT (which by nature of their size contain the most GOES by weight), imports accounted for over 80 percent of the domestic market.

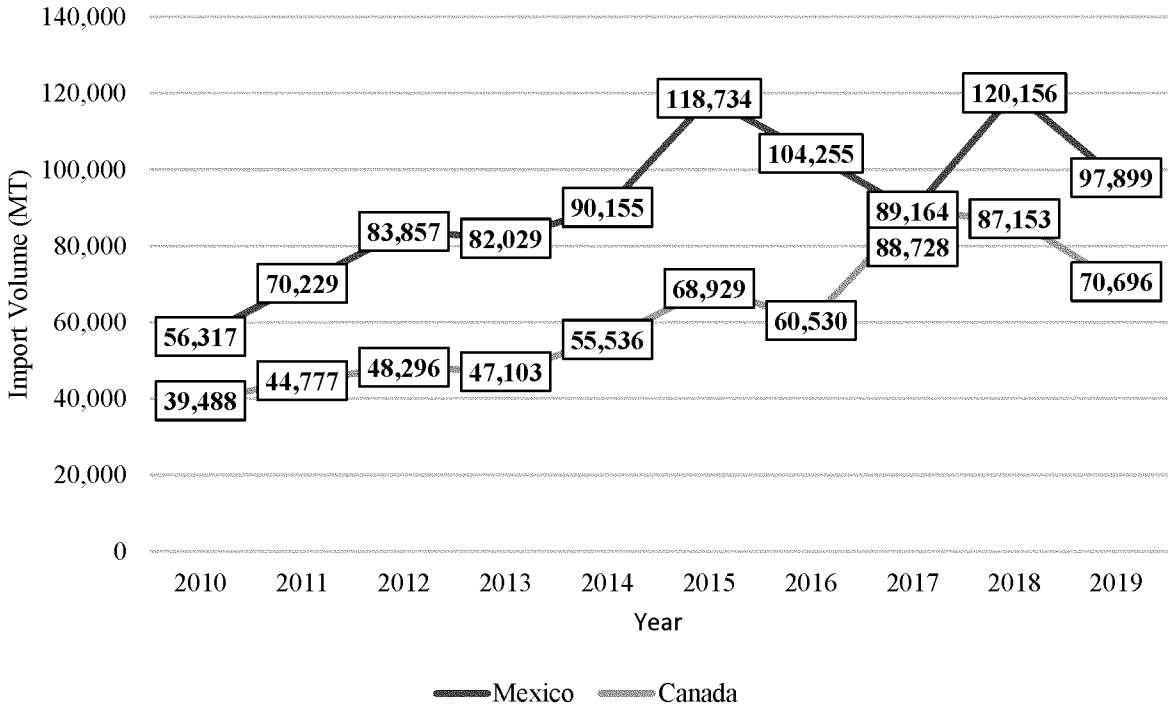
8. Source of GOES for Mexico and Canada

Corresponding to the migration of core and lamination production to Canada and Mexico from the United States was an increase in imports by these countries of GOES. As neither Canada nor Mexico have domestic GOES production capability, both needed to increase their imports of GOES in order to increase core and lamination production. The table below shows total imports of GOES by Canada and Mexico over the past ten years. Both are substantial consumers of GOES. The table shows that imports of GOES has been rising substantially over the ten year period, particularly between 2014 and 2016. For both countries, imports of GOES declined significantly in 2019 from 2018 levels, but are still higher than earlier in the decade.

[80] *https://ustr.gov/sites/default/files/files/agreements/FTA/USMCA/Text/04-Rules-of-Origin.pdf.*

[81] Trade data for cores are not collected by weight, but rather by units. Estimate of the weight of lamination and core imports is based on the estimates provided by the Core Coalition in its public comments.

**Figure VII-24. Canada and Mexico GOES Imports by Weight, 2010-2019**
**Includes HTS Codes 7225.11 and 7226.11**




Source: Global Trade Atlas, retrieved on October 1, 2020

The leading sources of GOES imports in Canada in 2019 were Japan and South Korea, but China and Russia were also sources. Note that the United Kingdom was also a major supplier to Canada throughout the period. There was one producer of GOES in the United Kingdom, Orb Steel (owned by Tata of India), which, as previously discussed, shut down production in 2019. One of Canada's leading transformer lamination and core manufacturers, Cogent Power, was, at the time, also owned by Tata and this might explain why the United Kingdom was such a major supplier. As discussed above, JFE Shoji recently acquired Cogent Power. In the case of Mexico, Japan was the leading supplier in 2019, with China and Russia ranked second and third. Imports of GOES from the United States declined to virtually zero in Mexico in 2019. In the case of Canada, 2019 imports of GOES from the United States accounted for less than three percent of the total (2,609 metric tons of 97,889 total metric tons), compared to about a third of imports as recently as 2015 (23,210 metric tons out of 68,929 total metric tons).

| Figure VII-25. Mexican GOES Import Quantities by Top 10 Countries (MT, 2010-2019) | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | SUM |
| **Japan** | 35,538 | 39,489 | 54,630 | 61,440 | 56,810 | 67,102 | 50,827 | 43,653 | 45,368 | 54,151 | **509,008** |
| **China** | 245 | 335 | 1,343 | 1,634 | 4,700 | 10,670 | 19,640 | 8,142 | 25,660 | 23,625 | **95,992** |
| **Russia** | 2,536 | 4,806 | 6,905 | 7,225 | 7,550 | 11,885 | 11,688 | 9,848 | 15,035 | 8,227 | **85,706** |
| **Korea South** | 2,807 | 6,540 | 8,000 | 2,544 | 5,150 | 6,858 | 4,107 | 4,714 | 4,101 | 3,822 | **48,643** |
| **Poland** | 84 | 1,663 | 701 | 278 | 3,119 | 6,567 | 5,099 | 10,438 | 13,781 | 6,325 | **48,056** |
| **United States** | 6,248 | 9,483 | 5,738 | 5,380 | 3,695 | 4,957 | 4,317 | 1,081 | 1,529 | 289 | **42,717** |
| **Czech Republic** | 1,028 | 1,345 | 1,531 | 398 | 1,540 | 1,685 | 1,789 | 3,979 | 2,111 | --- | **15,406** |
| **Germany** | 1,110 | 897 | 310 | 199 | 813 | 1,818 | 877 | 904 | 2,047 | --- | **8,975** |
| **France** | 780 | 1,232 | 923 | 348 | 382 | --- | 618 | 1,027 | 54 | --- | **5,363** |
| **Brazil** | 61 | --- | 81 | 20 | 1,331 | 298 | 295 | 207 | 1,190 | 106 | **3,590** |
| Source: Global Trade Atlas, U.S. Department of Commerce, Bureau of Industry and Security | | | | | | | | | | | |

Moreover, transformer components produced in Mexico and Canada were largely destined for the U.S. market. Virtually all of Mexico's exports of transformer components were to the United States (>99 percent), as were over 90 percent of Canada's exports of these items.[82] Mexico, also a significant manufacturing center for transformers, had domestic GOES requirements. However, here again, the United States is the primary destination for Mexico's transformer production so the GOES contained in them is also part of U.S. GOES consumption. Based on the data and statistics on Mexican and Canadian imports of GOES, some transformers in the United States likely contain GOES originating from China and Russia.

| Figure VII-26. 2019 Exports of Transformer Parts Under HTS Code 8504.90 from Mexico and Canada to the U.S. | | | |
|---|---|---|---|
| Country | Percent of Exports to the U.S./ to the World | Exports to the U.S. ($ millions) | Exports to the World ($ millions) |
| Mexico | 99.3% | $281.4 | $283.5 |
| Canada | 91.4% | $168.0 | $183.9 |
| Source: Global Trade Atlas, retrieved on September 12, 2020 | | | |

9. Amorphous Metal

While not technically subject to this investigation, amorphous metal (also known as metallic glass or metglas) competes with GOES as a material for transformer cores in certain power handling categories. Demand for amorphous metal cores increased as a result of the 2016 distribution transformer efficiency standards. As is the case with GOES, there is only one domestic source for amorphous metal ribbon—Metglas, Inc., based in Conway, South Carolina, which is a subsidiary of Hitachi Metals of Japan. In 1999, AlliedSignal bought Honeywell and took on the Honeywell name. In 2003, Hitachi Metals of Japan bought Metglas from Honeywell.

Just as AK Steel (then Armco Steel) invented GOES, Metglas pioneered amorphous metal in the 1970s (when the company was known as AlliedSignal). The first commercial transformer using the product in its core was installed in the United States in 1982; and commercial production of transformer core alloy began in 1989.[83]

While more expensive than GOES on a per kilogram basis, and more labor intensive to form into cores, the material has the potential to reduce costs in the long run for utilities over the life of the transformer due to lower core losses. The production technology has been widely adopted in developing countries, including China and India. As producing transformers cores using metglas is more labor intensive, it is more economical in countries with low labor costs. There are about 600,000 amorphous metal transformers installed in the United States, compared to over 1 million in China and 1.3 million in India.[84]

Metglas's patent on the production technology has expired; Metglas' competitive strength is its proprietary production process. The company has accused former employees of divulging

[82] Global Trade Atlas.

[83] *https://metglas.com.*

[84] Ibid.

confidential information to Chinese competitors and in 2017 filed a case under Section 337 of the Tariff Act of 1930 (investigations conducted by the International Trade Commission involving patent infringement or intellectual property theft in imported goods) against five Chinese companies. The case was suspended without prejudice. Metglas has lost 50 percent of its employees due its inability to compete with imports from China that have flooded the world market. Metglas alleges that the same avoidance of tariffs that occurred with GOES is happening on amorphous metal; in other words, that imported metal goes to Canada and Mexico, where it is made into cores that are shipped to the United States.

Despite this trend in imported amorphous metal cores (the trade statistics for which are combined with GOES cores), in June 2020, Metglas announced the commercial launch of its own amorphous metal transformer core business. The company now has in-house capability to produce distribution transformer cores using its amorphous alloy.

The use of amorphous metals in future innovations of the electric grid is an area of research interest to the Department of Energy/National Labs. The National Labs have partnered with Metglas to supply the metal ribbon to support this research; loss of domestic capability to imports would leave the U.S. Government dependent on foreign suppliers for this promising research.

## VIII. U.S. Production Capabilities, Industry Health and Competitiveness, and the Impact of Imports on National Security for Transformers

### *A. Introduction/Summary*

As discussed in Chapter V, LPTs are a critical component of the BPS. Distribution transformers and smaller power transformers are used extensively and play an essential role in the electrical grid of the United States in providing power to commercial and residential customers. In addition to their essential role in the electrical grid, distribution transformers, smaller power transformers, and, in particular, dry-type transformers that can be used indoors play a vital role in other critical infrastructure sectors such as manufacturing, hospitals, and in weapons systems. However, they are not considered to be part of the BPS, the security of which is subject to the Presidential Bulk Power Executive Order.

The Department's survey included 36 companies with domestic manufacturing of transformers of various types and power handling capacities, from 1 kVA to over 100,000 kVA. Table VIII–1 below lists these survey participants, as well as the type(s) of transformers that they manufacture. The survey responses indicate that companies tend to produce either liquid-dielectric transformer or dry-type transformers, although some major producers manufacture both types.

[TEXT REDACTED]

Aggregated data on U.S. production of transformers in various power handling capacities by survey participants are presented in Figure VIII–1. Note that most companies produce transformers in multiple categories. In all, the transformer companies participating in the Department's survey employed 15,238 production workers in the United States and had total transformer sales of $4.42 billion in 2019.

Over the five-year period covered by the survey, domestic production in each transformer product category was been relatively steady. Survey data indicated that the smaller the transformer in terms of power handling capacity, the greater the volume of production, with over one million liquid dielectric transformers with under 650 kVA capacity produced in 2019, compared to just 137 of the largest power transformers (>100,000 kVA).

[TEXT REDACTED]

Figure VIII–3 (below) illustrates the import penetration of a range of transformers of various power handling capacities, using the calculation (apparent consumption = domestic production + imports − exports). These import penetration figures are based on unit production of transformers as reported by respondents to the Department's survey, as well as export and import statistics from the U.S. Census Bureau. Note that actual domestic production is likely higher than listed because the Department's survey did not capture all producers (while the major players in each sector participated in the survey, it is possible that smaller manufacturers did not). This implies that the import penetration levels in the table are overstated, further verifying the conclusion that, with the exception of the largest transformers, import penetration in liquid dielectric transformer categories remains relatively low and domestic production is robust.

In comparison, dry-type transformers have higher levels of imports. However, particularly for the small dry transformer category (under <16 kVA), the Department's survey may represent an incomplete sample of the industry. Millions of these small transformers are produced (and imported) on an annual basis. Due to the lack of sufficient data on U.S. production of dry transformers, a reasonable estimate of import penetration is not possible.

**Figure VIII-3. Transformer Production, Imports, and Exports by Handling Capacity**

| Category (HTS code) | U.S. Production (units) | U.S. Imports | U.S. Exports | Import Penetration |
|---|---|---|---|---|
| Liquid <650 kVA (8504.21) | 1,035,055 | 210,999 | 33,871 | 17% |
| Liquid 650-10,000 kVA (8504.22) | 23,298 | 8,240 | 3,029 | 29% |
| Liquid 10,000-100,000 kVA (8504.23.0040) | 1,640 | 594 | 99 | 28% |
| Liquid >100,000 kVA (8504.23.0080) | 137 | 617 | 5 | 82% |

Source: BIS Survey (Production); USITC Dataweb (Exports and Imports)

The remainder of this section presents industry data and evaluates the status of the domestic industry, as well as the impact of imports, by grouping the transformer industry in general categories: Distribution transformers and small power transformers (liquid dielectric transformers with a power handling capacity up to 10,000 kVA); small and medium power transformers (with power handling capacity of 10,000–100,000 kVA); LPT (100,000 kVA and up); dry-type and other transformers (1 kVA–500 kVA); and voltage regulators.

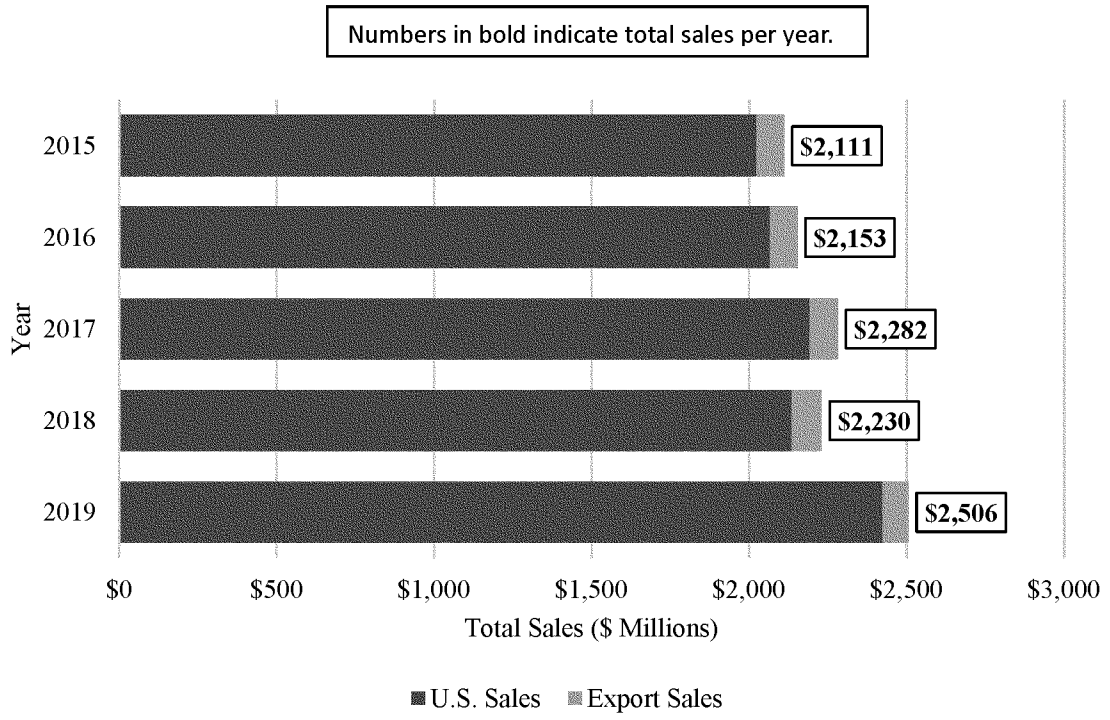
*B. Distribution and Small Power Transformers (Up to 10,000 kVA)*

There were 19 survey respondents reporting domestic production of small power transformers (up to 10,000 kVA) during the 2015–2019 period. Companies in this sector employed more than 10,000 production workers and sold more than a million transformer units, with a total value of $2.5 billion, in 2019.[85]

[TEXT REDACTED].

The data received via the Department's survey is largely consistent with DOE's 2009 market study, which identified that, from a manufacturing point of view, the six largest companies operating in the liquid-immersed distribution transformer market at that time were (in alphabetical order): [TEXT REDACTED]. Together, these six companies represented more than 80 percent of the sales revenue of liquid-immersed distribution transformers in the United States (up to 2,500 kVA) in 2009. [TEXT REDACTED].

**Figure VIII-4. Distribution and Small Power Transformers – Sales by Value (2015-2019)**




Source: U.S. Department of Commerce, Bureau of Industry and Security, Electrical Steel and Transformer-Related Products Survey, Q3b, F-G

*19 Respondents*

[85] Note that there is overlap with employment in other transformer categories as some survey recipients participate in multiple sectors.

[TEXT REDACTED].

[TEXT REDACTED]

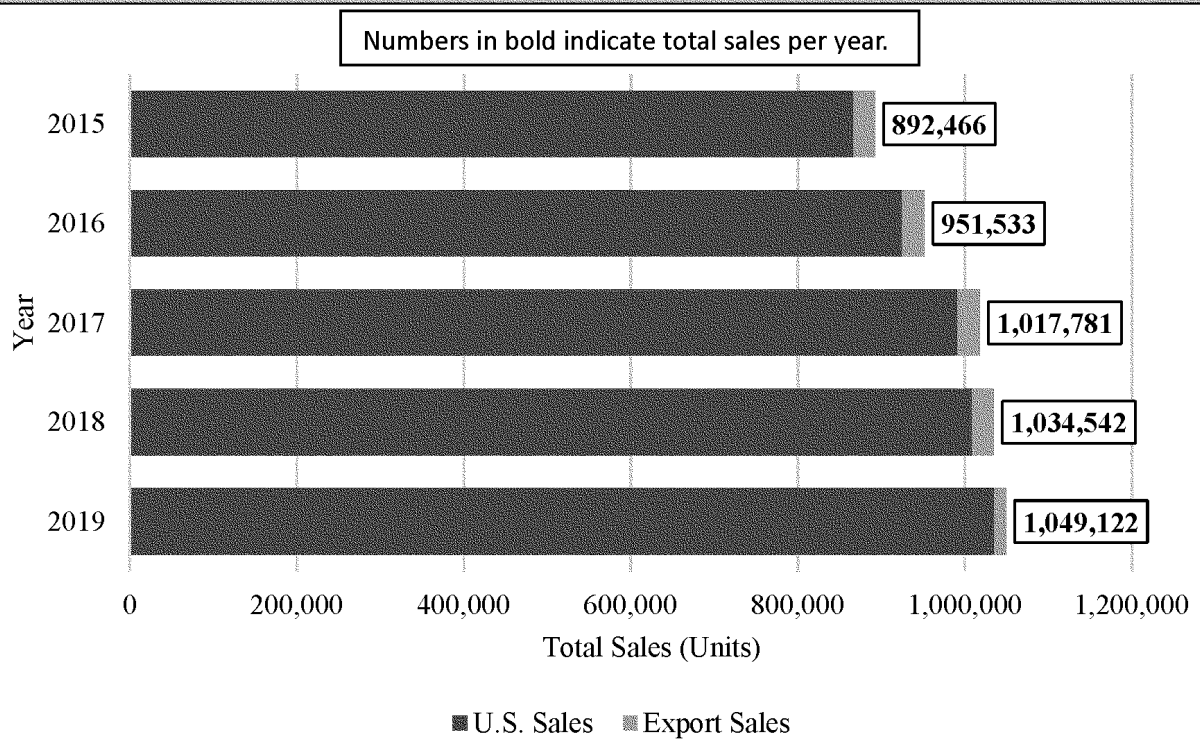
[TEXT REDACTED].

[TEXT REDACTED]

[TEXT REDACTED]

[TEXT REDACTED]

**Figure VIII-9. Distribution and Small Power Transformers – Sales by Volume (2015-2019)**




Source: U.S. Department of Commerce, Bureau of Industry and Security, Electrical Steel and Transformer-Related Products Survey, Q3b, F-G

*19 Respondents*

Both dollar sales and unit sales of transformers in this category have risen consistently over the past five years. The average price of transformers in this category was $55,000. A slight majority of these transformers use cores comprised of GOES (as opposed to other core materials, such as metglas), and on average GOES accounted for about 20 percent of the cost of each transformer.

[TEXT REDACTED]

Figure VIII–X assesses the financial status of the major players in this industry segment. The four market leaders all ranked as ''moderate/elevated risk'' based on the Department's financial risk metric.

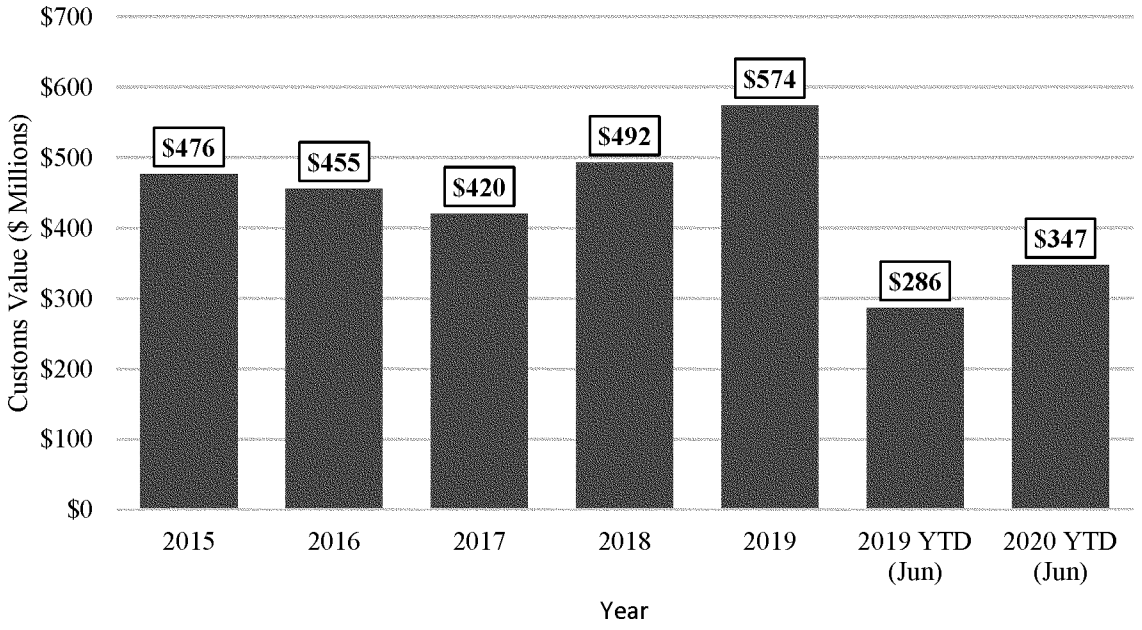
Overall, the companies manufacturing distribution transformers and small power transformers did not devote a high level of funding to research and development (R&D), as compared to R&D spending in other industry sectors. In total, the 19 companies spent about $650 million on R&D each year between 2015–2019, with one company—[TEXT REDACTED]. In part, the low level of R&D spending is because transformers are a mature technology. Other factors include the relatively poor financial status of domestic manufacturers.

Capital investment by the companies in this industry subsector showed a similar pattern: Capital expenditures ranged between $560 and $660 million per year, with [TEXT REDACTED]. The relatively low levels of capital investment is likely due to the factors listed above, including the maturity of the technology and the financial status of domestic manufacturers.

1. Apparent Consumption and Import Penetration

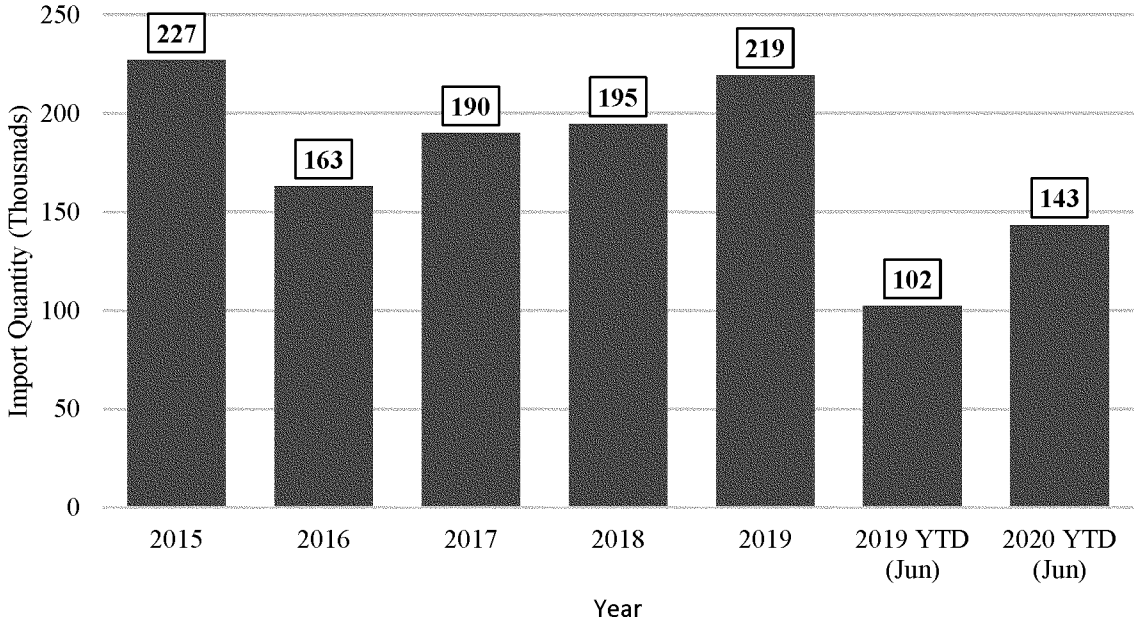
U.S. imports of distribution and small power transformers have remained consistent over the past ten years, averaging about 200,000 units and $500 million per year. Imports in 2019 were slightly above the long-term average, and imports for the first part of 2020 are significantly higher than during the same period in 2019. Mexico is by far the largest source of these imports, accounting for over 80 percent of the units in 2019. Many major global transformer companies have manufacturing facilities in Mexico [TEXT REDACTED], taking advantage of lower labor costs and duty-free access to the U.S. market. The significant suppliers of transformers of this power handling capacity located outside of Mexico are in Canada and China. However, imports from China have declined in recent years from 2013–2014 levels (likely due to the tariffs on many imports from China imposed in recent years), with an increase in the first part of 2020. Imports from Canada remained steady throughout the period.

**Figure VIII-11. Distribution Transformers & Small Power Transformers (<650 KVA to 10,000 KVA) Import Customs Value (2015-2020 YTD Jun)**




Source: United States International Trade Commission, U.S. Department of Commerce, Bureau of Industry and Security

**Figure VIII-12. Distribution Transformers & Small Power Transformers (<650 KVA to 10,000 KVA) Import Customs Quantity (2015-2020 YTD Jun)**




Source: United States International Trade Commission, U.S. Department of Commerce, Bureau of Industry and Security

| Figure VIII-13. Distribution Transformers & Small Power Transformers (<650 KVA to 10,000 KVA) Import Quantities by Top 10 Countries (Units, 2015-2020 YTD Jun) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Country** | **2015** | **2016** | **2017** | **2018** | **2019** | **2019 YTD (Jun)** | **2020 YTD (Jun)** | **SUM*** |
| **Mexico** | 150,696 | 136,823 | 145,907 | 151,687 | 178,375 | 85,592 | 105,622 | **869,110** |
| **China** | 29,833 | 3,706 | 11,465 | 16,270 | 9,075 | 2,069 | 4,531 | **74,880** |
| **Canada** | 11,675 | 10,441 | 11,776 | 12,321 | 13,937 | 6,672 | 6,219 | **66,369** |
| **Taiwan** | 1,121 | 713 | 710 | 2,722 | 6,430 | 138 | 21,873 | **33,569** |
| **United Kingdom** | 14,049 | 1,180 | 358 | 267 | 186 | 25 | 103 | **16,143** |
| **Poland** | - | - | 4,896 | 2,520 | 3,059 | 3,053 | 8 | **10,483** |
| **Hong Kong** | 6,297 | 795 | 40 | 32 | - | - | - | **7,164** |
| **India** | 903 | 5 | 4,481 | 1,007 | 6 | 5 | 7 | **6,409** |
| **Germany** | 1,295 | 1,117 | 915 | 1,140 | 779 | 552 | 605 | **5,851** |
| **Sri Lanka** | 5,567 | - | - | - | - | - | - | **5,567** |
| Source: United States International Trade Commission, U.S. Department of Commerce, Bureau of Industry and Security<br>*Excludes 2019 YTD (Jun) Data | | | | | | | | |

Based on sales information provided through survey responses and Census import and export statistics, import penetration was about 18 percent for this industry segment (liquid dielectric transformers up to 10,000 kVA) in 2019. Based on production data for transformers in these power handling capacities from the survey, import penetration was 20.6 percent.

2. Reliance on Foreign Sources for Transformer Components

Despite the relatively low level of the market for finished transformers accounted for by imports, domestic transformer producers rely heavily upon foreign sources for critical components. Using imported laminations and cores contributes to their competitiveness by reducing costs. Many of them never had or no longer have in-house capability to manufacture transformer cores. Even those that do have this capability have either begun to source some of these items from abroad in order to stay competitive or have eliminated in-house production all together. For the major companies in this industry segment:

- [TEXT REDACTED].
- [TEXT REDACTED].
- [TEXT REDACTED].
- [TEXT REDACTED].

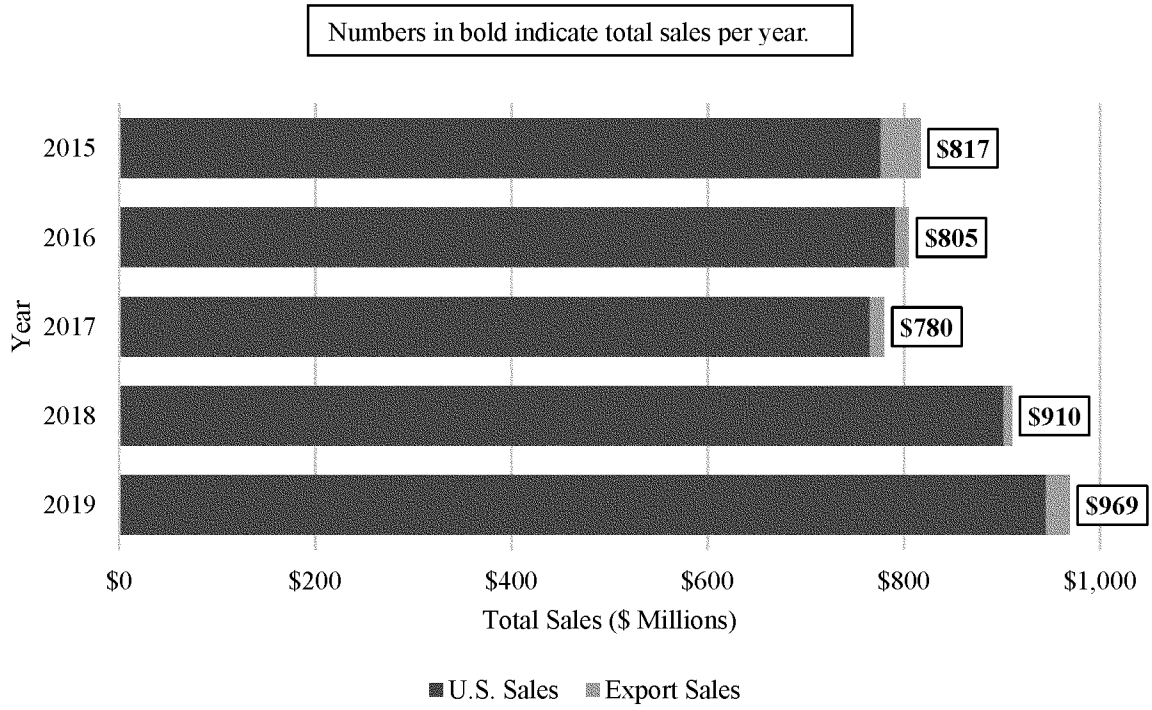
*C. Medium Power Transformers (10,000 kVA–100,000 kVA)*

Ten survey respondents indicated that they domestically produced transformers with power handling capacities between 10,000kVA and 100,000 kVA. The sales price of transformers in this broad category averaged about $500,000. About 90 percent of these transformers used GOES in their cores, and the cost of GOES accounted for about 13 percent of transformer production costs.

Total domestic employment in this industry segment was about 7,200 production workers. [TEXT REDACTED].

Survey participants had sales of transformers in this size range of about 1,700 units valued at $969 million in 2019. [TEXT REDACTED].

**Figure VIII-14. Medium Power Transformers – Sales by Value (2015-2019)**



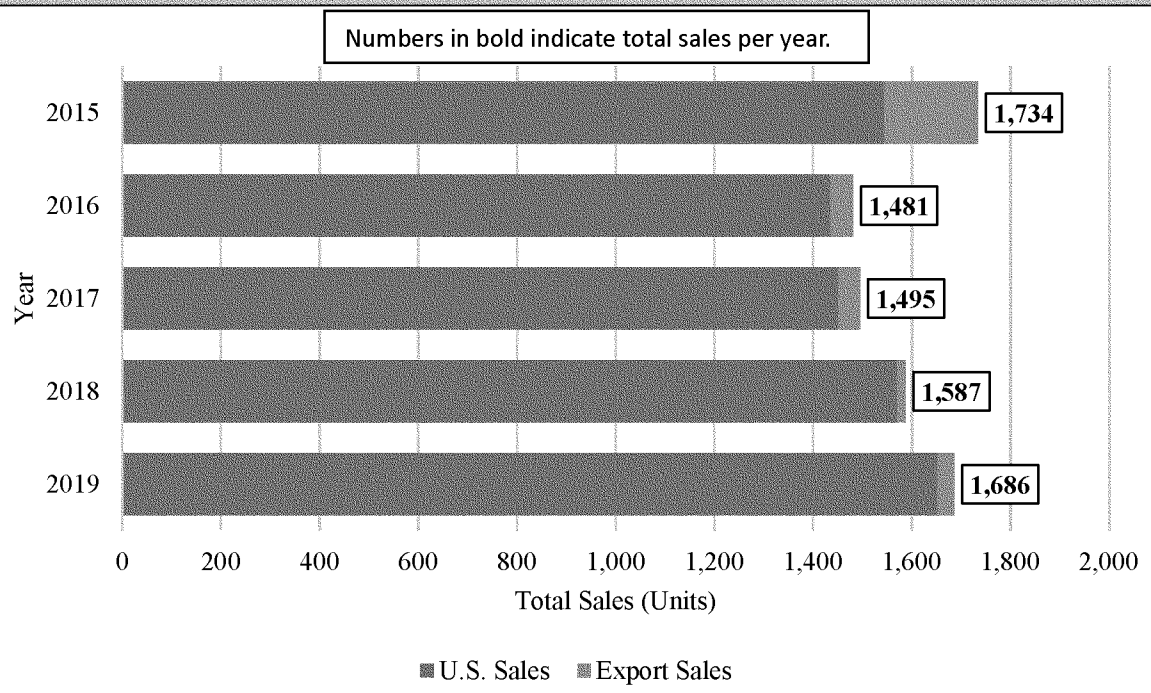

Source: U.S. Department of Commerce, Bureau of Industry and Security, Electrical Steel and Transformer-Related Products Survey, Q3b, H-I

*10 Respondents*

[TEXT REDACTED].

| |
|---|
| [TEXT REDACTED] |
| [TEXT REDACTED] |
| [TEXT REDACTED] |

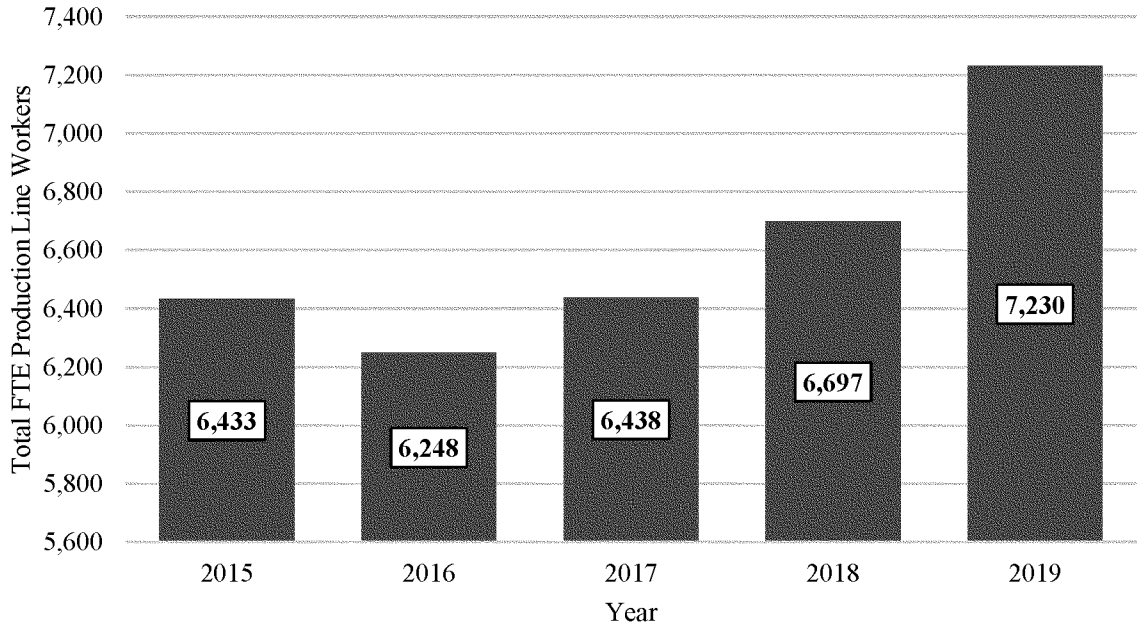
**Figure VIII-17. Medium Power Transformers – Sales by Volume (2015-2019)**




Source: U.S. Department of Commerce, Bureau of Industry and Security, Electrical Steel and Transformer-Related Products Survey, Q3b, H-I

*10 Respondents*

**Figure VIII-19. Medium Power Transformers Production Line Employment (2015-2019)**
[TEXT REDACTED]




Source: U.S. Department of Commerce, Bureau of Industry and Security, Electrical Steel and Transformer-Related Products Survey, Q7, A

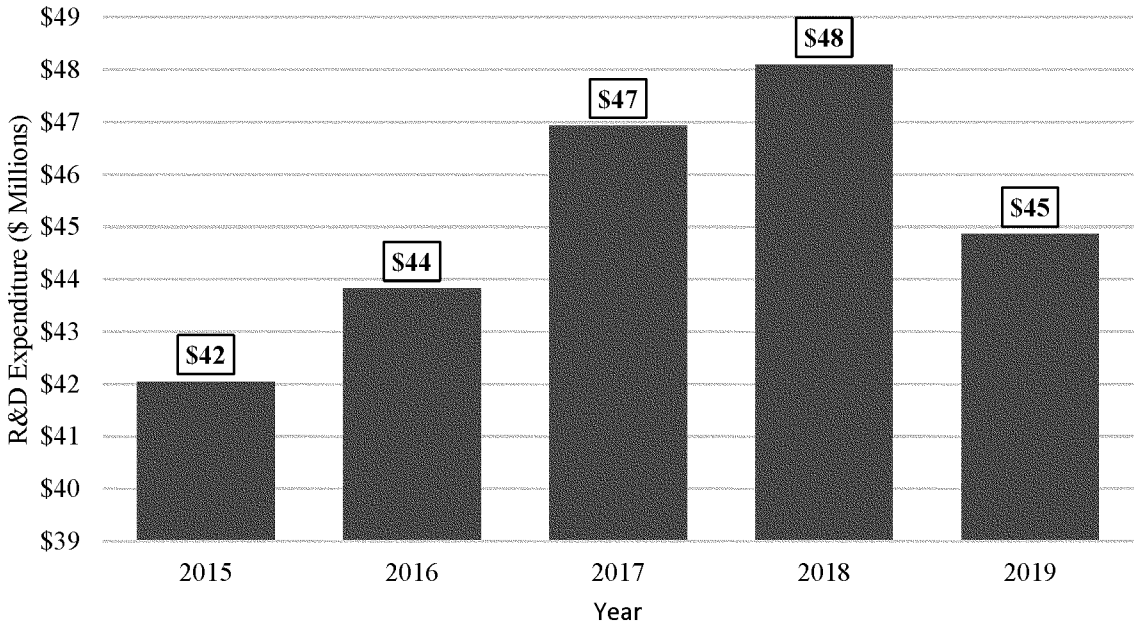
*9 Respondents*

[TEXT REDACTED]

A measure of the financial performance of the top firms in the medium power transformer category is presented in Figure VIII–20. In general, the market leaders are financially healthy based on the Department's metrics, with the exception of Hyundai. [TEXT REDACTED].

In total, the ten companies with production of transformers in this segment spent $45 million on R&D in 2019. Of this total, four companies—[TEXT REDACTED].

**Figure VIII-21. Medium Power Transformer Manufacturers R&D Expenditure (2015-2019)**

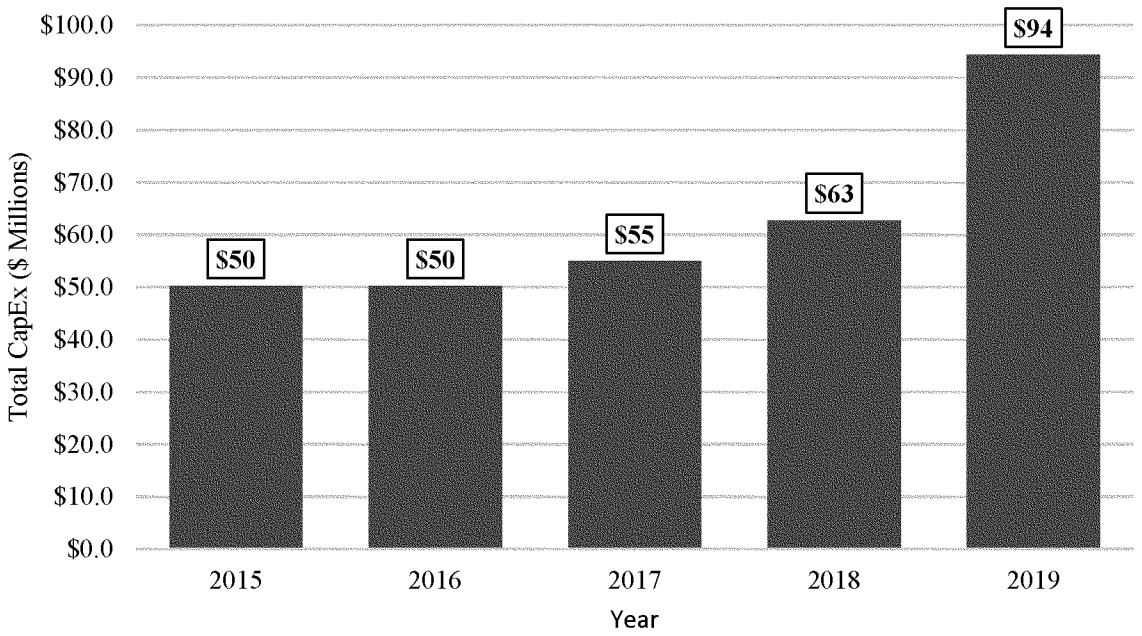



Source: U.S. Department of Commerce, Bureau of Industry and Security, Electrical Steel and Transformer-Related Products Survey, Q6

*10 Respondents*

Aggregated capital expenditures for the ten companies are presented below. [TEXT REDACTED].

**Figure VIII-22. Medium Power Transformer Manufacturers Capital Expenditure (2015-2019)**



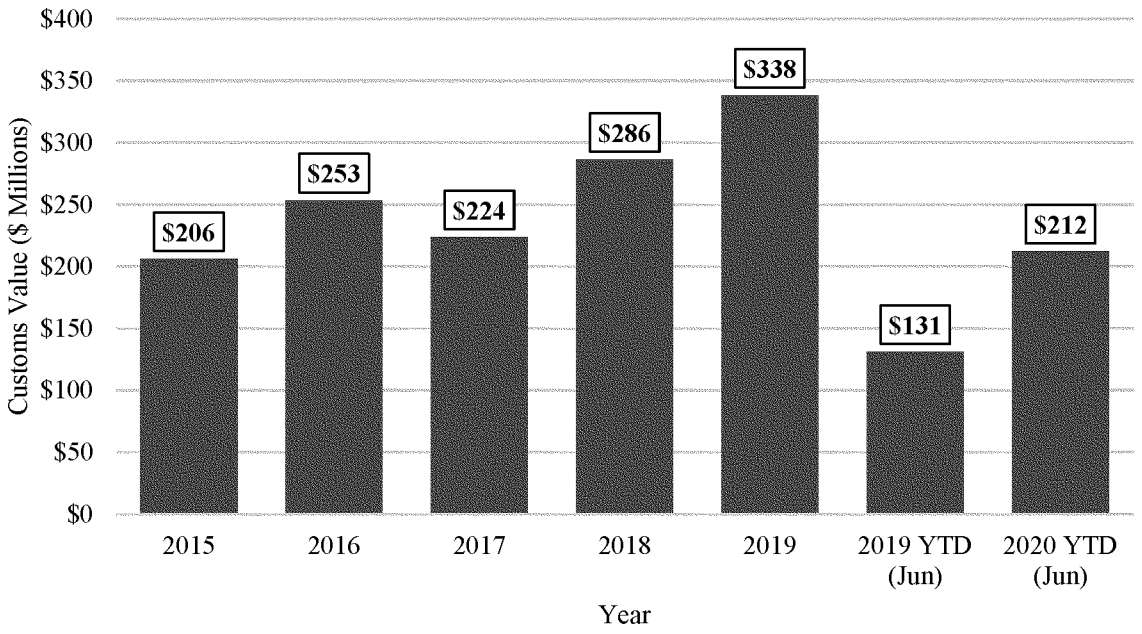

Source: U.S. Department of Commerce, Bureau of Industry and Security, Electrical Steel and Transformer-Related Products Survey, Q6

*19 Respondents*

1. Apparent Consumption and Import Penetration

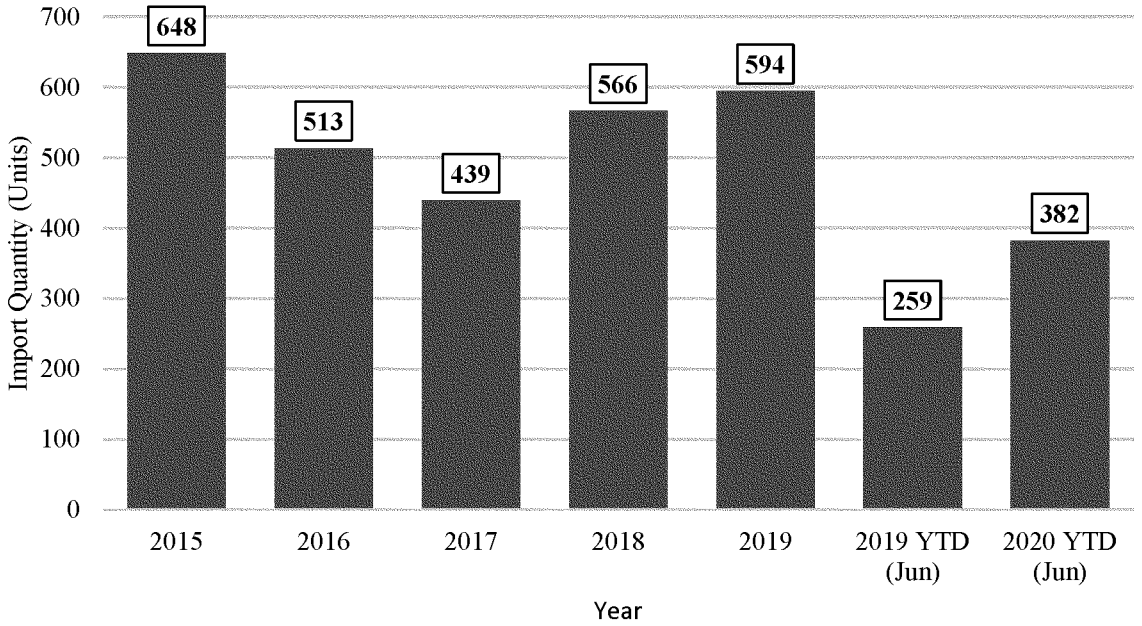
Imports of transformers in the medium power handling capacity range have increased over the past three years and are on track to exceed $400 million in 2020, on the basis of data from the first six months of the year. On a unit basis, imports show a similar trend, exceeding 600 units per year. Mexico and South Korea are by far the largest sources of imported transformers in this subsector.

**Figure VIII-23. Medium Power Transformers (10,000 KVA to 100,000 KVA) Import Customs Value (2015-2020 YTD Jun)**




Source: United States International Trade Commission, U.S. Department of Commerce, Bureau of Industry and Security

**Figure VIII-24. Medium Power Transformers (10,000 KVA to 100,000 KVA) Import Customs Quantity (2015-2020 YTD Jun)**




Source: United States International Trade Commission, U.S. Department of Commerce, Bureau of Industry and Security

**Figure VIII-25. Medium Power Transformers (10,000 KVA to 100,000 KVA) Import Quantities by Top 10 Countries (Units, 2015-2020 YTD Jun)**

| Country | 2015 | 2016 | 2017 | 2018 | 2019 | 2019 YTD (Jun) | 2020 YTD (Jun) | SUM* |
|---|---|---|---|---|---|---|---|---|
| **Mexico** | 430 | 234 | 255 | 254 | 280 | 135 | 150 | **1,603** |
| **South Korea** | 43 | 90 | 66 | 109 | 124 | 61 | 73 | **505** |
| **Taiwan** | 72 | 45 | 15 | 37 | 36 | 12 | 26 | **231** |
| **Germany** | 6 | 38 | 42 | 66 | 38 | 13 | 15 | **205** |
| **Austria** | 9 | 19 | 25 | 32 | 39 | 9 | 36 | **160** |
| **Portugal** | 41 | 6 | 14 | 14 | 30 | 9 | 10 | **115** |
| **Colombia** | 5 | 18 | 4 | 40 | 13 | 10 | 23 | **103** |
| **Brazil** | 0 | 11 | 4 | 1 | 0 | - | 23 | **39** |
| **Japan** | 12 | 4 | 2 | 0 | 8 | 0 | 12 | **38** |
| **Italy** | 14 | 4 | 1 | 4 | 3 | 0 | 1 | **27** |

Source: United States International Trade Commission, U.S. Department of Commerce, Bureau of Industry and Security
*Excludes 2019 YTD (Jun) Data

Based on production as reported on the Department's survey and Census Bureau-based import statistics, import penetration in this industry segment was 28 percent on both a unit and value basis.

As with other transformer categories, companies that produce transformers between 10,000 and 100,000 kVA rely heavily on imports for key components. The company snapshots show leading suppliers for the essential items—GOES, laminations, and/or cores.

*D. Dry-Type Transformers*

Of all of the transformer categories covered by this investigation, dry transformers had the greatest direct

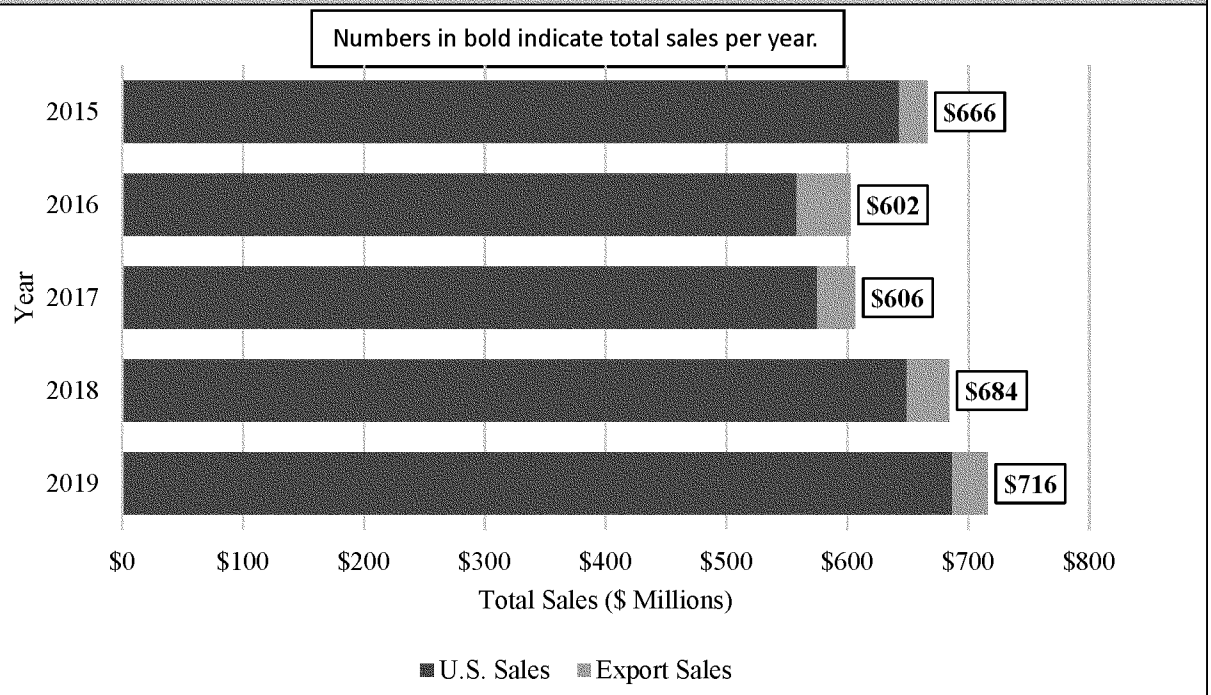
usage in defense applications. This is because this type of transformer is designed for safe usage indoors (including on ships and aircraft), as it poses fewer environmental and fire risks than do oil-immersed transformers. However, defense applications represent only a small percentage of sales of these types of transformers, which are also used extensively in the electrical grid, as well as in a multitude of industrial and commercial applications.

The Department's survey data capture input from the predominant players in the dry-type transformer category, but are less complete than for other industry sub-segments. Particularly for the smallest dry-type transformers (under <16kVA), production (and imports) is in the millions of units, and the survey did not fully capture this. Despite this, the survey provided useful information on industry trends and competitiveness issues.

Twenty-one survey participants with just over 9,000 production workers sold 1.8 million dry transformers of various power handling capacities between 2015 and 2019. However, production in the United States was about half of this unit total because most of the major players have both domestic and overseas production facilities and distribute the product from both in the United States. Total sales by these respondents were about $700 million, with the average transformer price about $13,000. In aggregate, about half of these dry-type transformers require GOES in their cores, according to the survey respondents; when it was used, it accounted for about 25 percent of the cost of the transformer.

Six respondents represent about 97 percent of dry-type transformer sales (of all capacities) by value from 2015–2019. [TEXT REDACTED]. Note that these sales values include transformers manufactured outside the United States, as reported by several of the survey recipients.

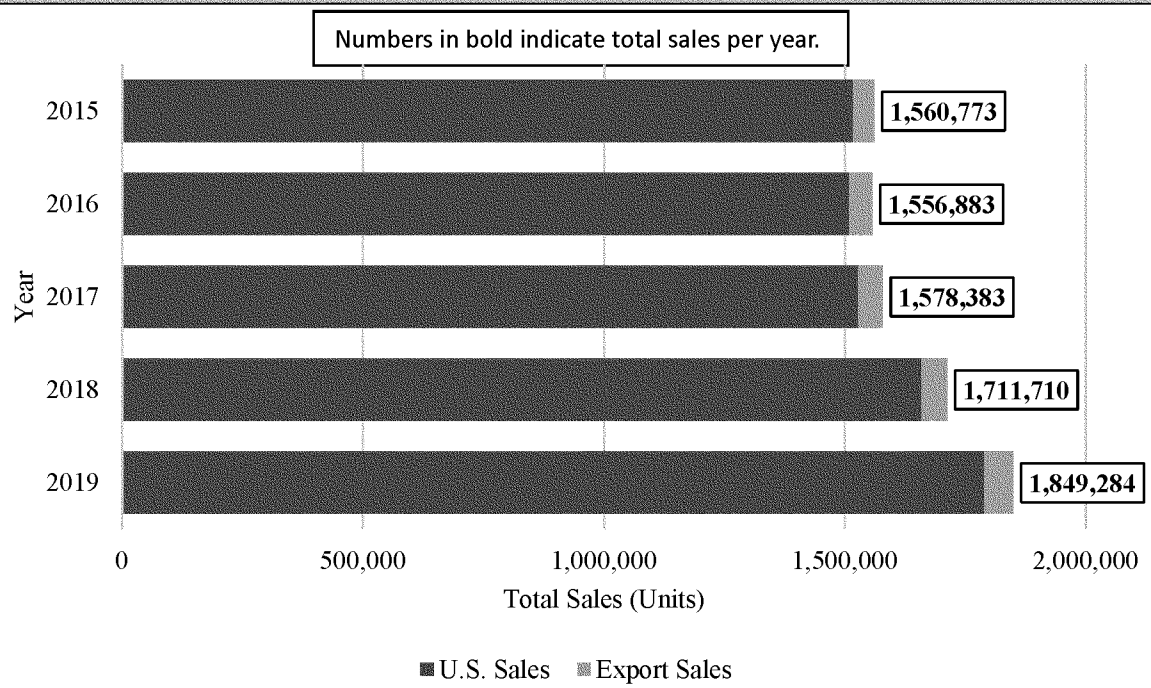
**Figure VIII-26. Dry –Type Transformers – Sales by Value (2015-2019)**




Source: U.S. Department of Commerce, Bureau of Industry and Security, Electrical Steel and Transformer-Related Products Survey, Q3b, K-M

*21 Respondents*

**Figure VIII-27. Dry-Type Transformers – Sales by Volume (2015-2019)**
[TEXT REDACTED]

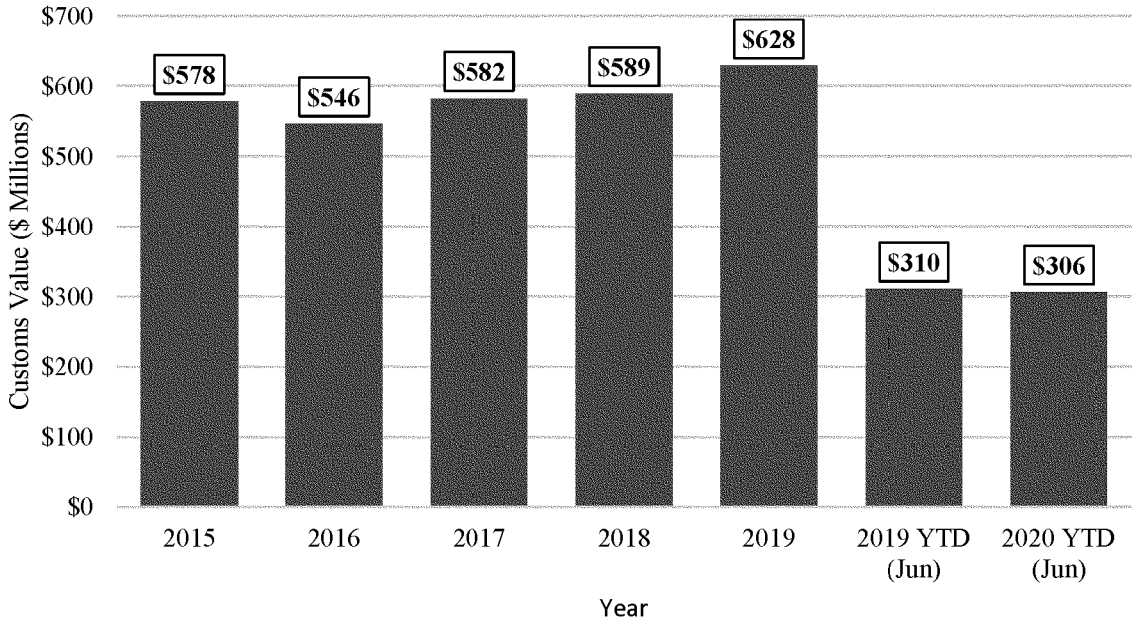



Source: U.S. Department of Commerce, Bureau of Industry and Security, Electrical Steel and Transformer-Related Products Survey, Q3b, K-M

*21 Respondents*

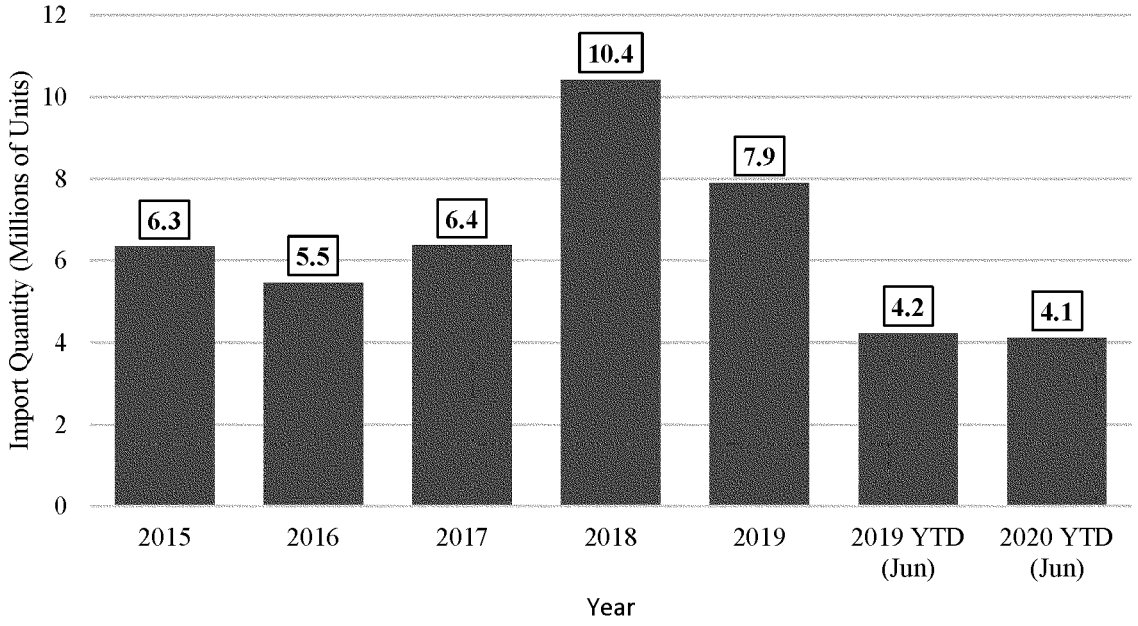
As indicated above, imports play a major role in the dry transformer sector. Countries with low cost labor—including China, Indonesia, and Mexico—are major sources of imported dry-type transformers. On a unit basis, more than half of dry-type transformer imports originate in China.

**Figure VIII-28. Dry-Type and Other Transformers Import Customs Value (2015-2020 YTD Jun)**



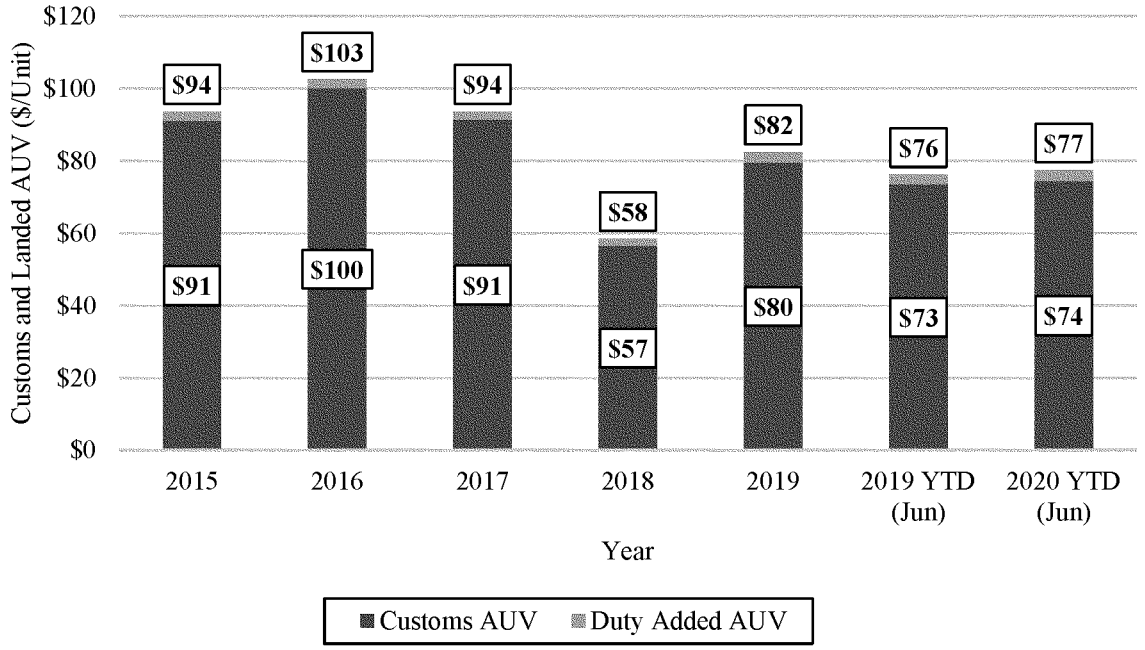

Source: United States International Trade Commission, U.S. Department of Commerce, Bureau of Industry and Security

**Figure VIII-29. Dry-Type and Other Transformers Import Customs Quantity (2015-2020 YTD Jun)**




Source: United States International Trade Commission, U.S. Department of Commerce, Bureau of Industry and Security

**Figure VIII-30. Dry-type and Other Transformers Import Customs AUV (2015-2020 YTD Jun)**




Source: United States International Trade Commission, U.S. Department of Commerce, Bureau of Industry and Security
*Data labels indicate the final Duty Landed AUV

**Figure VIII-31. Dry and Other Transformers Import Quantities by Top 10 Countries (Thousands of Units, 2015-2020 YTD Jun)**

| Country | 2015 | 2016 | 2017 | 2018 | 2019 | 2019 YTD (Jun) | 2020 YTD (Jun) | SUM* |
|---|---|---|---|---|---|---|---|---|
| **China** | 2,482 | 2,341 | 3,006 | 6,689 | 4,993 | 2,785 | 2,858 | **22,369** |
| **Indonesia** | 1,736 | 1,648 | 1,840 | 1,253 | 1,148 | 658 | 300 | **7,926** |
| **Mexico** | 667 | 528 | 605 | 1,082 | 754 | 315 | 323 | **3,959** |
| **India** | 291 | 253 | 207 | 230 | 260 | 157 | 87 | **1,328** |
| **France** | 248 | 18 | 36 | 336 | 223 | 72 | 130 | **991** |
| **Honduras** | 147 | 92 | 68 | 115 | 128 | 66 | 33 | **584** |
| **Germany** | 276 | 130 | 16 | 42 | 10 | 6 | 3 | **477** |
| **Taiwan** | 80 | 83 | 96 | 38 | 32 | 15 | 138 | **468** |
| **Canada** | 94 | 53 | 87 | 117 | 67 | 40 | 35 | **453** |
| **Malaysia** | 70 | 167 | 53 | 52 | 13 | 7 | 6 | **361** |

Source: United States International Trade Commission, U.S. Department of Commerce, Bureau of Industry and Security
*Excludes 2019 YTD (Jun) Data

During the time period, dry-type transformers in the 1–16 kVA range were both produced domestically and imported by the millions. Leading domestic producers, including [TEXT REDACTED], together accounted for over 80 percent of the production volume by survey participants in 2019. [TEXT REDACTED]. The average sales price was just $20. [TEXT REDACTED]. The primary application for these transformers is in industrial settings for power distribution.

[TEXT REDACTED].

While it was not possible to determine import penetration levels due to lack of data on U.S. production, based on official trade statistics, imports of dry-type transformers in the 1–16 kVA range have a significant market presence. In this sector, Mexico and China are the leading suppliers, with China accounting for much of the volume (over million units) and Mexico

much of the value of total imports (due to varying sizes and prices of transformers). As mentioned, a number of the U.S. companies in participating this sector have overseas production facilities and contribute to the import volume.

| Figure VIII-32. Dry and Other Transformers (<1 KVA to 16 KVA) Import Value by Top 10 Countries ($ Millions, 2015-2020 YTD Jun) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Country** | **2015** | **2016** | **2017** | **2018** | **2019** | **2019 YTD (Jun)** | **2020 YTD (Jun)** | **SUM*** |
| **Mexico** | $36.7 | $40.3 | $33.5 | $40.1 | $48.4 | $24.7 | $21.1 | **$220.1** |
| **China** | $31.0 | $33.5 | $31.1 | $24.1 | $20.8 | $8.3 | $13.1 | **$153.7** |
| **Canada** | $7.9 | $8.4 | $8.6 | $9.0 | $10.5 | $5.6 | $4.3 | **$48.8** |
| **Germany** | $6.5 | $6.6 | $4.8 | $7.0 | $6.3 | $2.9 | $2.9 | **$34.0** |
| **Japan** | $6.8 | $5.6 | $6.1 | $3.0 | $3.3 | $1.1 | $3.5 | **$28.4** |
| **Philippines** | $4.7 | $3.6 | $3.6 | $4.4 | $4.9 | $2.1 | $2.6 | **$23.7** |
| **Taiwan** | $4.2 | $3.7 | $2.8 | $3.4 | $3.7 | $1.7 | $1.9 | **$19.7** |
| **United Kingdom** | $2.8 | $1.9 | $2.8 | $3.0 | $2.3 | $1.3 | $1.4 | **$14.1** |
| **Sri Lanka** | $2.3 | $2.1 | $2.4 | $2.4 | $2.5 | $0.9 | $1.3 | **$13.1** |
| **France** | $1.6 | $3.2 | $2.2 | $1.6 | $2.3 | $0.8 | $0.8 | **$11.7** |
| **ROW** | $11.0 | $9.2 | $12.8 | $13.1 | $13.4 | $5.7 | $6.9 | **$66.5** |
| **Total** | **$115.6** | **$118.2** | **$110.8** | **$110.9** | **$118.4** | **$55.2** | **$59.9** | **$633.8** |
| **AVG AUV ($/Unit)** | $25.42 | $28.16 | $22.67 | $13.62 | $17.58 | $16.68 | $16.57 | $20.10 |

Source: United States International Trade Commission, U.S. Department of Commerce, Bureau of Industry and Security
(HTS 8504.32)
*Excludes 2019 YTD (Jun)

In the 16–500 kVA dry-type transformer category, the leading domestic producers were [TEXT REDACTED]. These transformers were produced domestically in the tens of thousands of units, are valued in the $2,500 to $25,000 range, and are used in electric power distribution for commercial and industrial customers. GOES is used in almost all transformers in this range, and accounts for up to 50 percent of production costs.

Manufacturers in this industry sector manufacture distribution transformers that are subject to the DOE Energy Efficiency Standards that took effect in 2016. The new standards increased manufacturers' demand for higher grades of GOES in order to remain competitive in the bidding process. Business decisions to remain competitive after the introduction of the DOE standards also increased demand for the quantity of GOES, as well as laminations, and cores, from global suppliers. For example, [TEXT REDACTED].

[TEXT REDACTED].

Statistics on imports of dry-type transformers between 16 and 500 kVA are presented in Table VIII–33 below. Once again, China and Mexico are the major sources for imports, with India and France also supplying substantial numbers. Based on survey data, it appears that transformers in this broad category that are manufactured in the United States have a higher unit value than imports.

| Figure VIII-33. Dry and Other Transformers (<16 KVA to 500 KVA) Import Quantities by Top 10 Countries (Thousands of Units, 2015-2020 YTD Jun) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Country** | **2015** | **2016** | **2017** | **2018** | **2019** | **2019 YTD (Jun)** | **2020 YTD (Jun)** | **SUM*** |
| **China** | 788 | 655 | 782 | 826 | 356 | 224 | 76 | **3,483** |
| **Mexico** | 279 | 206 | 241 | 720 | 237 | 122 | 116 | **1,800** |
| **India** | 258 | 231 | 184 | 213 | 232 | 142 | 76 | **1,194** |
| **France** | 247 | 17 | 35 | 332 | 223 | 72 | 130 | **984** |
| **Hong Kong** | 52 | 12 | 128 | 84 | 0.3 | 0.3 | 0.1 | **276** |
| **Canada** | 14 | 18 | 54 | 54 | 29 | 21 | 19 | **188** |
| **Germany** | 57 | 45 | 10 | 5 | 3 | 1 | 1 | **122** |
| **Taiwan** | 25 | 29 | 25 | 8 | 15 | 7 | 9 | **112** |
| **Hungary** | 26 | 0.003 | 5 | 1 | 1 | 1 | 0.1 | **32** |
| **Spain** | 0.1 | 0.4 | 1 | 1 | 25 | 0 | 3 | **31** |
| **ROW** | 14 | 31 | 10 | 16 | 30 | 17 | 14 | **116** |
| **Total** | **1,762** | **1,245** | **1,475** | **2,260** | **1,150** | **607** | **445** | **8,337** |
| **Average AUV** | $177 | $258 | $245 | $158 | $320 | $360 | $404 | $275 |

Source: United States International Trade Commission, U.S. Department of Commerce, Bureau of Industry and Security
(HTS 8504.33)
*Excludes 2019 YTD (Jun) Data

In the largest dry-type transformer category (>500kVA), the domestic industry leaders are [TEXT REDACTED].

The average value of Federal Pacific's transformers in this size range was $23,000. They are used for electrical power delivery to industrial, commercial, and residential customers. High-quality GOES is required in order to meet DOE energy efficiency standards for this product, and accounts for 50 percent of the cost of the transformers. [TEXT REDACTED].

As with the other dry-type transformer categories, imports are significant and the major sources are China, Mexico, and India. Imports in 2015 were significantly greater than in other years, due to high import levels that year reported from China and India. In 2019 and the first six months of 2020, Mexico was by far the leading supplier.

| Figure VIII-34. Dry and Other Transformers (>500 KVA) Import Quantities by Top 10 Countries (Units, 2015-2020 YTD Jun) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Country** | **2015** | **2016** | **2017** | **2018** | **2019** | **2019 YTD (Jun)** | **2020 YTD (Jun)** | **SUM*** |
| **China** | 15,466 | 3,828 | 456 | 730 | 1,137 | 432 | 1,051 | **22,668** |
| **Mexico** | 1,691 | 1,986 | 1,812 | 1,671 | 3,967 | 2,334 | 1,673 | **12,800** |
| **India** | 3,388 | 392 | 36 | 274 | 1,235 | 793 | 513 | **5,838** |
| **Canada** | 958 | 718 | 800 | 683 | 793 | 384 | 390 | **4,342** |
| **Hong Kong** | 2,040 | 1 | 3 | 13 | 1 | 1 | - | **2,058** |
| **Germany** | 571 | 506 | 193 | 172 | 291 | 168 | 161 | **1,894** |
| **Malaysia** | 214 | 100 | 336 | 360 | 35 | 18 | 103 | **1,148** |
| **South Korea** | 142 | 49 | 32 | 466 | 98 | 65 | 95 | **882** |
| **Poland** | 13 | 51 | 259 | 334 | 202 | 89 | - | **859** |
| **Spain** | 101 | 29 | 144 | 237 | 211 | 160 | 136 | **858** |
| **ROW** | 827 | 1,046 | 614 | 767 | 441 | 116 | 439 | **4,134** |
| **Total** | **25,411** | **8,706** | **4,685** | **5,707** | **8,411** | **4,560** | **4,561** | **57,481** |
| **Average AUV** | $5,936 | $12,216 | $23,349 | $21,137 | $16,884 | $17,276 | $19,911 | $16,673 |

Source: United States International Trade Commission, U.S. Department of Commerce, Bureau of Industry and Security
(HTS 8504.34)
*Excludes 2019 YTD (Jun) Data

*E. Large Power Transformers*

LPTs are the transformers most critical to the BPS and the critical energy infrastructure of the United States. They are used to ''step-up'' power at the power generation site for long-distance transmission, and then to ''step-down'' the power to the levels that are needed for industrial, commercial, military and household consumers. Because they serve the greatest number of customers, the failure or destruction of just a single LPT can have a large impact on U.S. economic, public health, and security interests. Moreover, long procurement lead times and limited availability of spare LPTs and the parts thereof have serious implications for the resiliency of critical infrastructure.

[TEXT REDACTED].[86] Power transformers fell into the highest category for both criticality and supply chain vulnerability. In terms of criticality, transformers are complex, vulnerable to failure, have a significant impact on the BPS in the case of failure, and have a lengthy replacement time. The Market Study also found transformers pose a high risk in the supply chain, as suppliers are dominated by foreign-owned companies, with a minimum of four years required to establish domestic manufacturing capability.

The U.S. market for LPTs is less than 1,000 units per year; their average lifespan is 30 to 40 years and relatively few are needed because they serve large populations. Despite the relatively small quantities produced and purchased annually, there is a sizable market for LPTs because each has a value in the millions of dollars. Moreover, because of their enormous size (up to 400 tons), these LPTs account for a significant percentage of consumption of GOES by weight.

1. Domestic Production Capacity

The Department's survey gathered detailed industry data on all domestic manufacturers of LPTs (here defined as those with greater than 100 MVA power handling capacity, HTS 8504.23.0080). While most of these manufacturers of LPTs also make liquid transformers of lesser power handling capacities, manufacturers of smaller power transformers cannot easily produce larger units, as they typically do not have the necessary equipment, such as large overhead cranes and annealing equipment, to produce LPTs.

In 2019, seven companies manufactured LPTs of 100 MVA or more in the United States: [TEXT REDACTED]. In 2020, Mitsubishi sold its Memphis transformer facility, and no longer manufactures LPTs (or any transformers) in the United States. Hyosung (HICO) of Korea purchased the facility and intends to manufacture transformers there, including LPTs, but as of the date of this report had not begun production.

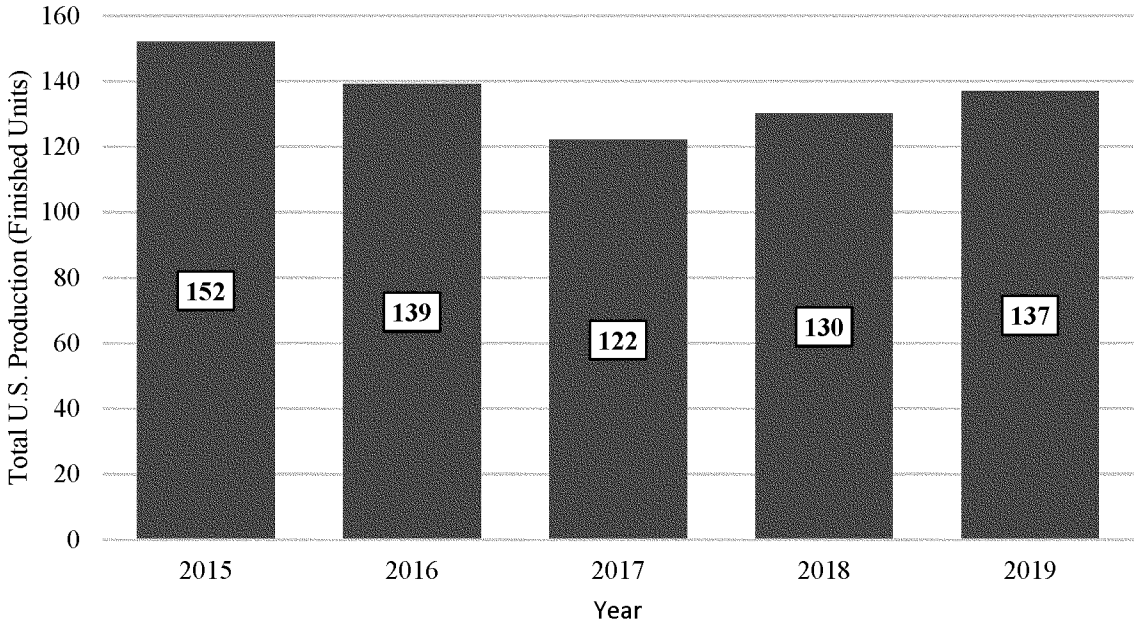
[TEXT REDACTED][87]

Domestic production of LPTs has been fairly steady over the past five years, albeit at a low level of about 130 units per year (see Figure VIII–35). [TEXT REDACTED].

[86] [TEXT REDACTED].

[87] [TEXT REDACTED].

**Figure VIII-36. U.S. Liquid-Dielectric Transformer Over 100,000 KVA Production (2015-2019)**




Source: U.S. Department of Commerce, Bureau of Industry and Security, Electrical Steel and Transformer-Related Products Survey, Q3a, J

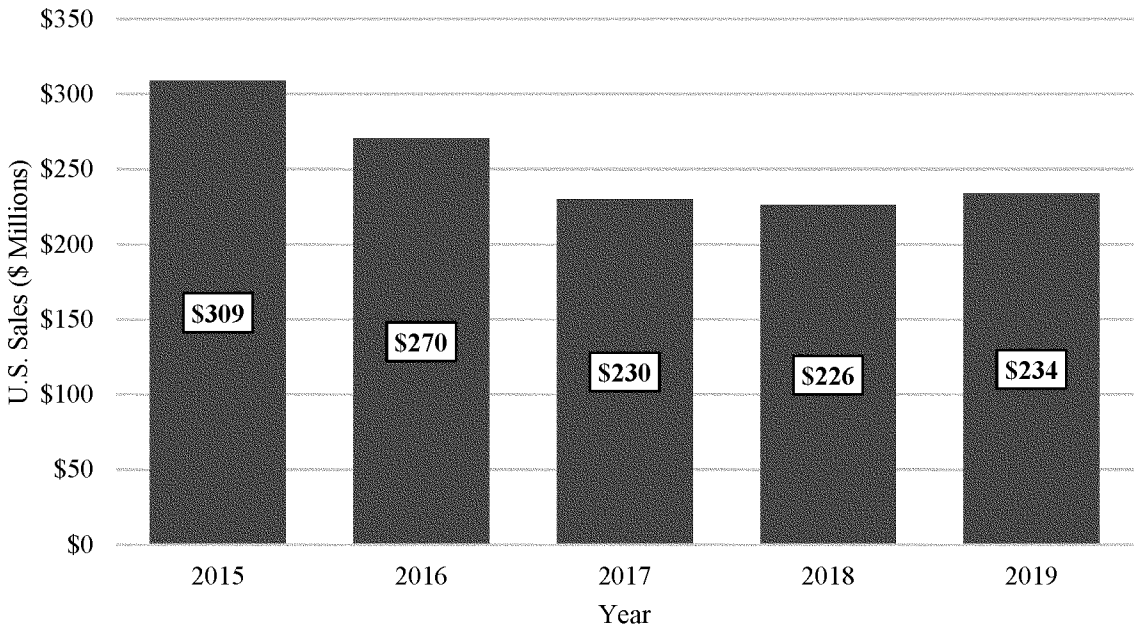
*7 Respondents*

In 2019, [TEXT REDACTED]. Whereas most domestic producers of LPTs also manufacture transformers of lesser power handling capacities in the same facility, [TEXT REDACTED].

In terms of LPT sales, the trend is similar to production, with total sales averaging around $250 million per year (Figure VIII–36). [TEXT REDACTED]. Export sales of U.S.-produced large transformers are negligible, with none reported in 2019 by the domestic manufacturers.

[TEXT REDACTED]

**Figure VIII-38. Liquid-Dielectric Transformer Over 100,000 KVA U.S. Sales (2015-2019)**
****Note: Excludes companies that distribute Liquid-Dielectric Transformer Over 100,000 KVA*****




Source: U.S. Department of Commerce, Bureau of Industry and Security, Electrical Steel and Transformer-Related Products Survey, Q3b, J

*7 Respondents*

Overall domestic production capacity of LPTs remains inadequate to meet domestic demand, particularly with regard to the extra high voltage (EHV) transformers (those with >345 kV voltage rating) that are vital for long distance electricity transmission. While accounting for only a small percentage of units, EHV transformers are the most critical to the security and reliability of the electrical grid, because they handle over 60 percent of all electricity in the country.[88] The loss of Mitsubishi Electric Power (MEPPI) as a domestic manufacturer is significant in this regard, as their facility produced EVH transformers.

Only three companies—[TEXT REDACTED].

[TEXT REDACTED]

The domestic industry is in a constant state of flux—due to plant closures, company exits and entrances, and acquisitions—that affects production capacity. As noted above, Mitsubishi ceased production at its facility in Memphis, with a loss of 200 jobs. HICO (Korea) purchased this facility and plans to invest $103 million in the plant and hire 131 workers by 2021, but at present the facility is not operational. Another company that had briefly produced LPTs in the United States, Portugal-based EFACEC, sold its plant in Rincon, Georgia to Virginia Transformer in 2014.

In addition, ABB shuttered its St. Louis LPT manufacturing facility in late 2018, with a loss of 250 jobs; it also laid off 177 workers at its South Boston, VA plant that primarily produces smaller transformers and has limited capacity to produce LPTs. Some of the production formerly done in the United States will be performed at ABB's Varennes, Quebec plant, which is reportedly Canada's largest LPT manufacturing facility. ABB is also reportedly adding to its transformer production capabilities in India and China.[89]

Moreover, ABB's Power Grids business—including transformers—was sold to Hitachi of Japan in 2018 for $11 billion (with the deal due to close in mid-2020).[90] Hitachi has not indicated its plans for ABB's U.S. operations, which are substantial (including distribution transformer production). If Hitachi decides not to continue operations once it finalizes the purchase of ABB's U.S operations, the impact will be significant; ABB claims that it was the manufacturer for 70 percent of the power transformers installed in the U.S. electric grid (including those made by Westinghouse's Transmission and Distribution Division, which ABB acquired in 1989).

2. Apparent Consumption and Import Penetration

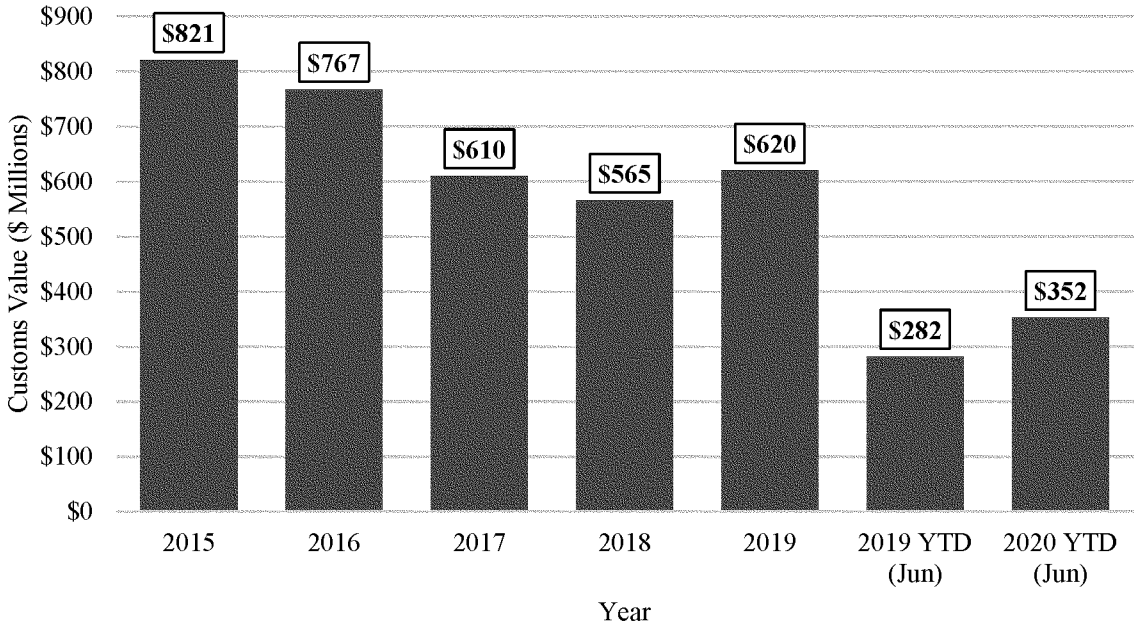
As noted above, domestic demand for the mature LPTs market is relatively stable from year to year and is largely based on the replacement and modernization of aging equipment. Given the limited production and capacity of domestic manufacturers, the majority of demand is met through imports.

[88] Public Comments submitted by the Government of Canada, July 2, 2020.

[89] STLtoday. Nov. 6, 2017. *https://www.stltoday.com/business/local/abb-to-discontinue-production-in-st-louis-120-jobs-lost/article_c18fe08f-ab76-5e02-87d7-e4ea49c1d358.html.*

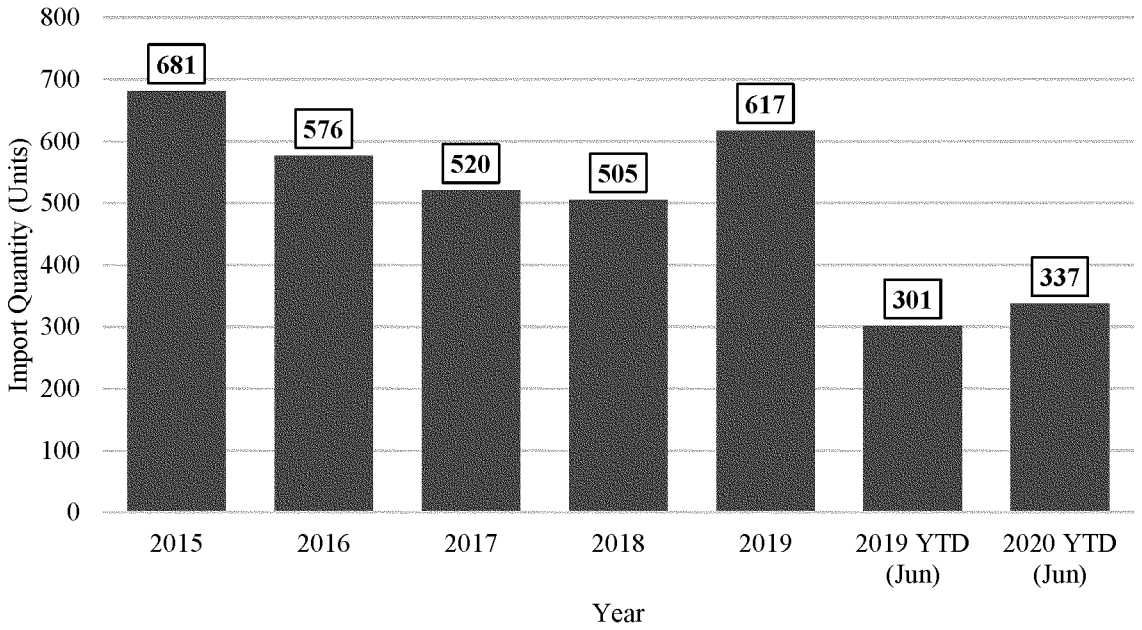
[90] Powermag.com, Dec. 17, 2018. *https://www.powermag.com/hitachi-acquires-abb-power-grids-business-in-11-billion-deal/.*

**Figure VIII-40. Large Power Transformers (>100,000 KVA) Import Customs Value (2015-2020 YTD Jun)**




Source: United States International Trade Commission, U.S. Department of Commerce, Bureau of Industry and Security

**Figure VIII-41. Large Power Transformers (>100,000 KVA) Import Customs Quantity (2015-2020 YTD Jun)**




Source: United States International Trade Commission, U.S. Department of Commerce, Bureau of Industry and Security

**Figure VIII-42. Large Power Transformers (>100,000 KVA) Import Quantities by Top 10 Countries (Units, 2015-2020 YTD Jun)**

| Country | 2015 | 2016 | 2017 | 2018 | 2019 | 2019 YTD (Jun) | 2020 YTD (Jun) | SUM* |
|---|---|---|---|---|---|---|---|---|
| **Mexico** | 297 | 151 | 124 | 150 | 202 | 92 | 139 | **1,063** |
| **South Korea** | 100 | 128 | 123 | 73 | 67 | 27 | 25 | **516** |
| **Austria** | 39 | 60 | 89 | 60 | 103 | 57 | 32 | **383** |
| **Netherlands** | 49 | 88 | 51 | 61 | 41 | 20 | 23 | **313** |
| **Canada** | 44 | 41 | 44 | 46 | 63 | 38 | 25 | **263** |
| **China** | 47 | 27 | 22 | 23 | 25 | 18 | 31 | **175** |
| **Taiwan** | 10 | 19 | 18 | 24 | 40 | 20 | 6 | **117** |
| **Spain** | 24 | 12 | 8 | 31 | 1 | 1 | 2 | **78** |
| **Brazil** | 6 | 7 | 16 | 8 | 14 | 7 | 12 | **63** |
| **Poland** | 6 | 8 | 10 | 13 | 16 | 11 | 3 | **56** |

Source: United States International Trade Commission, U.S. Department of Commerce, Bureau of Industry and Security
*Excludes 2019 YTD (Jun) Data

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Consistent with stable demand, the level of imports of LPTs was been relatively steady between 2015–2019 at between 500 and 700 units annually. Total value of U.S. imports of these items in 2019 was $617 million. The leading sources for LPTs (≤100 MVA) into the United States in 2019 (by unit) were Mexico, where several global transformer manufacturers have manufacturing facilities (202 units); Austria, where [TEXT REDACTED]. These four countries accounted for 70 percent of U.S. imports by unit in 2019. On a value basis, the leading supplier was Austria with $188 million out of total U.S. imports of $620 million, which implies that the LPTs from Austria are on average more expensive than those from Mexico.

One notable trend is that imports from Korea fell from a high of 128 units in 2016 to 67 in 2019, replaced by

production at Hyundai's U.S. facilities, which was not subject to tariffs. In addition, while not among the top five sources in 2019, China also supplied some LPTs for the U.S. electric grid. Although imports from China have declined from high of 47 units in 2015, 31 units were imported from China in the first six months of 2020, a number only behind Mexico and Austria. This is significant, as the President's emergency declaration and Bulk Power Executive Order is particularly concerned with possible vulnerabilities in the critical energy infrastructure due to sourcing from potential adversaries such as Russia and China.

Based on the level of imports compared to domestic production, it is clear that the U.S. BPS is heavily dependent on imported LPTs, which are among the most critical elements in the BPS. The U.S. dependency on foreign sources for LPTs has persisted for at least a decade; there has been little net change in total U.S. production capacity during this timeframe, with new investments offset by plant closures.

U.S. apparent consumption of LPTs was 750 units in 2019 (domestic production of 137 + imports of 617 − exports of 4 units). Thus, the import penetration level is over 82 percent. On a value basis, import penetration is slightly lower—about 73 percent based on apparent consumption of $851 million (domestic sales of $234 million, plus imports of $620 million, less exports of $2.6 million). The dependence of the U.S. electric grid on imported LPTs negatively affects the domestic GOES industry because imported transformers most often utilize foreign-origin GOES.

In contrast to the inadequate domestic production capacity for LPTs in the United States, China has abundant production capabilities. With Chinese demand for LPTs comparable to that of the United States, China has at least 30 LPT manufacturers. China's top three manufacturers can each produce double the total U.S. production capacity.[91]

As noted above, the grim state of domestic manufacturing capability for LPTs has persisted for more than a decade. In 2011, the ITC completed its antidumping investigation into imports of LPT from Korea. The investigation presented a detailed analysis of the state of the domestic industry at that time.[92] In 2010, there were six domestic manufacturers of LPTs, who were operating at an average capacity utilization rate of just 39.9 percent. Imports accounted for 85 percent of apparent consumption (based on the total power handling capacity of units sold) or 81 percent of apparent consumption (value basis). The ITC found that the domestic industry was materially injured by the imports of LPTs from Korea that were being sold at less than fair value, which led to the imposition of tariffs.

In 2012, with an update in 2014, DOE also issued reports highlighting the deficiencies in domestic LPT industry. DOE's reports drew upon on ITC's industry data, but analyzed the information from the perspective of the implications for the nation's critical energy infrastructure rather than unfair trade practice issues. In its reports, DOE expressed concern over the lack of domestic production capabilities for large power transformers. DOE's 2014 update noted that some foreign investment in U.S. manufacturing facilities (*e.g.,* by EFACEC, Hyundai, and Mitsubishi), as well as expansions by U.S. firms (SPX), contributed to a slight increase in domestic production capacity in the mid 2010's but that production still fell far short of domestic demand). Of the three foreign companies noted in DOE's report, only Hyundai still manufactures domestically and overall domestic production capacity has not increased.

In September 2018, five years after the imposition of antidumping duties on imports from Korea, the ITC reassessed the status of the domestic industry.[93] Since its initial report in 2011, the ITC noted a number of changes, both positive and negative, in domestic capacity/production (*e.g.,* facilities closed, bought by other companies, opened). The ITC also examined the health of the domestic LPT industry compared to five years earlier (in 2013) and found that on all measures, the industry had deteriorated. Although the ITC withheld specific data from the public report, the report stated that employment, wages, sales, shipments, market share, and financial performance had all declined.

3. Reliance on Imported Key Components

Lack of domestic production capability for LPTs is exacerbated by the fact that most domestic manufacturers rely on imports for key transformer components, including electrical steel, laminations, and cores. In fact, none of the remaining domestic LPT manufacturers source laminations or cores from U.S. suppliers, which highlights the lack of domestic capability in this area. Imported laminations and cores rely on almost exclusively non-U.S. GOES, which is significant because GOES, along with the copper used in the windings, accounts for a significant percentage of the cost of an LPT (up to 25 percent). GOES also accounts for between 75 percent and 90 percent of the cost of laminations, and 50–60 percent of the cost of transformer cores, based on the Department's survey data. As a result, price volatility and global market conditions for GOES continue to have an impact on the manufacturing and procurement strategies of LPT producers.

Specific company sourcing decisions, based on company responses detailed in the Department's survey, are as follows:

- [TEXT REDACTED].
- [TEXT REDACTED].
- [TEXT REDACTED].
- [TEXT REDACTED].
- [TEXT REDACTED].

4. Other Issues Affecting LPT Manufacturers

Most of the domestic manufacturers of LPTs reported difficulty in hiring qualified workers, with more than 90 days required to source and train new employees. The companies reported experiencing a shortage of skilled production workers (*e.g.,* testers, welders, and winders), field technicians, and design engineers. In addition, the workforce is aging, and it is difficult to attract younger workers to this industry and to the geographical regions in which the companies are located.

Several of the companies also reported being negatively impacted by foreign competition, particularly from South Korea and Mexico. Despite the successful antidumping investigation that resulted in the imposition of import duties, domestic transformer manufacturers stated that they continue to be disadvantaged due to the protection/subsidization of South Korean manufacturers by their government. Specific to Mexico, domestic producers cited the low cost labor there as to their detriment. In addition, some domestic transformer companies that make laminations and cores in-house reported adverse effects vis-à-vis their foreign competitors as a result of the Section 232 tariffs on GOES.

*F. Voltage Regulators*

Six companies responding to the Department's survey indicated domestic

[91] DOE LPT Report, 2014.

[92] *https://www.usitc.gov/publications/701_731/Pub4256.pdf.*

[93] ITC, ''Large Power Transformers from Korea,'' Investigation No. 731–TA–1189, September, 2018, pp. 30–31. See Appendix F for additional information.

production of voltage regulators; most of these companies also produce liquid dielectric transformers in the United States. [TEXT REDACTED]. It is a major player in many of the other transformer categories, but the production of these products takes place in at offshore locations. [TEXT REDACTED].

The top four companies, which accounted for over 95 percent of reported production, were [TEXT REDACTED]. Imports of voltage regulators have fallen slightly in recent years, to $81 million in 2019. The leading sources of imports were Canada, Germany, the United Kingdom, and Mexico.

[TEXT REDACTED]

Import statistics do not appear to represent the voltage regulator segment of this investigation well. The large volume of imports (with low average unit values) captured by the Harmonized Tariff Schedule category under which voltage regulators fall (HTS 9032.89.4000 [94]) includes many products unrelated to this investigation. Therefore, import penetration levels cannot be calculated. However, as mentioned, the manufacturers of voltage regulators are all major players in the other transformer categories that are addressed in this report.

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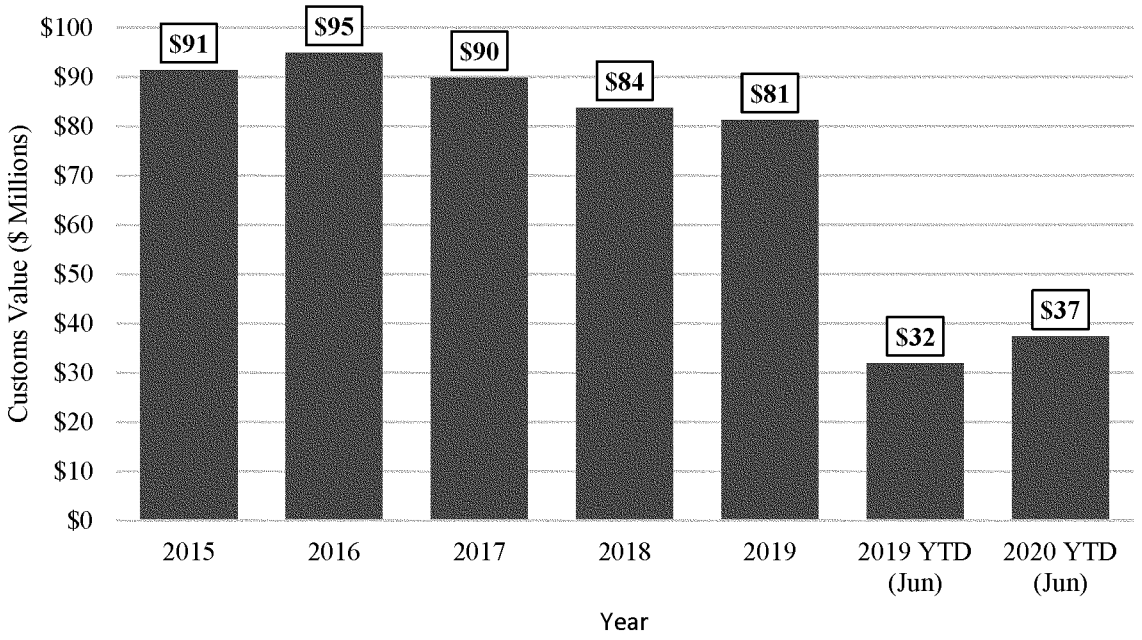
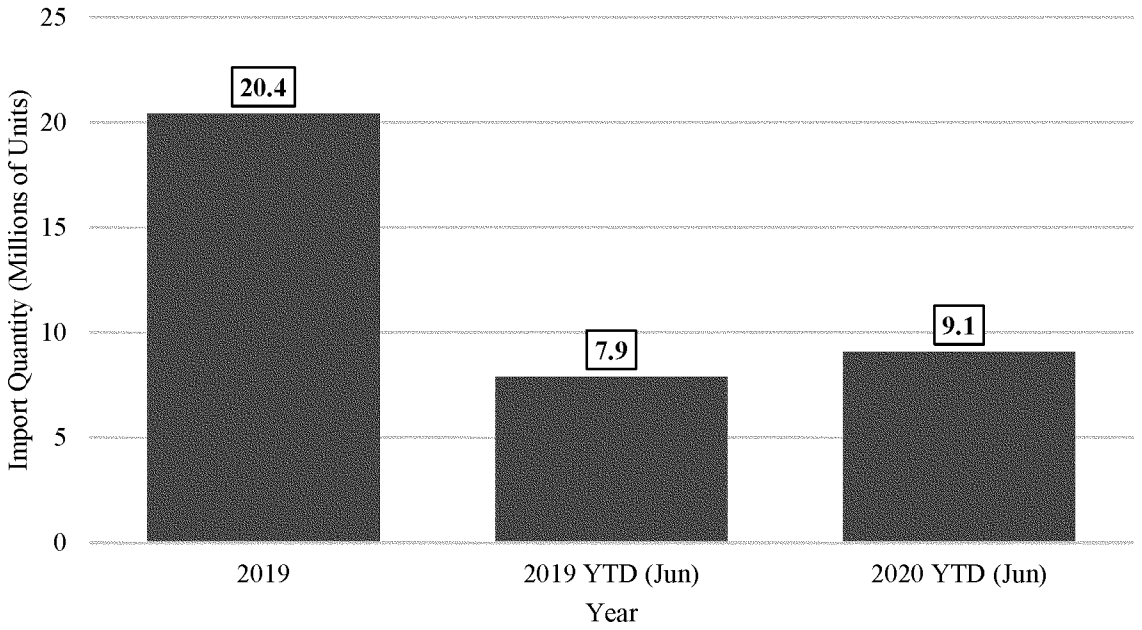
**Figure VIII-44. Voltage Regulators Import Customs Value (2019-2020 YTD Jun)**




Source: United States International Trade Commission, U.S. Department of Commerce, Bureau of Industry and Security

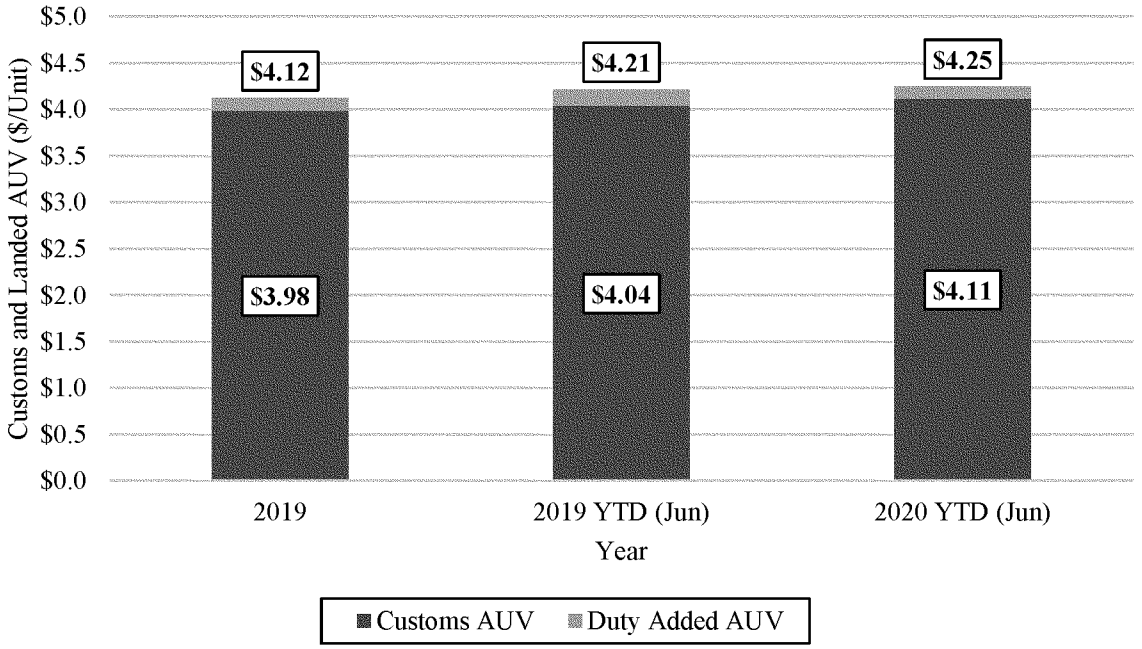
[94] Automatic voltage and voltage-current regulators, other than designed for use in a, 12, or 24 V system.

**Figure VIII-45. Voltage Regulators Import Customs Quantity (2019-2020 YTD Jun)***




Source: United States International Trade Commission, U.S. Department of Commerce, Bureau of Industry and Security
*Quantity Data Pre-2019 Unavailable

**Figure VIII-46. Voltage Regulators Import Customs AUV (2019-2020 YTD Jun)**




Source: United States International Trade Commission, U.S. Department of Commerce, Bureau of Industry and Security
*Data labels indicate the final Duty Landed AUV
**Quantity Data Pre-2019 Unavailable

| Figure VIII-47. Voltage Regulators<br>Import Quantities by Top 10 Countries (Thousands of Units, 2019-2020 YTD Jun) | | | | |
|---|---|---|---|---|
| **Country** | **2019** | **2019 YTD (Jun)** | **2020 YTD (Jun)** | **SUM*** |
| **Canada** | 9,025 | 3,435 | 6,039 | **15,064** |
| **Germany** | 4,671 | 1,482 | 154 | **4,824** |
| **United Kingdom** | 2,163 | 989 | 697 | **2,859** |
| **Mexico** | 1,165 | 463 | 641 | **1,807** |
| **France** | 650 | 186 | 384 | **1,035** |
| **China** | 746 | 353 | 238 | **984** |
| **Philippines** | 58 | 52 | 468 | **526** |
| **Japan** | 280 | 157 | 138 | **419** |
| **Singapore** | 411 | 224 | 0,028 | **411** |
| **India** | 260 | 161 | 32 | **292** |

Source: United States International Trade Commission, U.S. Department of Commerce, Bureau of Industry and Security
*Excludes 2019 YTD (Jun) Data
**Quantity Data Pre-2019 Unavailable

| Figure VIII-48. Voltage Regulators<br>Customs Value Imports AUV by Top 10 Countries ($/Unit, 2019-2020 YTD Jun) | | | | |
|---|---|---|---|---|
| **Country** | **2019** | **2019 YTD (Jun)** | **2020 YTD (Jun)** | **AVG*** |
| **Singapore** | $1.9 | $2.1 | $1,798.1 | **$900.0** |
| **Japan** | $10.0 | $7.3 | $13.6 | **$11.8** |
| **Mexico** | $10.0 | $6.4 | $12.8 | **$11.4** |
| **Philippines** | $15.0 | $12.9 | $1.9 | **$8.5** |
| **Germany** | $2.6 | $3.0 | $14.2 | **$8.4** |
| **China** | $7.1 | $7.9 | $8.9 | **$8.0** |
| **United Kingdom** | $6.2 | $5.1 | $5.6 | **$5.9** |
| **India** | $2.8 | $3.3 | $6.0 | **$4.4** |
| **France** | $4.5 | $6.5 | $3.5 | **$4.0** |
| **Canada** | $2.3 | $2.4 | $2.2 | **$2.2** |

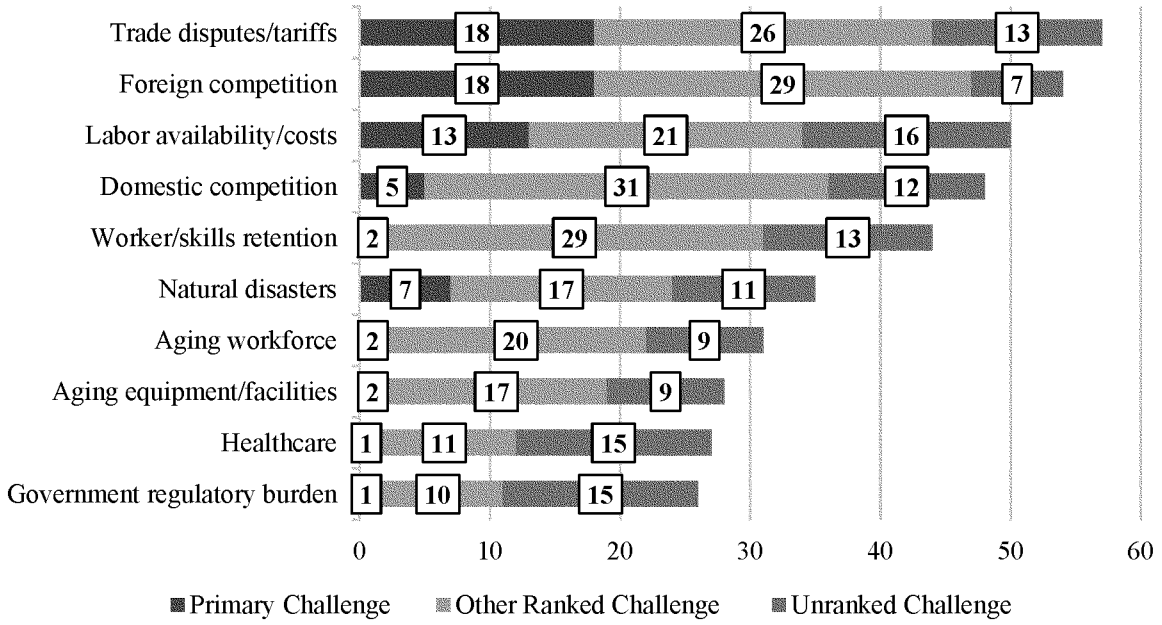
Source: United States International Trade Commission, U.S. Department of Commerce, Bureau of Industry and Security
*Weighted Average by Quantity, Excludes 2019 YTD (Jun) Data
**Quantity Data Pre-2019 Unavailable

## IX. Competitiveness and Labor Issues

### *A. Competitiveness*

Recipients of the Department's survey were asked to identify and rank the top five challenges or issues affecting their global competitiveness position from a list of more than thirty options. In general, there was little difference in responses among the respondents by specific transformer-related product sector. The most commonly identified primary challenge to their competitiveness reported was either trade disputes/tariffs or foreign competition. Seventy-six percent of respondents identified trade disputes/tariffs as a challenge, including 24 percent of respondents that noted it as the number one issue affecting their company's competitiveness. Similarly, 72 percent of respondents identified foreign competition as a challenge. Labor availability/cost was the third most commonly identified challenge and will be addressed in more detail in section B of this chapter.

**Figure IX-1. Top 10 Challenges/Issues Affecting Electrical Steel and Transformer-related Products Respondents**
*****Note: Excludes blank or "Not Applicable" responses**




Source: U.S. Department of Commerce, Bureau of Industry and Security, Electrical Steel and Transformer-Related Products Survey, Q10, B

*75 Respondents*

1. Transformer Components

While mentioned by a majority of survey recipients across product categories, foreign competition is a particularly significant problem for the transformer cores and laminations sector. Of the survey respondents who produce laminations and cores for incorporation into transformers, 91 percent indicated that foreign competition is a major challenge. These responses are consistent with import data which show that imports of laminations increased 57 percent and imports of cores increased 61 percent between 2018 and 2019.[95]

Almost all of the domestic transformer lamination and core producers participating the in Department's survey took the opportunity to provide specific commentary on competitiveness issues. In particular, they were asked to describe how their competitiveness has been affected and to provide any recommendations specific to the U.S. Government's response, including steps to mitigate the challenges that they face (Survey question 10 D). All the respondents in this sector presented similar information on the issues affecting their competitiveness but had different approaches and suggestions to address them. While many recommended imposing tariffs on downstream transformer components and finished transformers, others recommended removing the tariffs on imported GOES.

- [TEXT REDACTED].
- [TEXT REDACTED].
- [TEXT REDACTED].
- [TEXT REDACTED].
- [TEXT REDACTED].
- [TEXT REDACTED].
- [TEXT REDACTED].
- [TEXT REDACTED].
- [TEXT REDACTED].
- [TEXT REDACTED] to preserve what is left of the U.S. transformer industry.

While the domestic manufacturers of laminations and cores have been negatively affected by imports, some transformer companies that purchase these components for incorporation into transformers benefitted during the same time period. In particular, increased competition in the lamination and core sector was beneficial to their competitiveness, as it led to reduced costs for these items.

2. Distribution, Small & Medium Power Transformers and Dry-Type Transformers

As compared to survey respondents from the transformer core and laminations sector, while increasing foreign competition was also a significant challenge for distribution, small and medium power, and dry-type transformer producers, a larger number of this group of survey respondents indicated labor-related issues as their number one concern. Labor challenges were listed by 17 out of the 19 distribution and small-power transformer manufacturers, and by nine out of ten medium-power transformer manufacturers. With regard to dry-type transformers, seventy percent of manufacturers indicated trade disputes/tariffs were challenges. Similarly, 60 percent and 55 percent of respondents in this group regarded foreign competition and labor availability/costs as challenges, respectively.

With regard to competitiveness issues, several of the transformer companies expressed strong opposition to the expansion of tariffs to downstream

[95] [TEXT REDACTED].

products because such an expansion would harm their competitiveness by increasing their costs and disrupting their supply chain.) Instead, they recommended the elimination of existing tariffs on GOES [TEXT REDACTED]. However, other transformer companies, facing the same competitive pressures due to rising material costs, recommended extending the tariffs to include complete transformers [TEXT REDACTED].

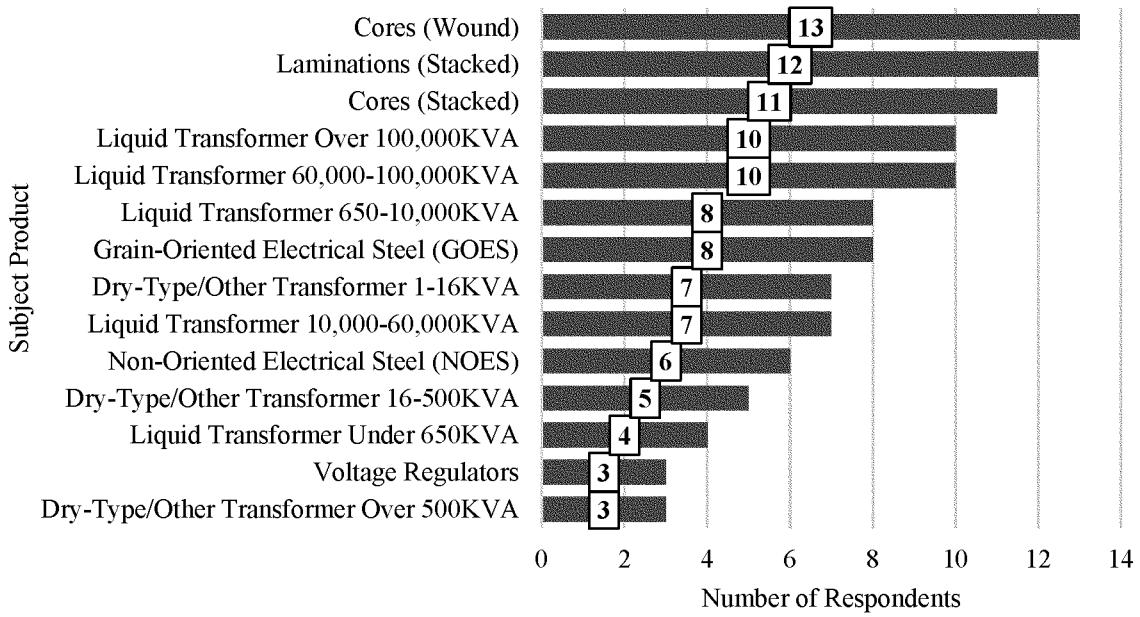
3. Large Power Transformers

For the manufacturers of LPTs, foreign competition was again the leading problem. All seven survey participants in this industry sector expressed this concern. The domestic producers were particularly concerned about competition from South Korea, where companies benefit from subsidies and protection by the South Korean Government. Increased competition from Mexico was also identified as a challenge. Other frequently mentioned issues affecting the competitiveness of large power transformer manufacturers were trade disputes/tariffs (specifically the increased production costs due to GOES tariffs), labor availability/costs, and aging equipment, facilities, or infrastructure.

4. Changes in Competition

In addition to identifying specific factors affecting them, survey respondents were asked to indicate whether or not there had been a significant change since 2018 with regard to foreign competition in any of the product categories subject to this investigation and whether the change was positive, negative, or neutral. Not surprisingly, respondents reported that significant increases in import competition are most prevalent in the wound cores, stacked laminations, and stacked cores product categories (*i.e.,* the product categories of which GOES is the primary input).

**Figure IX-2. Electrical Steel and Transformer-related Products by Increased Import Competition Since 2018**

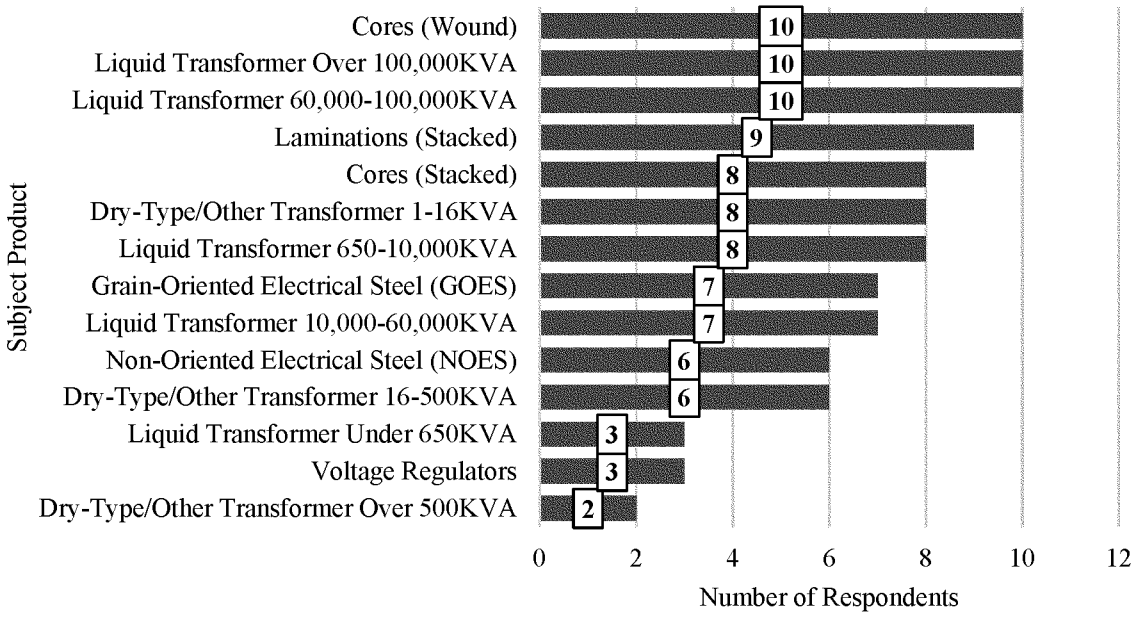



Source: U.S. Department of Commerce, Bureau of Industry and Security, Electrical Steel and Transformer-Related Products Survey, Q10, A

*39 Respondents*

An overwhelming majority of the respondents that indicated an increase in import competition also indicated that the increase in competition had a negative effect on their organizations. However, as mentioned above, some transformer manufacturers have benefitted from increased competition, specifically in the component sector from which they source.

**Figure IX-3. Electrical Steel and Transformer-related Products Import Competition Change Since 2018 by Negative Organization Impact**

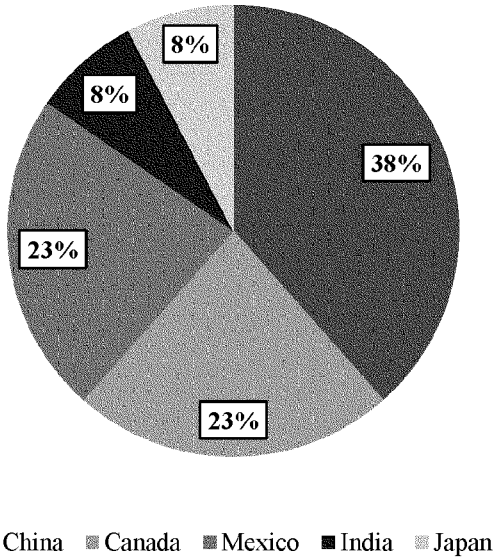



Source: U.S. Department of Commerce, Bureau of Industry and Security, Electrical Steel and Transformer-Related Products Survey, Q10, A

*36 Respondents*

The countries most often listed as the source of increased foreign competition were Canada, China, Japan, and Mexico. For wound cores, Japan was mentioned most frequently, followed by Canada and Mexico. In contrast, Japan was not mentioned as a source of competition for laminations; Canada was most often mentioned, followed by China and Mexico. For stacked cores, import competition was identified as coming from Canada, China, Mexico, and Japan.

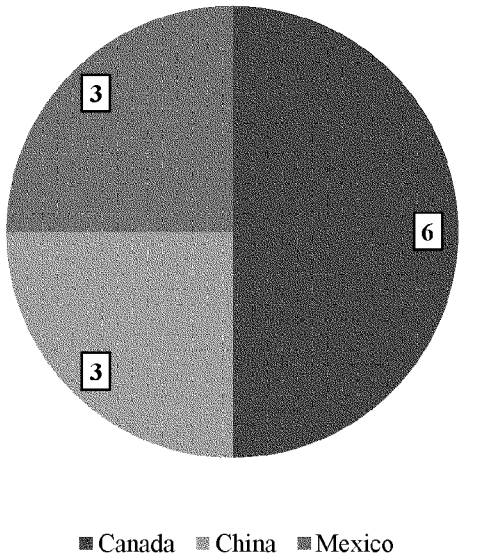
**Figure IX-4. Cores (Wound) – Primary Source Country of Increased Import Competition Since 2018**




Source: U.S. Department of Commerce, Bureau of Industry and Security, Electrical Steel and Transformer-Related Products Survey, Q10, A

*13 Respondents*

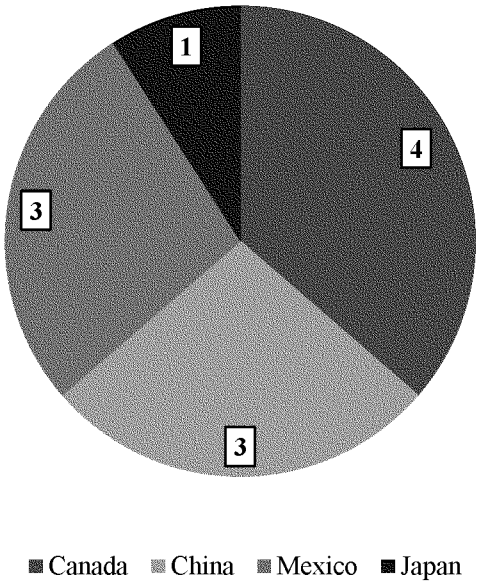
**Figure IX-5.Laminations (Stacked) – Primary Source Country of Increased Import Competition Since 2018**




Source: U.S. Department of Commerce, Bureau of Industry and Security, Electrical Steel and Transformer-Related Products Survey, Q10, A

*12 Respondents*

**Figure IX-6. Cores (Stacked) – Primary Source Country of Increased Import Competition Since 2018**




Source: U.S. Department of Commerce, Bureau of Industry and Security, Electrical Steel and Transformer-Related Products Survey, Q10, A

*11 Respondents*

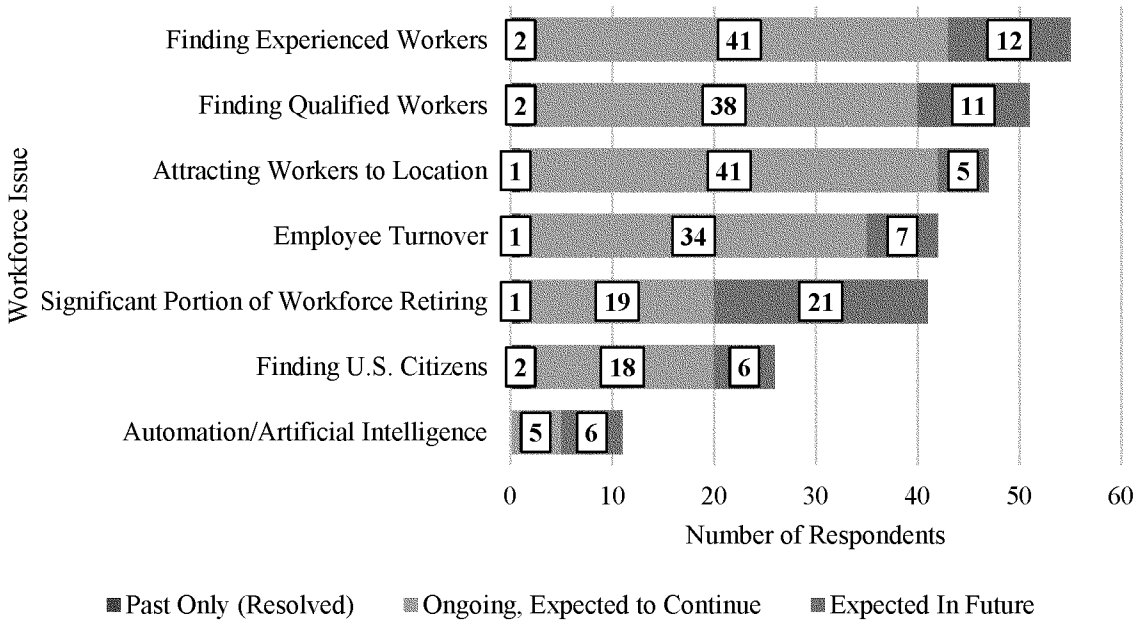
*B. Labor*

In addition to questions about the labor-related issues affecting competitiveness, survey recipients were asked specific questions related to their workforce. On average, survey respondents that manufactured transformers or transformer components in the United States indicated that labor accounted for 36 percent of their costs, with a range between 1 percent and 83 percent.

Eighty-nine percent of survey respondents reported having had difficulties in finding qualified or experienced workers, including 66 percent that identified the problem as an ongoing issue. This is significant, as transformer manufacturing requires specialized skills including welding, coil winding, and transformer testing. Survey respondents indicated that U.S. high schools do not offer programs that train young people for skills such as these. Transformer manufacturers also experienced difficulties in hiring employees with certain educational backgrounds or training, including manufacturing engineers, power electrical engineers, quality control, and electrical design engineers. Several respondents mentioned that few universities offer training in these areas.

Survey respondents reported an aging workforce and trouble attracting and retaining younger workers. Seventy-eight percent of respondents that identified anticipated future workforce issues regarded the possibility of a significant portion of their workforce retiring as a challenge affecting their company. The location of the production facilities in remote and/or less desirable/economically challenged areas was cited by nearly 80 percent of survey respondents as a factor inhibiting attracting qualified labor.

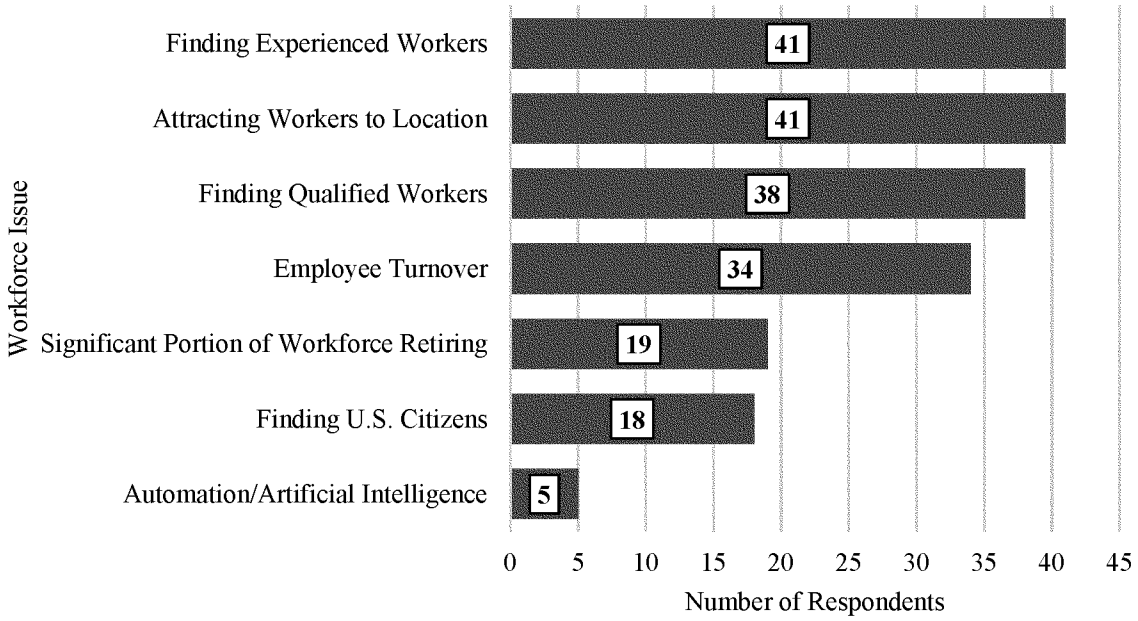
**Figure IX-7. Workforce Issues Experienced by Electrical Steel and Transformer-related Products Respondents**
*****Note: Excludes blank or "Not Applicable" responses**




Source: U.S. Department of Commerce, Bureau of Industry and Security, Electrical Steel and Transformer-Related Products Survey, Q7, B

*62 Respondents*

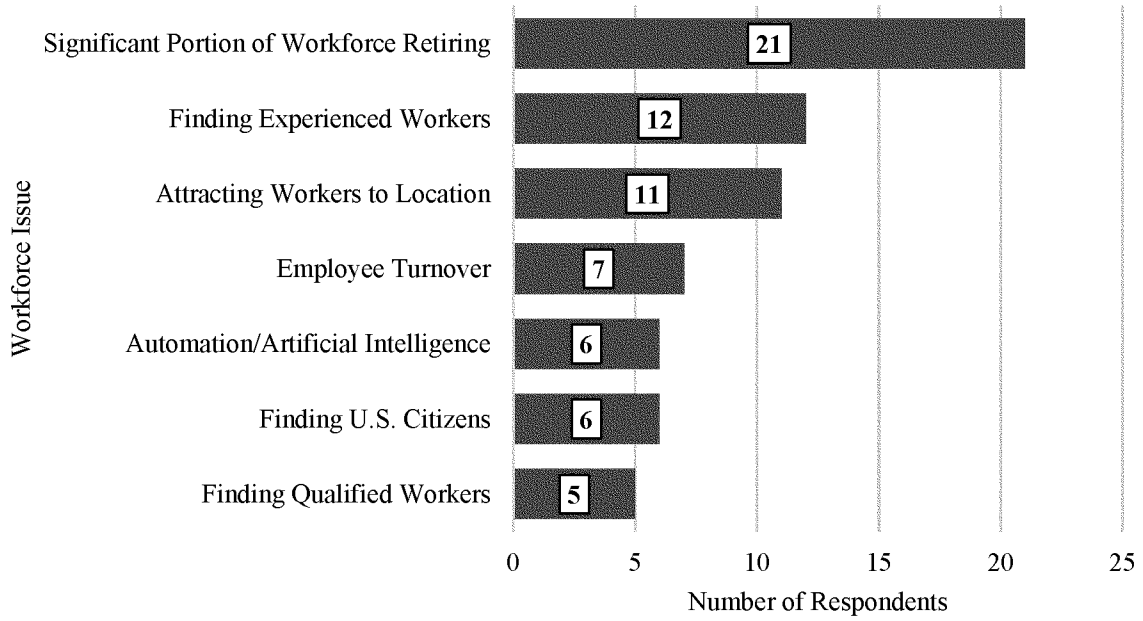
**Figure IX-28. Ongoing Workforce Issues Experienced by Electrical Steel and Transformer-related Products Respondents**
*****Note: Excludes blank or "Not Applicable" responses**




Source: U.S. Department of Commerce, Bureau of Industry and Security, Electrical Steel and Transformer-Related Products Survey, Q7, B

*52 Respondents*

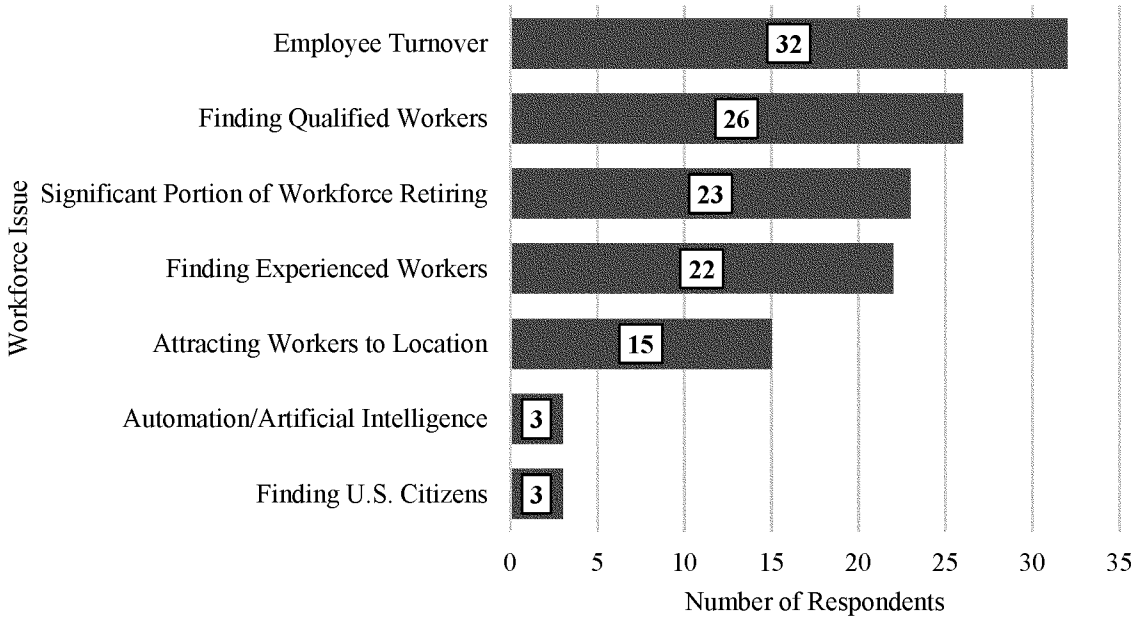
**Figure IX-9. Expected Future Workforce Issues Experienced by Electrical Steel and Transformer-related Products Respondents**
*****Note: Excludes blank or "Not Applicable" responses**




Source: U.S. Department of Commerce, Bureau of Industry and Security, Electrical Steel and Transformer-Related Products Survey, Q7, B

*27 Respondents*

**Figure IX-10. Workforce Issues Affecting Production Line Workers among Electrical Steel and Transformer-related Products Respondents**
*****Note: Excludes blank or "Not Applicable" responses**




Source: U.S. Department of Commerce, Bureau of Industry and Security, Electrical Steel and Transformer-Related Products Survey, Q7, B

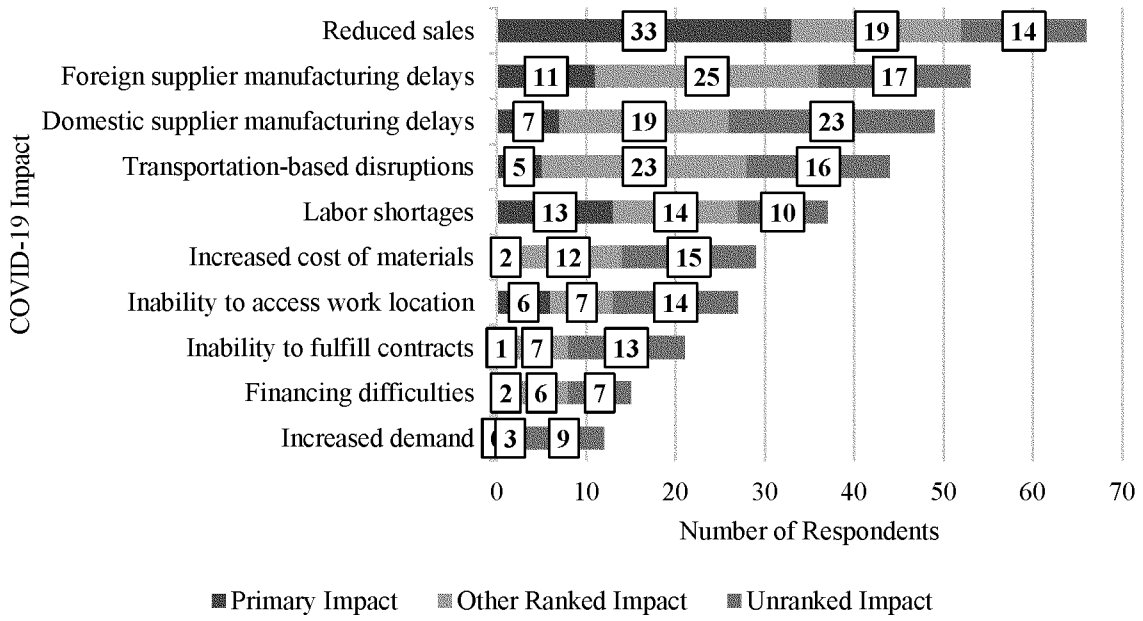
*47 Respondents*

*C. COVID–19 Impact*

This investigation and the industry survey associated with it were conducted during the time of the COVID–19 pandemic in the United States. The Department included questions on the survey related to COVID–19, as situations such as a global pandemic can disrupt supply chains and production. If they persist, these disruptions may have implications on the ability of the industry to support critical national security and energy infrastructure needs.

Survey respondents were queried on specific ways the pandemic impacted their organization and their responses are listed in the tables below (note that respondents could list multiple impacts/responses). Only three respondents indicated that they experienced no impact from COVID–19. Of the remaining respondents, 79 percent indicated that the pandemic reduced their organization's sales, including 38 percent that noted reduced sales as the primary coronavirus-related impact. Similarly, 63 percent and 58 percent of respondents, respectively, experienced foreign and domestic supplier manufacturing delays.

**Figure IX-11. Top COVID-19 Impacts Experienced by Electrical Steel and Transformer-related Products Respondents**
*****Note: Excludes blank responses**



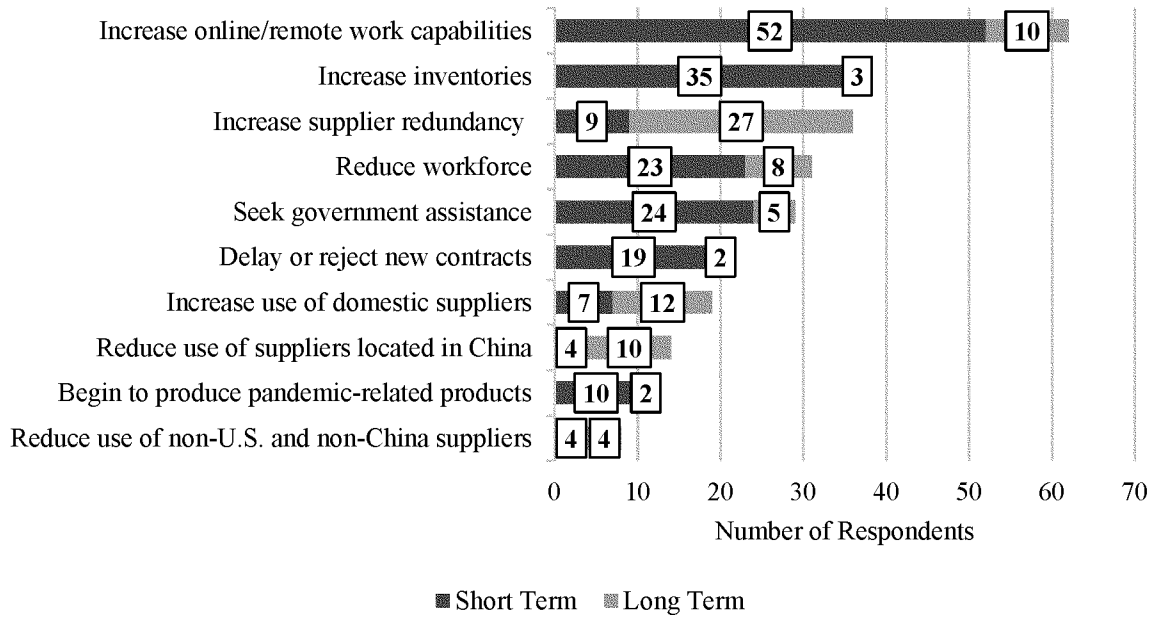

Source: U.S. Department of Commerce, Bureau of Industry and Security, Electrical Steel and Transformer-Related Products Survey, Q11, A

*84 Respondents*

As reported, foreign supplier delays as a result of the Covid–19 pandemic were most prevalent among transformer manufacturers. Of the transformer manufactures that experienced foreign supplier delays, 50 percent manufacture dry-type/other transformers 1–16 KVA. An additional 43 percent and 40 percent of respondents that experienced foreign supplier delays manufacture liquid-dielectric transformers 650–10,000KVA and dry-type/other Transformers 16–500KVA, respectively. However, only one wound core manufacturer reported that COVID–19 resulted in foreign supplier manufacturing delays; such delays were not reported by any lamination or stacked core manufacturers. These percentages generally correspond to the numbers of each type of manufacturer participating in the survey, they do not indicate that foreign supplier delays or other impacts were concentrated in any particular sector.

The most common response to the pandemic was to allow non-production line workers to work remotely, with 76 percent of respondents increasing online/remote work capabilities, including 63 percent of respondents that classified it as a short-term solution. Similarly, 45 percent and 44 percent of respondents increased their inventories and supplier redundancy, respectively. Five respondents indicated that their organizations took no action in response to the COVID–19 pandemic.

**Figure IX-12. Top Actions Taken in Response to COVID-19 by Electrical Steel and Transformer-related Products Respondents**
*****Note: Excludes blank responses**

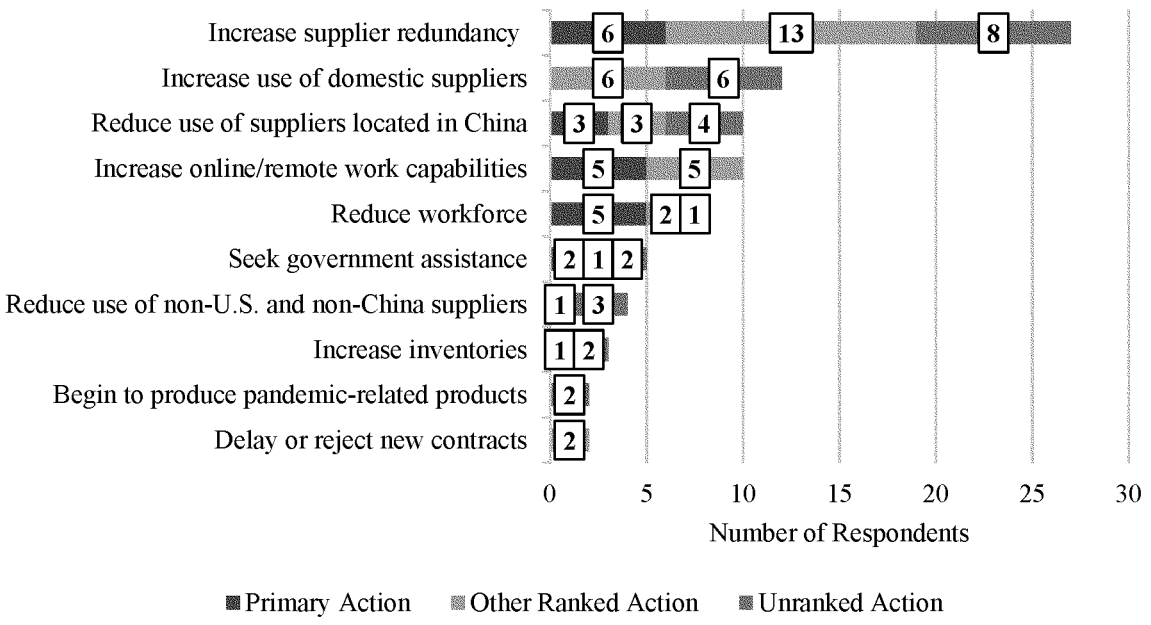



Source: U.S. Department of Commerce, Bureau of Industry and Security, Electrical Steel and Transformer-Related Products Survey, Q11, A

*82 Respondents*

Thirty-five respondents indicated that their organizations took no long-term actions in response to the pandemic. Of the respondents that took long-term action, 52 percent indicated that they increased supplier redundancy. Similarly, 23 percent of respondents increased their use of U.S. suppliers and reduced their use of suppliers in China.

**Figure IX-13. Top Long Term Actions Taken in Response to COVID-19 by Electrical Steel and Transformer-related Products Respondents**
*****Note: Excludes blank responses**




Source: U.S. Department of Commerce, Bureau of Industry and Security, Electrical Steel and Transformer-Related Products Survey, Q11, A

*52 Respondents*

BILLING CODE 3510–33–C

## X. Findings and Recommendations

### *A. Findings*

1. Grain-Oriented Electric Steel

As was determined by the 2017 Section 232 Investigation on the Impact of Imports of Steel on the National Security, GOES is critical to the national security. The United States must maintain a secure supply and robust production capacity for GOES, which was found to be harmed by imports brought on by unfair trade practices and artificially-induced global excess capacity. GOES is essential to the production and function of transformers of all power handling capacities that form the backbone of the U.S. electrical grid. Sufficient domestic production capacity for GOES is necessary in order to ensure the ability of the United States to address threats facing our critical energy infrastructure.

This investigation finds that imports of downstream GOES products, namely laminations for incorporation into transformers, and stacked and wound cores for incorporation into transformers, have negatively affected domestic GOES production, as these key transformer components are the primary market for GOES. The value of U.S. imports of laminations has more than doubled from $15 million in 2015 to $33 million in 2019. Core imports were $22 million in 2015 and soared to $167 million in 2019. Together, Mexico and Canada account for more than 95 percent of these imports. As domestic demand for transformers has not increased, increased imports of laminations and cores represent displaced domestic production, and hence, domestic consumption of GOES.

There is only one remaining domestic producer of GOES (AK Steel), at which capacity utilization stands at [TEXT REDACTED] in 2019 due to loss of the domestic market to imported laminations and cores. At this capacity utilization level, the company cannot operate profitably and there is a risk it will cease GOES production altogether. Moreover, poor profitability over a number of years has impeded and will impede the ability of the sole U.S. manufacturer of GOES to invest in modern capital equipment necessary for it to produce sufficient quantities and qualities of GOES to meet domestic demand.

2. Transformer Laminations and Stacked and Wound Cores

The large increase in imports of transformer laminations and cores has not only hindered domestic GOES production, but also leaves the United States with a lack of sufficient capacity to produce these items that are essential to modern, efficient transformers. The United States transformer industry has become highly dependent on foreign sources for laminations and cores, and imports have displaced domestic production, leaving domestic capacity to manufacture them insufficient and in some cases is in danger of closing down. While the majority of imports of these items come from Canada and Mexico, neither country has indigenous production capability for the GOES which is the main material in them. Therefore, imports of transformer laminations and cores contain foreign-origin GOES, including some from potentially unreliable suppliers in China and Russia. Lack of domestic capacity and dependence on imports for these transformer components puts at risk the ability to maintain and repair the existing electric grid in the face of increasingly emboldened foreign adversaries.

3. Large Power Transformers

This investigation further finds that imports of LPT (those with power handling capacities of 100 MVA and above), pose a dual threat to the national security by constraining U.S. GOES production, as well as materially harming domestic LPT production. In this sector, imports account for over 80 percent of consumption, and the five remaining U.S.-based manufacturers are operating at less than 40 percent of capacity. Domestic production capability, even if operating at full capacity, falls far short of the ability to meet demand. Of particular concern is lack of domestic capacity with regard to extra high voltage transformers (those with >345 kV voltage rating) that are vital for long distance electricity transmission. This excessive level of foreign dependence on imported LPT, which are uniquely critical to the BPS, puts the resiliency of the critical energy infrastructure at risk. The global pandemic of 2020 has shown U.S. vulnerability to supply-chain shocks and has highlighted the need to ensure the availability of key equipment and major subcomponents thereof from American companies.

The Secretary therefore finds that laminations for incorporation into transformers, stacked and wound cores for incorporation into transformers, and LPT are being imported into the United States in such quantities and under such circumstances as to threaten to impair U.S. national security.

Because electricity, and therefore transformers, are vital to the nation's national defense and economy, the United States must maintain sufficient capacity to produce GOES, transformer laminations and cores, and LPT that can be drawn upon to address sudden disruptions or outages in the electric grid, be they due to natural disasters, physical strikes or cyberattacks. Moreover, extreme reliance on foreign sources for these essential items leaves the United States vulnerable to disruptions in the supply chain, whether due to interruptions in transportation routes, production processes (*e.g.,* pandemics, civil unrest, work stoppages) or foreign government economic sanctions.

With regard to other electrical transformers (dry-type and liquid dielectric transformers with less than 100 MVA power handling capacity) and transformer regulators that were also subject to this investigation, the Secretary does not find that these items are being imported in such quantities or under such circumstances as to threaten to impair the national security at this time.

Overall, domestic production of these products is sufficient to support critical infrastructure and national security requirements, and U.S. firms remain competitive. However, domestic manufacturers of these products were found to be highly dependent on imported transformer laminations and cores and the foreign-origin GOES contained in them. Robust domestic production capability for these subcomponents, including GOES, will minimize supply chain risks for manufacture of these transformers and transformer regulators and support critical infrastructure requirements across all levels of the distribution system.

*B. Options*

The following are seven non-mutually exclusive options to address the threats to United States national security posed by imports that the Secretary identified in this investigation. A discussion of the potential benefits and drawbacks of each option follows.

1. Negotiate either bilaterally or trilaterally with Canada and Mexico to reduce imports of subject products and/or to utilize more U.S. GOES in their production
2. Impose tariffs or quotas on imports of some or all of the products subject to this investigation
3. Provide direct production subsidies or R&D, capital expenditure loans, or other financial incentives to support domestic production of subject products.
4. Impose domestic content requirements for transformers
5. Establish a Stockpile for some or all of the subject products
6. Change the Harmonized Tariff classification for laminations and cores to the steel HTS category rather than the transformer category
7. Establish a working group to provide further recommendations

1. Negotiate With Canada and Mexico

As this investigation found, Canada and Mexico are the leading sources of imports of products subject to this investigation. Imports of transformer laminations and transformer cores from Canada have increased dramatically since 2015, and with imports from Mexico, account for over 95% of U.S. imports of these products. In addition, Mexico has a substantial transformer manufacturing industry, and is the leading source for LPT for the U.S. electrical grid.

Mexico, and especially Canada, are close allies and trading partners. Per agreement, Canada is considered part of the U.S. Defense and Technology Base. In addition, both countries have highly interconnected electrical grids with the United States and cooperate on ways to ensure the resiliency and address threats to the North American BPS. Neither country has production capability for GOES that is a key material supporting equipment in the electrical grid. It is therefore not only in the security interests of the United States to maintain a source of GOES, but also in the interests of Canada and Mexico as well.

Thus, negotiate with Canada and Mexico to address the threats to the North American security posed by the potential loss of U.S. GOES production. Seek through negotiations to increase consumption by Mexican and Canadian transformer and transformer component manufacturing sectors of U.S. GOES and sub-assemblies. This option may include purchasing agreements with both countries, as well as voluntary agreements limiting imports from select countries. This option is expected to be budget neutral and ensures continued cooperation on behalf of all parties through the USMCA and other bi- and multi-lateral treaties.

Under this agreement, a purchasing agreement will increase the demand and production for domestic GOES. A purchasing agreement would guarantee a United States market share in both the Canadian and Mexican transformer manufacturing sectors. Canadian and Mexico primarily export their transformers and transformer components to the United States. A purchasing agreement will ensure that domestically consumed transformers will rely on United States GOES production despite their manufacture in Canada and Mexico. Should a purchasing agreement not be feasible, voluntary trade restrictions may be another option.

A voluntary trade agreement to limit the import of GOES from China and Russia by Canada and/or Mexico could encourage demand for U.S. GOES. To complement Executive Order 13920 (E.O. 13920 or Bulk Power Executive Order), limiting GOES, laminations, and core imports from China and Russia will ensure greater security for United States, Canadian, and Mexican BPS. The Secretary of Commerce recommends pursuing both a purchasing agreement and a voluntary limitation on imports from China and Russia.

2. Tariff/Quota/Tariff-Rate-Quota Duties

Extend proclamation 9705 to the following HTS codes: 8504.90.9634, 8504.90.9638, and 8504.90.9642. Should

this option be selected, a 25 percent global tariff rate will be applied to imports of laminations and cores (both stacked and wound) for incorporation into electric transformers. This will result in positive tariff revenues and has the potential to reduce the import of laminations and cores (stacked and wound). The alternative is to issue a new global tariff rate on laminations and cores (stacked and wound) and set it to 100 percent. This rate was requested by the domestic GOES producer as they believe it will incentivize both domestic GOES consumption and lamination and core (stacked and wound) production. In the short term, this does not address the shortcomings of domestic GOES production with regard to all grades of GOES.

Applying a quota, or tariff-rate-quota will negatively impact the transformer industry and could be contrary to national security interests as that sector is also vital. Given that the dependency of the U.S. transformer industry on imported laminations and cores (stacked and wound) for incorporation into transformers, applying a tariff rate to only laminations and cores (stacked and wound) will negatively impact the industry by raising input costs. Transformer manufacturers are likely to offshore their domestic production facilities in order to avoid the increased costs. In addition, offshoring domestic transformer production will likely decrease the demand for domestic GOES in the longer term, as transformer manufacturers can procure cheaper imports elsewhere.

3. Production Subsidies, R&D, Capital Expenditure Loans, or Other Financial Incentives

Issue a capital expenditure grant or loan to the domestic GOES manufacture to upgrade facilities in order to reduce operating costs and increase production capacity for high grade GOES. This option is the most direct way to address shortcomings identified in this investigation with regard to domestic the GOES industrial capabilities and has the potential to increase the competitiveness of domestic GOES in both U.S. and foreign markets in the medium to long term. Any production subsidy should consider and account for the different grades of GOES to ensure that subsidies are in fact making domestic GOES price competitive with imports across all grades. In addition, a production subsidy should have a clear termination date in order to avoid overreliance on financial assistance.

Production subsidies however are not solely limited to the existing domestic GOES manufacturer. New entrants could take advantage of such subsidies in order to better compete on price while increasing their production capacities. As production subsidies are directly targeted towards GOES manufacturers, downstream costs are not expected to increase.

This option is expected to be budget negative in the short run, however, it has the potential to be budget neutral, or positive in the long run. Budget neutrality or positivity can be achieved by preferable interest rates or combining a capital expenditure loan with a strategic stockpile option (which can be liquidated at a future date for profit). This option is not expected to explicitly increase the costs for electrical steel or transformer-related products.

Improving the domestic GOES manufacturer's facilities are expected to reduce operating costs. More importantly, upgrading their machinery can increase capacity for certain GOES grades which would address concerns raised by industry. New entrants into the market may also take advantage of a production subsidy or capital expenditure loan to subsidize their startup costs and encourage future domestic GOES demand and competition. A capital expenditure loan is more preferable than a production subsidy as it has set terms which expire. Special attention, however, will need to be given to the underlying factors which will support this option.

In order for a capital expenditure loan to succeed in reducing operating costs, demand for domestic GOES has to increase. Should demand not increase, there is no guarantee that the loan can be recouped. In addition, low-priced imports may pose a threat as there is no guarantee that after the facilities are upgraded, they will be able to compete with imports on price. Further review into regulations and other agreements may be necessary to further reduce domestic operating costs. The Secretary of Commerce recommends combining the capital expenditure loan with establishing a strategic stockpile to ensure long-term budget positivity.

4. Enact Domestic Content Requirements

Enact a domestic content requirement through the Defense Federal Acquisition Regulations (DFAR) and Federal Acquisition Regulations (FAR) to require that all electric transformers purchased by the U.S. government are compliant with the Buy American Act. This option is expected to increase demand for domestic GOES, which will in turn increase demand for transformers produced domestically. This option is expected to be budget neutral and will not explicitly increase the cost of GOES or transformer-related products. Special provisions will have to be implemented in order to avoid explicitly increasing costs.

The main drawback of this option is that direct Department of Defense and U.S. Government purchases of transformers account for only a small percentage of transformer production, and so will have limited impact on domestic GOES production unless the domestic content requirement can be extended to purchases of transformers by public and private utility companies that make up the majority of the market.

5. Establish a Strategic Stockpile of GOES

Establish a strategic stockpile of domestic GOES and subsequent transformer-related products to satisfy U.S. defense and essential civilian transformer demand in case of a national emergency. In fact, the Defense Logistics Agency is seeking funding for inclusion of GOES in the National Stockpile. This option is expected to be budget negative in the short run, however, it can be budget neutral or positive in the long run. This option will ensure that the domestic GOES producer retains business in order to support the stockpile in the short run.

In the long run, a strategic stockpile on its own does not guarantee success for the domestic GOES producer. Should the stockpile be comprised of GOES, a domestic lamination and core (stacked and wound) industry is necessary in order to process the GOES. Should the stockpile include both GOES and laminations and cores (stacked and wound), multiple gauges and specified products will need to be stockpiled to ensure ample coverage. The risk of stockpiling outdated or mismatched GOES also increases as new developments and efficiency standards are implemented. Long lead times may further complicate the stockpiling process in order to balance current U.S. demand and stockpile demand.

6. Reclassify the Lamination and Cores HTS Codes

Reclassify the HTS codes for laminations and cores (stacked and wound) from chapter 85 to chapter 72. This option is expected to be budget positive as reclassifying the HTS codes to 72 would mean that proclamation 9705 (which imposes tariffs/quotas on steel imports) would apply to laminations and cores (stacked and wound). This option is similar to extending proclamation 9705 to laminations and cores (stacked and wound) (the Tariff/Quota option)

however, it is a more permanent shift as HTS codes will have to be re-harmonized. This would forgo the need to apply tariffs on downstream transformer products.

Reclassifying the HTS codes for laminations and cores (stacked and wound) can prove challenging given the re-harmonization efforts required. Given that a 25 percent tariff rate is guaranteed, downstream product costs are expected to increase. This option does not guarantee new entrants into the market as transformer manufacturing will likely offshore in order to avoid the increased costs.

7. Establish a Working Group To Provide Further Recommendations

Establish a working group comprised of the Department of Defense, Department of Energy, Department of Homeland Security, Department of State, Department of Commerce, and industry stakeholders to conduct further negotiations and research in order to recommend further options. This option is expected to be budget neutral and will not explicitly increase costs across the industry. It will also encourage further dialogue at the USG and industry level in order to recommend other solutions and provide more specific actions.

Establishing a working group, however, does not address the immediate threat of imports of electrical steel, transformer laminations and cores, or LPT. As a consequence of this, the domestic GOES manufacturer will likely continue to face financial hardships, and new entrants into the market are unlikely. The United States will continue to be threatened by imports and have insufficient capacity to produce transformer laminations, cores, and LPT.

**Matthew S. Borman,**

*Deputy Assistant Secretary for Export Administration.*

[FR Doc. 2021–24958 Filed 11–17–21; 8:45 am]

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# FEDERAL REGISTER

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Part III

## Department of Labor

Employee Benefits Security Administration

Proposed Exemptions From Certain Prohibited Transaction Restrictions; Notice

## DEPARTMENT OF LABOR

### Employee Benefits Security Administration

### Proposed Exemptions From Certain Prohibited Transaction Restrictions

**AGENCY:** Employee Benefits Security Administration, Labor.

**ACTION:** Notice of proposed exemptions.

**SUMMARY:** This document contains notices of pendency before the Department of Labor (the Department) of proposed exemptions from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (ERISA or the Act) and/or the Internal Revenue Code of 1986 (the Code). If granted, these proposed exemptions allow designated parties to engage in transactions that would otherwise be prohibited provided the conditions stated there in are met. This notice includes the following proposed exemptions: L–12002, Retirement System of the American National Red Cross; D–11955, Morgan Stanley & Co. LLC, and Current and Future Affiliates and Subsidiaries.

**DATES:** All interested persons are invited to submit written comments or requests for a hearing on the pending exemptions, unless otherwise stated in the Notice of Proposed Exemption, by January 3, 2022.

**ADDRESSES:** All written comments and requests for a hearing should be sent to the Employee Benefits Security Administration (EBSA), Office of Exemption Determinations, U.S. Department of Labor, Attention: Application No.____, stated in each Notice of Proposed Exemption via email to *e-OED@dol.gov* or online through *http://www.regulations.gov* by the end of the scheduled comment period. Any such comments or requests should be sent by the end of the scheduled comment period. The applications for exemption and the comments received will be available for public inspection in the Public Disclosure Room of the Employee Benefits Security Administration, U.S. Department of Labor, Room N–1515, 200 Constitution Avenue NW, Washington, DC 20210. See **SUPPLEMENTARY INFORMATION** below for additional information regarding comments.

**SUPPLEMENTARY INFORMATION:**

### Comments

In light of the current circumstances surrounding the COVID–19 pandemic caused by the novel coronavirus which may result in disruption to the receipt of comments by U.S. Mail or hand delivery/courier, persons are encouraged to submit all comments electronically and not to follow with paper copies. Comments should state the nature of the person's interest in the proposed exemption and the manner in which the person would be adversely affected by the exemption, if granted. A request for a hearing can be requested by any interested person who may be adversely affected by an exemption. A request for a hearing must state: (1) The name, address, telephone number, and email address of the person making the request; (2) the nature of the person's interest in the exemption and the manner in which the person would be adversely affected by the exemption; and (3) a statement of the issues to be addressed and a general description of the evidence to be presented at the hearing. The Department will grant a request for a hearing made in accordance with the requirements above where a hearing is necessary to fully explore material factual issues identified by the person requesting the hearing. A notice of such hearing shall be published by the Department in the **Federal Register**. The Department may decline to hold a hearing where: (1) The request for the hearing does not meet the requirements above; (2) the only issues identified for exploration at the hearing are matters of law; or (3) the factual issues identified can be fully explored through the submission of evidence in written (including electronic) form.

*Warning:* All comments received will be included in the public record without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be confidential or other information whose disclosure is restricted by statute. If you submit a comment, EBSA recommends that you include your name and other contact information in the body of your comment, but DO NOT submit information that you consider to be confidential, or otherwise protected (such as Social Security number or an unlisted phone number) or confidential business information that you do not want publicly disclosed. However, if EBSA cannot read your comment due to technical difficulties and cannot contact you for clarification, EBSA might not be able to consider your comment. Additionally, the *http://www.regulations.gov* website is an ''anonymous access'' system, which means EBSA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email directly to EBSA without going through *http://www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public record and made available on the internet.

### Notice to Interested Persons

Notice of the proposed exemptions will be provided to all interested persons in the manner agreed upon by the applicant and the Department, unless otherwise stated in the Notice of Proposed Exemption, within 15 days of the date of publication in the **Federal Register**. Such notice shall include a copy of the notice of proposed exemption as published in the **Federal Register** and shall inform interested persons of their right to comment and to request a hearing (where appropriate).

The proposed exemptions were requested in applications filed pursuant to section 408(a) of the Act and/or section 4975(c)(2) of the Code, and in accordance with procedures set forth in 29 CFR part 2570, subpart B (76 FR 66637, 66644, October 27, 2011).[1] Effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978, 5 U.S.C. app. 1 (1996), transferred the authority of the Secretary of the Treasury to issue exemptions of the type requested to the Secretary of Labor. Therefore, these notices of proposed exemption are issued solely by the Department.

The applications contain representations with regard to the proposed exemptions which are summarized below. Interested persons are referred to the applications on file with the Department for a complete statement of the facts and representations.

### Retirement System of the American National Red Cross

### Located in Washington, DC

### [Exemption Application No. D–12002]

### Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Employee Retirement Income Security Act of 1974, as amended (ERISA or the Act), and section 4975(c)(2) of the Internal Revenue Code of 1986, as amended (the Code), and in accordance with the procedures set forth in 29 CFR part 2570, subpart B (76 FR 66637,

[1] The Department has considered exemption applications received prior to December 27, 2011 under the exemption procedures set forth in 29 CFR part 2570, subpart B (55 FR 32836, 32847, August 10, 1990).

66644, October 27, 2011).[2] As described in more detail below, the applicant for the exemption is the American National Red Cross (the Red Cross or the Applicant) who seeks to contribute nine condominiums to the Retirement System of the American National Red Cross (Plan).[3] The proposed contribution (the Contribution) and the proposed assignment of certain rights and obligations from the Red Cross to the Plan in connection with the Contribution, would violate certain prohibited transaction provisions of ERISA and the Code, and therefore would require an exemption from those provisions.

**Summary of Facts and Representations** [4]

1. The Red Cross is a Congressionally-chartered organization with its principal offices at 430 17th Street NW, Washington, DC 20006. The Red Cross control group consists of its National Headquarters and its individual chapters and Biomedical units.

2. The Red Cross sponsors and maintains the Plan, a tax-qualified defined benefit pension plan covering its eligible National Headquarters employees and the eligible employees of its chapters and Biomedical units that have elected to participate in the Plan. Benefit accruals under the Plan generally were frozen effective January 1, 2013, for Plan participants other than certain groups represented by labor unions. The Plan had approximately 22,588 participants and net assets valued at $2,412,180,496 on June 30, 2020.

3. The Plan administrator is the Benefit Plan Committee of The American National Red Cross (the BPC), which serves as the Plan's named fiduciary with respect to its operation and administration as well as the oversight of its investments.[5]

4. The Red Cross owns nine condominium units (the Red Cross Condos, as defined in Section II(e) below) in a building (the Building) located at 2025 E Street NW, Washington, DC (the Property). The Building, part of the Red Cross's former headquarters, has 808,478 square feet of gross building area and was constructed between 1999 and 2002. The Building's net rentable area consists of 540,000 square feet of Class A Office space, of which the Red Cross Condos comprise 390,670 square feet of net rentable area.[6] The overall building is designed as 10-stories (above grade) North and five-stories (above grade) South tower, connected by an atrium with four below grade levels. As described in further detail below, the Red Cross Condos are currently subject to a pre-existing ground lease (with the Red Cross as lessee), a space lease (with the Red Cross as lessor), a property management agreement, a purchase and sale agreement, and reciprocal rights agreement. These agreements which are described below, were reviewed by an independent fiduciary acting on behalf of the Plan and negotiated at arm's-length between the Red Cross and the U.S. General Services Administration (GSA). The Plan would be directly or indirectly subject to the agreements if the condominiums are contributed to the Plan.

5. *The Ground Lease.* The Building was constructed on United States (U.S.) government property. Congress authorized the Red Cross to redevelop and improve the original building and directed GSA, on behalf of the U.S., to enter into a ground lease (the Ground Lease) with the Red Cross as lessee, on July 29, 1999. The Ground Lease has a 99-year term that runs from July 29, 1999, through July 28, 2098, and covers 1.97 acres. The Ground Lease contains a right of first offer in favor of GSA. The Red Cross can sell the Red Cross Condos to a third party, provided the purchaser agrees to abide by the terms of the Ground Lease.

6. The Red Cross pays a ground rent of $1.00 over the term of the lease, and all taxes, insurance and operating costs associated with the Red Cross Condos. During the Ground Lease's 99-year term, the Red Cross owns the leasehold improvements, including the Red Cross Condos, which are part of the Building. After that, the improvements revert to the U.S. government.

7. *The Space Lease.* On July 1, 2009, Red Cross entered into a space lease (the Space Lease) with GSA on behalf of the U.S. Department of State (the State Department) for portions of the building through June 30, 2020. The State Department currently occupies and leases all of the nine Red Cross condominiums. The Space Lease gives GSA an option to renew the lease for two ten-year periods. On June 26, 2019, GSA exercised the first ten-year renewal option extending the Space Lease through June 30, 2030.[7]

8. *Property Management Agreement.* The Applicant represents that the 2025 E Street Office Leasehold Condominium Unit Owners Association, Inc. (the Condo Association), a District of Columbia nonprofit corporation, entered into a property management agreement with the Red Cross as managing agent with respect to the Building, effective on January 18, 2017. Pursuant to the Agreement, the Red Cross may receive a property management fee of approximately $1 million annually. However, if this exemption is granted and the proposed Contribution is made, the Applicant represents that any provision of services by the Red Cross in connection with the Plan's ownership of a condominium would comply with the requirements of ERISA Section 408(b)(2). Further, the Red Cross would not receive any consideration for such services other than the reimbursement of ''direct expenses,'' as described in 29 CFR 2550.408b–2(e)(3). In this regard, this proposed exemption provides relief solely for the contribution of the Red Cross Condos to the Plan and does not provide relief for the Red Cross to receive any compensation in connection with its management of the Red Cross Condos, or for any other reason, in excess of Red Cross's ''direct expenses.''

9. *Purchase and Sale Agreement.* The Applicant represents that the Red Cross and GSA entered into a purchase and sale agreement, dated December 20, 2016, (the Purchase and Sale Agreement) under which GSA may

[2] For purposes of this proposed exemption, references to the provisions of Title I of ERISA, unless otherwise specified, refer also to the corresponding provisions of the Code.

[3] The Red Cross made its request pursuant to ERISA Section 408, and in accordance with the procedures set forth in 29 CFR part 2570, subpart B (76 FR 66637, 66644, October 27, 2011). Effective December 31, 1978, section 102 of the Reorganization Plan No. 4 of 1978, 5 U.S.C. app 1 (1996) transferred the authority of the Secretary of the Treasury to issue administrative exemptions under Code section 4975(c)(2) to the Secretary of Labor. Accordingly, this notice of proposed exemption is being issued solely by the Department.

[4] The Department notes that availability of this exemption, is subject to the express condition that the material facts and representations contained in application D–12002 are true and complete and accurately describe all material terms of the transactions covered by the exemption. If there is any material change in a transaction covered by the exemption, or in a material fact or representation described in the application, the exemption will cease to apply as of the date of such change.

[5] The BPC was established effective March 7, 2019, as the successor to two separate committees, the Benefit Plan Administrative Committee of the American National Red Cross (BPAC) and the Benefit Plan Investment Committee of the American National Red Cross (BPIC). Certain statements herein describe actions or authorities of the former BPIC and BPAC, because these were the named fiduciaries at the time.

[6] The Red Cross Condos are subject to a condominium regime and consist of the following units and 273 parking spaces: LL2, LL1, 400, 500, 600, 700, 800, 900, and 1,000.

[7] As per the terms of the Space Lease, the second ten-year period would extend the Space Lease until June 30, 2040, provided that such option to renew is exercised no later than 12 months before the close of the first 10-year renewal term (by June 30, 2029). For this second renewal term to be effective, GSA and Red Cross (or the Plan as assignee of the Red Cross) must execute a separate lease agreement.

purchase the nine Red Cross Condos for approximately $230 million. Pursuant to the Purchase and Sale Agreement, GSA purchased five of the 14 condominium units in January 2017 for a total purchase price of $85,607,500 (the GSA Condos).

10. *The Proposed Contribution.* Red Cross proposes to contribute the Red Cross Condos to the Plan (*i.e.,* the Contribution), and assign to the Plan its rights and obligations under (1) the condominium declaration together with condominium by-laws, Condominium plat and plans, and such other documents as describe the rights and obligations of Red Cross as a condominium unit owner, (2) the Ground Lease, (3) the Space Lease, (4) the Purchase and Sale Agreement between the Red Cross and GSA dated December 20, 2016, and (5) the reciprocal rights agreement between the Red Cross and GSA dated December 20, 2016 (the Reciprocal Rights Agreement, described below). The Applicant states that the Red Cross Condos otherwise would be contributed free of debt and encumbrance.

11. The proposed contribution constitutes a ''sale or exchange'' of property between the Plan and the Red Cross, which is prohibited by ERISA Section 406(a)(l)(A). Further, the assignment of the rights and obligations the Red Cross Condos are subject to constitutes a ''transfer to, or use by or for the benefit of'' the Red Cross, which is prohibited by ERISA section 406(a)(1)(D). Since the Red Cross is a fiduciary with respect to the Plan, and the proposed contribution could reduce future funding obligations of the Red Cross to the Plan, the proposed transaction is also prohibited by the fiduciary anti-conflict of interest and self-dealing provisions of ERISA Sections 406(b)(l) and 406(b)(2).[8]

12. *Applicant's Reasons for Entering the Transaction.* The Applicant states that it is entering into the transaction to increase the funded status of the Plan and provide a reliable stream of inflation-adjusted rental income for the Plan that is expected to exceed its long-term expected rate of return on a consistent basis. The Applicant represents that the proposed transaction would benefit Plan participants and beneficiaries by permitting the Plan to accept and hold valuable real estate assets (the Red Cross Condos), which have been and are currently fully occupied. The Applicant represents that the Red Cross Condos provide a stream of annual cash flow while GSA obtains the necessary appropriations to purchase the remaining Red Cross Condos, and can be readily liquidated.

13. *Applicant States that the Proposed Contribution Would Be in the Interest of the Plan.* The Applicant represents that the Red Cross Condos' rental income would provide the Plan with an immediate, substantial and predictable source of income for the payment of Plan benefits and expenses. Moreover, the Applicant states that the proposed contribution of the Red Cross Condos to the Plan would diversify the Plan's investments, because the Plan's assets currently do not include real property.[9]

14. The Applicant represents that the proposed Contribution would be a voluntary contribution in addition to the Red Cross's minimum required contribution (MRC) under Code sections 412 and 430. The Applicant represents that the Plan had a credit balance of approximately $431,490,000 on January 23, 2020 (the Existing Credit Balance). As described below, the Applicant represents the value of the Contribution would not be added to the Plan's Existing Credit Balance, and the Red Cross would permanently waive the additional credit balance generated by the Contribution of the Red Cross Condos. The Applicant represents that the Contribution would not effectively substitute for the Red Cross cash MRCs in future years, and, therefore, the Contribution could (1) substantially increase the Plan's funding level, (2) reduce the Plan's variable-rate Pension Benefit Guaranty Corporation (PBGC) premiums, and (3) significantly reduce the Plan's unfunded vested benefits.[10]

15. The Applicant maintains that the Red Cross Condos would provide the Plan with a steady source of rental income (approximately $15 million of annual net), because the Red Cross Condos currently are fully occupied through at least June 30, 2030, by a reliable tenant (the State Department through GSA). The Applicant states that a near-term market for the Red Cross Condos exists, because GSA has agreed to pay a price consistent with the Red Cross Condos' percentage interest of the Building's fair market value as independently appraised in connection with the arm's-length negotiations between Red Cross and GSA pursuant to the Purchase and Sale agreement.

16. *Downside Risk Protections.* The Red Cross proposes to provide the following additional downside risk protections to the Plan:

17. *First Plan Protection.* The Applicant represents that the Contribution of the Red Cross Condos would not be used to satisfy the Red Cross's MRC to the Plan. The Contribution would be an additional voluntary contribution that the Red Cross intends to: (i) Improve the Plan's funding status; (ii) diversify the Plan's investments while providing the Plan with a steady source of rental income; and (iii) decrease the Plan's PBGC premium expenses, which are payable from Plan assets. In this regard, although the Contribution of the Red Cross Condos would generate a credit balance that typically could be used as a dollar-for-dollar credit against the Red Cross' future MRCs, the Red Cross will permanently waive that credit balance, so that the Contribution would not be used by the Red Cross to reduce future cash MRCs that it otherwise would be required to make to the Plan.

18. *Second Plan Protection.* The Red Cross proposes to make a minimum $5 million cash contribution to the Plan in any year in which: (i) Any or all of the Red Cross Condos are retained as assets of the Plan; and (ii) the Red Cross uses the Existing Credit Balance to reduce its cash MRC.

According to the Applicant, the minimum $5 million cash contribution represents the Red Cross' commitment to enhance the Plan's funding status in years when the Red Cross reduces its cash MRC with a portion of the Existing Credit Balance.

19. *Third Plan Protection.* As an additional protection to the Plan from downside risk, the Red Cross will extend a Parallel Reversion Commitment (the Commitment) to the Plan, as defined in Section II(a) below, if GSA does not extend the Space Lease through June 30, 2040. The Applicant states that if such event occurs, the Red Cross will purchase back from the Plan any remaining Red Cross Condos the Plan still owns on June 30, 2030, for a price equal to the value of the condos for pension funding purposes at the time the Red Cross contributed them to the Plan upon the demand of the Qualified Independent Fiduciary (as defined in Section II(c) below). The Applicant states that the Commitment will provide the Plan with sufficient

[8] See Interpretive Bulletin 94–3, 29 CFR 2509.94–3(b) (the Interpretive Bulletin) (an in-kind contribution of unencumbered property ''constitute(s) a prohibited transaction even if the value of the contribution is in excess of the sponsor's or employer's funding obligation for the plan year in which the contribution is made . . . because the contribution would result in a credit against funding obligations which might arise in the future.'').

[9] The Plan's Investment Policy Statement has been revised to accommodate the Red Cross Condos as assets of the Plan. See Section 4.6.8 of the Plan's Investment Policy Statement.

[10] The impact of the Contribution on the Plan's variable-rate PBGC premium depends on whether the Contribution would bring the Plan under the PBGC variable rate premium cap.

resources to liquidate its investment in the Red Cross Condos if the Qualified Independent Fiduciary determines that it would be advantageous for the Plan to do so, because the Plan would not have to invest its resources to re-market the Red Cross Condos.

20. *Department's Note:* The Department acknowledges that the Commitment could provide meaningful downside protection to the Plan in appropriate circumstances. However, a sale of a Red Cross Condo from the Plan to the Red Cross under the Commitment would violate several ERISA prohibited transaction provisions. At the present time, the Department does not have sufficient information to affirmatively determine the appropriate circumstances under which a sale of the Red Cross Condos from the Plan to the Red Cross under the terms of the Commitment would be in the interest and protective of the Plan and its participants and beneficiaries, and administratively feasible as required by ERISA Section 408(a). However, the Qualified Independent Fiduciary would have the option to invoke the Commitment if he or she finds it to be in the Plan's interest, subject to receiving a prohibited transaction exemption from the Department.

21. The Applicant represents that GSA must exercise its right to extend the Space Lease for an additional ten-year term (through June 30, 2040) by June 30, 2029. Therefore the Qualified Independent Fiduciary would know whether GSA will extend the lease agreement a year before the Space Lease expires. The one-year period will provide the Qualified Independent Fiduciary with sufficient time before the expiration of the Space Lease to determine whether the Plan would benefit from exercising the Commitment. Accordingly, the Qualified Independent Fiduciary must determine by June 30, 2029, whether implementation of the Parallel Reversion Commitment would be advantageous to the Plan if GSA does not extend the Space Lease through June 30, 2040. This determination must be submitted to the Department within sixty days after the date it is made by the Qualified Independent Fiduciary. If the Qualified Independent Fiduciary determines that the exercise of the Commitment would be advantageous to the Plan, the Applicant must submit an associated individual prohibited transaction exemption application to the Department within six months after the date the Qualified Independent Fiduciary's determination is filed with the Department.

22. *Fourth Plan Protection.* The Red Cross previously entered into a Reciprocal Rights Agreement with GSA dated December 20, 2016, which was amended on September 30, 2020.[11] The agreement, as amended, grants the Red Cross a reversion right that would provide the Plan (as the Red Cross's assignee) with the right (but not the obligation) to buy back the Red Cross Condos purchased by GSA at the same price that GSA paid for them, if GSA fails to: (1) Purchase all of the Red Cross Condos on or before June 30, 2030; and (2) extend the Space Lease for an additional ten-year term (through June 30, 2040).[12]

23. *Fifth Plan Protection.* As a final protection from downside risk, the Applicant states that for each Plan year during which the Red Cross Condos remain assets of the Plan, the Red Cross will contribute sufficient amounts to the Plan to ensure that its adjusted funding target attainment percentage (AFTAP), within the meaning of Code Section 436, is at least equal to 80 percent. This will ensure that the Plan would not become subject to the limitation on benefits and benefit accruals imposed by Code Section 436 that are applied based on the Plan's AFTAP.

24. *Qualified Independent Fiduciary.* Pursuant to a written agreement among Fiduciary Counselors Inc. (FCI), the Red Cross, the BPC and the Plan, dated January 11, 2019 (hereinafter, the Qualified Independent Fiduciary Agreement), FCI was retained to serve as the Plan's Qualified Independent Fiduciary with respect to the Contribution. FCI is an investment adviser registered with the Securities and Exchange Commission under the Investment Advisers Act of 1940. The firm primarily acts as an independent fiduciary for employee benefit plans and has served in this capacity since 2001.

25. FCI represents and warrants that it is independent of and unrelated to the Red Cross, and that: (i) It does not directly or indirectly control, is not controlled by, and is not under common control with the Red Cross; (ii) neither it, nor any of its officers, directors, or employees is an officer, director, partner or employee of the Red Cross (or is a relative of such persons); (iii) it does not directly or indirectly receive any compensation or other consideration for its own account in connection with the Qualified Independent Fiduciary report (the Qualified Independent Fiduciary Report), except that FCI may receive compensation from the Red Cross for performing the services described in the Qualified Independent Fiduciary Agreement as long as the amount of such payment is not contingent upon or in any way affected by FCI's ultimate decision; and (iv) the percentage of FCI's revenue that is derived from any party in interest or its affiliates involved in the Transaction is less than five percent (5%) of its previous year's annual revenue from all sources.[13] In addition, FCI represents that it understands its duties and responsibilities under ERISA in acting as an independent fiduciary on behalf of the Plan.

26. No party associated with this exemption application has or will indemnify the Qualified Independent Fiduciary, in whole or in part, for negligence or any violations of state or federal law that may be attributable to the Qualified Independent Fiduciary in performing its duties with respect to the proposed Contribution. In addition, no contract or instrument purports to waive any liability under state or federal law for any such violations.

27. Pursuant to the Qualified Independent Fiduciary Agreement, FCI is responsible for completing the following duties:

(i) Determining whether and on what terms the Plan should engage in the proposed transaction, including the transaction price (the value to be attributed to the Contribution for ERISA funding purposes) and whether the proposed transaction is in the interests of the Plan's participants and beneficiaries;

[11] Originally, GSA's purchase option under the Reciprocal Rights Agreement extended to June 30, 2030, only if it purchased five Red Cross Condos (increasing its ownership percentage to 75 percent) by June 30, 2020. That date passed, and GSA did not purchase additional Red Cross Condos. The Red Cross and GSA amended the Reciprocal Rights Agreement, dated September 30, 2020, to extend the deadline for GSA to exercise its option to purchase the remaining Red Cross Condos until June 30, 2030, consistent with the current extension of the Space Lease through that date. This proposed exemption requires the Qualified Independent Fiduciary to determine that the Reciprocal Rights Agreement, and the other Red Cross Condo Documents, as amended, are in the interest of, and protective of, the Plan.

[12] Specifically, the Reciprocal Rights Agreement provides that, if (1) or (2) occurs, the Red Cross will have the right (but not the obligation) to cause the reversion to Red Cross of title to all GSA units that were purchased by GSA from the Red Cross, and continue to be owned by GSA, by refunding to GSA all purchase funds paid by GSA to the Red Cross for all such units.

[13] FCI represents that revenue for this assignment has been recognized over multiple years, as follows. In 2019, FCI recognized revenue that was 2.11% of its total 2018 income. In 2020, FCI recognized revenue that was 0.69% of its total 2019 income. FCI has not recognized any revenue in 2021. If additional services are needed from FCI as a result of the exemption being granted, FCI will recognize revenue as appropriate. Such revenue in any year will not exceed 5% of FCI's total income for the previous year.

(ii) Performing all other work in connection with the Red Cross's submission of its exemption application to the Department, including: (a) Preparing a preliminary report for the Department; (b) responding to the Department's questions; (c) assisting in the preparation of material for, and attending, a pre-submission conference, if scheduled; (d) conducting a due diligence analysis; (e) engaging a qualified appraiser (*i.e.,* the Qualified Independent Appraiser, as defined in Section II(b), below) to value the Red Cross Condos, as well as the 50 parking spaces retained by the Red Cross and the impact on the fair value of the Ground Lease; (f) reviewing the Qualified Independent Appraiser's opinion of value for consistency with sound principles of valuation; (g) reviewing the terms of the Contribution to ensure that they are in the interest of the Plan and the Plan's participants; (h) reviewing the Property management services provided by the Red Cross to the Condo Association and the arrangement for the use of 50 parking spaces by the Red Cross; (i) ensuring that all terms and conditions of the proposed transaction are met and, if necessary, taking action to ensure compliance with each term and condition; (j) preparing and issuing a final report to the Department; (k) reviewing and commenting on the draft exemption application and responding to any relevant comments received by the Department if it determines to publish a notice of proposed exemption in the **Federal Register**.

28. The First Independent Appraiser. FCI hired an appraiser in connection with the Contribution (the First Appraiser). The First Appraiser's engagement was subject to provisions stating that the First Appraiser was not liable for an act of negligence by the First Appraiser for any amount in excess of the total professional fees paid to the appraiser under the agreement or an addendum thereto.

29. The First Appraiser's insistence on limiting responsibility for negligent work, and FCI's acceptance of such a limitation, raised concerns for the Department regarding whether adequate protections were in place to warrant proposing an exemption.

30. ERISA's prohibited transaction provisions are designed to protect plans and their participants and beneficiaries from the dangers posed by transactions involving significant conflicts of interest. In determining whether to grant a prohibited transaction exemption, the Department expects independent fiduciaries to exercise special care when hiring a qualified independent appraiser to value hard-to-value assets that are an essential component of the exemption transaction, and to insist that those appraisers perform their work in accordance with expert standards and without protection from loss or the imposition of financial burden resulting from work that fails to adhere to those standards. The role of the Qualified Independent Appraiser in this transaction is critical to the Department's determination of whether to grant a proposed exemption, and the appraiser's work product must be held to the highest standard of care, diligence and accuracy. Releases from and limitations on liability for work that fail to adhere to those standards are not protective of the Plan and its participants and beneficiaries and do not support the Department's grant of a proposed exemption in this matter. An independent fiduciary's decision to hire an expert with these liability limitations calls into question the prudence of the independent fiduciary's decision, reduces the reliability of the appraisal report, and negates the purpose of requiring an independent appraisal of the Red Cross Condos.

31. *The Qualified Independent Appraiser.* The Department conveyed its concerns to the Red Cross and FCI. Thereafter, FCI engaged Chaney & Associates (Chaney) to serve as the Qualified Independent Appraiser in connection with the proposed Contribution, pursuant to an engagement agreement (the Engagement Agreement) dated June 9, 2020, which does not include indemnification provisions. In this regard, no party related to this exemption request has or will indemnify the Qualified Independent Appraiser, in whole or in part, for negligence or any violations of state or federal law that may be attributable to the Qualified Independent Appraiser in performing its duties with respect to the proposed Contribution. In addition, no contract or instrument purports to waive any liability under state or federal law for any such violations. Mark A. Chaney of Chaney performed the subject appraisal. Mr. Chaney is licensed in the District of Columbia as an Appraiser Certified General and has experience with commercial real estate and business valuations. Chaney has appraised 14 office properties within the 12 months before the Engagement Agreement, four of which were condominium regimes.

32. Pursuant to the Engagement Agreement, Chaney was retained to perform two appraisals of the Red Cross Condos. The first appraisal report is discussed below, and the second appraisal report will be performed to ensure the Red Cross Condos are accurately valued as of the date of the Contribution.

33. Chaney represents that it adhered to professional appraisal standards and concluded that the Red Cross Condos should be valued for purposes of this transaction at approximately $528/SF for the above grade units, and about $286/SF for the below grade units. Chaney notes that the appraisal will be updated as of the date of the Contribution.[14]

34. With respect to the overall building sales comparables, Chaney states that the continued operation of the subject as a rental, predicated on the extraordinary assumption that GSA does not exercise any of its purchase options, results in an investment value of $200,138,360 by way of the sales comparison approach or $200,140,000 rounded, on June 30, 2020.

35. The values determined pursuant to the different methodologies employed are depicted below.

[14] The Department expects and assumes that Chaney has properly discharged its obligations as an appraiser, and that expectation and assumption is material to the Department's determination to propose the exemption.

| Value | Investment<br><br>Extraordinary assumption GSA does not exercise any of its purchase options | Market As Is<br><br>Extraordinary assumption GSA exercises all its purchase options by 6/30/30 |
|---|---|---|
| Income Capitalization Approach (yield) | $205,730,000 | $220,710,000 |
| Income Capitalization Approach (direct) | $209,686,200 | N/A |
| Sales Comparison Approach | $200,140,000 | N/A |
| | | |
| CONCLUSIONS | $205,180,800 | $220,710,000 |

36. All values are estimated as of June 30, 2020, and reflect the leasehold interest; subject to the sublease of the Red Cross Condos to the State Department/GSA. Chaney states that the estimated marketing period is about 12 months, which is predicated on a survey of sales of similar properties occurring during the past few years locally.

37. Based on Chaney's highest and best use analysis, the current investment value of the Red Cross Condos, predicated on the extraordinary assumption that GSA does not exercise any of its purchase options, equates to $205,180,000 as of June 30, 2020, as shown in the table above. The market value as is of the Red Cross Condos, predicated on the extraordinary assumptions GSA exercises all its purchase options by June 30, 2030, is $220,710,000, also as of June 30, 2020.

38. *The Qualified Independent Fiduciary Report.* The Qualified Independent Fiduciary submitted to the Department its report, dated December 23, 2020 (*i.e.,* the Qualified Independent Fiduciary Report) where it represented that it considered the following, among other things: (i) Whether the Contribution is a permitted Plan investment; (ii) the valuation of the Contribution; (iii) whether the proposed Contribution would negatively impact the diversification of the Plan's investments; (iv) whether the Plan would have sufficient liquidity to meet its benefit payments on a going-forward basis; (v) whether the Contribution would sufficiently improve the funded status of the Plan; and (vi) whether the Contribution may be readily liquidated. The Qualified Independent Fiduciary represents that as of October 31, 2020, the Plan was well diversified with total assets of $2.3 billion, and that while the Contribution will increase the Plan's illiquid assets, assuming the Contribution was contributed on October 31, 2020 with a value of $212,945,000, illiquid assets would go from 7.1% pre-Contribution level to a level of 14.9% post-Contribution, which would be within the 0–25% targeted range. The Qualified Independent Fiduciary expects that the allocation will return to pre-Contribution levels as GSA exercises its purchase option. Consequently, the Qualified Independent Fiduciary stated that the Contribution will not cause any significant disruptions to the Plan's asset allocation. Based on the valuation provided by Chaney, which the Qualified Independent Fiduciary has determined to be reliable and current, and based on the Qualified Independent Fiduciary's adherence to the requirements of ERISA Section 404, the Qualified Independent Fiduciary determined that the market value of the Red Cross as of June 30, 2020 was $212,945,000.[15] The Qualified Independent Fiduciary stated this value reflects the fact that State Department desires to have GSA exercise the purchase options on its behalf, but that because funding for the purchases is uncertain and dependent on Congressional appropriations, neither Chaney nor the Qualified Independent Fiduciary has sufficient information to determine which assumption is more likely to be realized.

39. The Qualified Independent Fiduciary represents that Willis Towers Watson, the Plan's actuary, computed the AFTAP for the plan year beginning July 1, 2020, to be 122.46%. The Qualified Independent Fiduciary concluded that adding the Contribution of $212,945,000 would significantly improve the Plan's funded status. Finally, the Qualified Independent Fiduciary stated that the Contribution could be readily liquidated based on the fact that GSA and the Red Cross have already negotiated and extended a purchase option for GSA to purchase the Red Cross Condos. The Qualified Independent Fiduciary represents that, in the unlikely event that GSA does not purchase any or all of the remaining Red Cross Condos, the Red Cross Condos may be readily liquidated, since they are located in a Class A office condo building in a desirable part of the District of Columbia. During the course of the Qualified Independent Fiduciary's review of the proposed transaction, it held discussions with Red Cross' senior management and staff, as well as the Plan's outside ERISA counsel. In addition, the Qualified

[15] The Department expects and assumes that the Qualified Independent Fiduciary has properly discharged its obligations as a fiduciary, and that expectation and assumption is material to the Department's determination to propose the exemption.

Independent Fiduciary conducted several due diligence conversations with the Qualified Independent Appraiser. Further, the Qualified Independent Fiduciary reviewed the Plan's Actuarial Valuation Reports, the appraisal report, the Plan's Investment Performance Report, the Ground Lease, the Space Lease, the Purchase and Sale Agreement and other relevant documents discussed herein, and applied its reasonable judgement when making determinations with respect to the proposed transaction in accordance with ERISA Section 404. In that regard, the Qualified Independent Fiduciary represents that it prudently selected the Qualified Independent Appraiser to value the Red Cross Condos for purposes of the proposed Contribution, ensured the Qualified Independent Appraiser's independence, made sure that the information given to the Qualified Independent Appraiser was complete, current, and accurate, and concluded that, in accordance with its fiduciary responsibilities under ERISA, it was reasonable to rely upon the appraisal under the circumstances following the review of the appraisal and conversations with the Qualified Independent Appraiser.

40. The Qualified Independent Fiduciary considered certain terms and conditions to which the Red Cross has agreed, including, among other things, that: the Red Cross will assume all costs and expenses associated with accepting and disposing of the Contribution; no portion of the Contribution will be counted as a contribution to the Plan for minimum funding purposes; and the Red Cross will make additional cash contributions to the Plan if necessary to maintain an 80% AFTAP until the Contribution is liquidated.

41. Based on the above analysis of the proposed transaction, the Qualified Independent Fiduciary stated its view that the Contribution is in the interests of the Plan and its participants and beneficiaries, and protective of the rights of participants and beneficiaries of the Plan. The Qualified Independent Fiduciary concluded that the Plan should accept the Contribution at a value it determines with the assistance of the Qualified Independent Appraiser.

42. Based on the foregoing, the Department has tentatively determined that the proposed exemption is:

(a) Administratively feasible because, among other things, the Qualified Independent Fiduciary has reviewed and approved the terms of the proposed Contribution, and will monitor compliance with the terms of the Contribution and the conditions of this proposed exemption, if granted;

(b) In the interests of the Plan and its participants and beneficiaries because, among other things, the Contribution would significantly increase the Plan's funding level and provide a significant stream of income for the Plan; and

(c) Protective of the rights of the Plan and of its participants and beneficiaries because, among other things, the exemption contains several provisions designed to limit or eliminate any downside risk to the Plan's acquisition and holding of a Red Cross Condo. For example, the proposed Contribution would be completely voluntary and would not be added to the Plan's Existing Credit Balance. Therefore, the Red Cross effectively would be contributing to the Plan an asset most recently valued between $205,180,800 and $220,710,000 that would provide funding to the Plan it otherwise would not have. The voluntary contribution would provide significant additional retirement income security to the Plan's participants and beneficiaries by helping to ensure that benefits promised to them by the Red Cross will be paid.

**Proposed Exemption**

*Section I—Covered Transactions*

If the proposed exemption is granted, the restrictions of ERISA Sections 406(a)(1)(A), 406(a)(1)(D), 406(b)(1), and 406(b)(2) and the sanctions resulting from the application of Code Section 4975, by reason of Code Sections 4975(c)(1)(A), (D) and (E), shall not apply to the: In-kind contribution (the Contribution) by the American National Red Cross (the Red Cross or the Applicant) of certain condominium units (the Red Cross Condos) located at 2025 E Street NW, Washington, DC (the Building) to the Retirement System of The American National Red Cross (the Plan); and the transfer by the Red Cross to the Plan of Red Cross's rights and obligations under the Red Cross Condo Documents, as defined in Section II(d) below, provided that the definitions in Section II and the conditions in Section III have been met.

*Section II—Definitions*

(a) The term ''Parallel Reversion Commitment'' means the agreement entered into between Red Cross and the Plan on or before the date of the Contribution whereby if GSA does not extend the Space Lease through June 30, 2040, upon the demand of the Qualified Independent Fiduciary, the Red Cross will purchase back from the Plan any remaining condos the Plan still owns on June 30, 2030, for a price equal to the value of such Red Cross Condos for funding purposes at the time of their contribution to the Plan. The Parallel Reversion Commitment can only be implemented after the conditions in Section III(g)(4) of this exemption have been met and the Department grants separate exemptive relief.

(b) A ''Qualified Independent Appraiser'' means Chaney & Associates (Chaney) or any individual or entity subsequently retained by the Qualified Independent Fiduciary to value the Red Cross Condos for purposes of the exemption, who meets the qualifications in the Department's regulation at 29 CFR 2570.31(i). Notwithstanding the above, the term ''Qualified Independent Appraiser'' does not include any entity whose terms of engagement include a provision that indemnifies the entity, in whole or in part, for negligence or for any violations of state or federal law that may be attributable to the Qualified Independent Fiduciary in performing its duties with respect to the proposed Contribution. In addition, no contract or instrument purports to waive any liability under state or federal law for any such violations.

(c) A ''Qualified Independent Fiduciary'' means Fiduciary Counselors Inc. (FCI), or an individual or entity that is subsequently retained by the Red Cross to represent the Plan for purposes of this exemption, and who meets the qualifications set forth in the Department's regulation at 29 CFR 2570.31(j). The term ''Qualified Independent Fiduciary'' does not include any entity whose terms of engagement include a provision that indemnifies the entity, in whole or in part, for negligence or for any violations of state or federal law that may be attributable to the Independent Fiduciary in performing its duties with respect to the proposed Contribution. In addition, no contract or instrument purports to waive any liability under state or federal law for any such violations.

(d) The term ''Red Cross Condo Documents'' means the following documents: (1) Condominium declaration together with condominium by-laws, Condominium plat and plans, and such other documents as describe the rights and obligations of Red Cross as a condominium unit owner, (2) the ground lease between the United States and the Red Cross dated July 29, 1999, (3) the space lease (the Space Lease) between the Red Cross and the U.S. General Services Administration (GSA) dated July 1, 2009, (4) the purchase and sale Agreement between the Red Cross and GSA dated December 20, 2016, and (5) the reciprocal rights agreement between the Red Cross and GSA, dated December 20, 2016, as amended.

(e) The term ''Red Cross Condos'' means the nine condominium units in a building located at 2025 E Street NW, Washington, DC.

*Section III—Conditions*

(a) For purposes of the Contribution, the Red Cross Condos are valued at their current fair market value, as determined by the Qualified Independent Fiduciary following its consideration and review of an appraisal, updated as of the date of the Contribution, performed by a Qualified Independent Appraiser;

(b) All rights and obligations attributable to the Red Cross Condo Documents are transferred to the Plan along with the Contribution of the Red Cross Condos;

(c) As of the date of the Contribution, there are no adverse claims, liens, debts, or encumbrances levied, or to be levied, against the Red Cross Condos;

(d) A Qualified Independent Fiduciary, exercising reasonable judgement in accordance with ERISA Section 404 when acting on behalf of the Plan, represents the interests of the Plan and its participants and beneficiaries with respect to the Contribution, and in doing so:

(1) Reviews, negotiates, and approves the terms of the Contribution;

(2) Determines that the Contribution is in the interests of the Plan and of its participants and beneficiaries and is protective of the rights of participants and beneficiaries of the Plan;

(3) Determines that the Red Cross Condos are valued for purposes of the Contribution at the Red Cross Condos' fair market value as of the date of the Contribution based on an updated appraisal that will be completed by a date that is within 30 days before the date of the Contribution, and exercises reasonable judgement in accordance with ERISA Section 404 when making this determination;

(4) Reviews the Appraisal to approve of the methodology used by the Qualified Independent Appraiser and to verify that the Qualified Independent Appraiser's methodology was properly applied;

(5) Ensures compliance with the terms of the Contribution and the conditions of this exemption are maintained at all times;

(6) Reviews the terms of the Red Cross Condo Documents, as amended, and determines that the terms are in the interest of and protective of the Plan;

(7) Will negotiate the terms of any future transaction with respect to the Red Cross Condos as an asset of the Plan, including without limitation to determine whether to continue to engage the Red Cross as property manager with respect to the Building and the terms of such engagement;

(e) The Plan does not pay any commissions, costs, or other expenses in connection with the Contribution, including any fees that are currently charged or accrued in the future by the Qualified Independent Fiduciary or the Qualified Independent Appraiser;

(f) The terms and conditions of the Contribution are no less favorable to the Plan than the terms and conditions that would be negotiated at arm's-length between unrelated third parties under similar circumstances;

(g) Downside Risk Protections:

(1) The Contribution of the Red Cross Condos will be in addition to the Red Cross's annual minimum required contributions (MRCs) determined in accordance with Code section 430 of the Code for the year in which the Contribution is made, and the Red Cross will permanently waive the credit balance generated by the Contribution of the Red Cross Condos, so that the Contribution will not substitute for cash contributions that the Red Cross otherwise would be required to make in the future;

(2) The Red Cross will make a minimum $5 million cash contribution to the Plan in any year in which:

(i) Any or all of the Red Cross Condos are retained as assets of the Plan; and

(ii) the Red Cross uses an existing credit balance to reduce its cash MRC;

(3) The Red Cross will contribute sufficient amounts to the Plan to ensure that its adjusted funding target attainment percentage, within the meaning of section 436 of the Code, is at least equal to 80 percent, for each Plan year during which the Red Cross Condos remain assets of the Plan;

(4) If GSA fails to purchase all the Red Cross Condos by June 30, 2030 and if the Space Lease fails to be extended through June 30, 2040, the Qualified Independent Fiduciary will determine whether implementation of a Parallel Reversion Commitment, as defined in Section II(a), is advantageous to the Plan as of June 30, 2030. This determination must be filed with the Department within sixty days thereafter. If the Qualified Independent Fiduciary determines that implementation of the Parallel Reversion Commitment would be advantageous to the Plan, the Applicant must submit an exemption request in connection therewith within six months after the Qualified Independent Fiduciary's determination is filed with the Department;

(h) Any provision of services by the Red Cross in connection with the Plan's ownership of a Red Cross Condo must comply with the requirements of ERISA Section 408(b)(2). Further, the Red Cross may not receive any consideration for such services other than the reimbursement of ''direct expenses,'' as described in 29 CFR 2550.408b–2(e)(3);

(i) All the facts and representations set forth in the Summary of Facts and Representation must be true and accurate.

**Notice to Interested Persons**

Notice of the proposed exemption will be provided to all interested persons within 15 days of the publication of the notice of proposed exemption in the **Federal Register**. The notice will be provided to all interested persons in the manner agreed upon by the Applicant and the Department and will contain a copy of the notice of proposed exemption as published in the **Federal Register** and a supplemental statement, as required pursuant to 29 CFR 2570.43(a)(2). The supplemental statement will inform interested persons of their right to comment on and to request a hearing with respect to the pending exemption. All written comments and/or requests for a hearing must be received by the Department within forty-five days of the date of publication of this proposed exemption in the **Federal Register**.

All comments will be made available to the public. *Warning:* If you submit a comment, EBSA recommends that you include your name and other contact information in the body of your comment, but DO NOT submit information that you consider to be confidential, or otherwise protected (such as a Social Security number or an unlisted phone number) or confidential business information that you do not want publicly disclosed. All comments may be posted on the internet and can be retrieved by most internet search engines.

**FOR FURTHER INFORMATION CONTACT:** Ms. Anna Vaughan of the Department, telephone (202) 693–8565. (This is not a toll-free number.)

**Morgan Stanley & Co. LLC, and Current and Future Affiliates and Subsidiaries (Morgan Stanley or the Applicant)**

**Located in New York, New York**

**[Application No. D–11955]**

**Proposed Exemption**

The Department is considering granting an exemption under the authority of 408(a) of the Act and section 4975(c)(2) of the Code, in accordance with the procedures set forth in 29 CFR part 2570, subpart B (76 FR 46637, 66644, October 27, 2011). If the exemption is granted, certain

restrictions of sections 406(a) and 406(b) of the Act, and certain sanctions resulting from the application of section 4975 of the Code,[16] shall not apply to transactions involving Morgan Stanley and Mitsubishi (described below) that are modeled after the following class exemptions: Prohibited Transaction Exemption (PTE) 75–1, Part III and Part IV, PTE 77–3, PTE 77–4, PTE 79–13, PTE 86–128, and PTE 2002–12, provided the conditions of this exemption are met.[17]

**Summary of Facts and Representations** [18]

1. *Morgan Stanley.*

Morgan Stanley is a global financial services firm headquartered in New York, New York. In the ordinary course of its business, Morgan Stanley provides a range of financial services to clients which include IRAs and pension, profit sharing and 401(k) plans qualified under section 401(a) of the Code. Morgan Stanley maintains significant market positions in each of its business segments, which include: Institutional Securities, Wealth Management and Investment Management. As of December 31, 2019, Morgan Stanley had over 60,000 employees.

Through its Wealth Management segment, Morgan Stanley provides financial services and solutions to individual investors and small to medium-sized businesses and institutions. These services include brokerage and investment advisory services, financial and wealth planning services, annuity and insurance products, credit and other lending products, and banking and retirement plan services. Through its Investment Management segment, Morgan Stanley provides investment strategies and products that span geographies, asset classes, and public and private markets. Institutional clients include defined benefit and defined contribution plans, foundations, endowments, government entities, sovereign wealth funds, insurance companies, third-party fund sponsors and corporations. Through its Institutional Securities segment, Morgan Stanley provides investment banking, sales and trading, lending and other services to corporations, governments, financial institutions and high net worth clients.

Morgan Stanley Investment Management Inc. is a registered investment adviser subject to the Investment Advisers Act of 1940. Morgan Stanley & Co. LLC is a SEC-registered broker dealer.

2. *Mitsubishi.*

Mitsubishi UFJ Financial Group, Inc. is a bank holding company incorporated as a joint stock company (kabushiki kaisha) under the Companies Act of Japan. Mitsubishi UFJ Financial Group, Inc. owns entities that provide brokerage, custody and investment management services to clients that include plans. Mitsubishi UFJ Financial Group, Inc., together with its affiliates (hereinafter, any of these entities is referred to as Mitsubishi), is one of the world's largest and most diversified financial groups with total assets of ¥297.19 trillion, as of March 31, 2017.

3. *Mitsubishi's Investment in Morgan Stanley.*

On October 13, 2008, Mitsubishi made an equity investment to acquire a 21 percent ownership interest in Morgan Stanley on a fully diluted basis. Under the terms of the transaction, Mitsubishi acquired: (a) 7,839,209 shares of Series B Non-Cumulative Non-Voting Perpetual Convertible Preferred Stock (''Series B Preferred Stock'') with a 10 percent dividend and a conversion price of $25.25 per share; and (b) 1,160,791 shares of Series C Non-Cumulative Non-Voting Perpetual Preferred Stock (''Series C Preferred Stock'') with a 10 percent dividend. The transaction also permits Mitsubishi to nominate one member to Morgan Stanley's twelve-member board of directors and to designate an additional ''observer'' to be present at meetings of Morgan Stanley's board.

On June 30, 2011, Mitsubishi and Morgan Stanley agreed to convert all Mitsubishi-owned Morgan Stanley Series B Preferred Stock (face value of $7.8 billion; carrying value of $8.1 billion) into Morgan Stanley common stock. Immediately after the conversion, Mitsubishi-owned shares of Morgan Stanley Common Stock represented approximately 22.56% of the outstanding shares of Morgan Stanley Common Stock. Subsequently, the Mitsubishi's ownership percentage of Morgan Stanley common stock gradually increased because of Morgan Stanley's ongoing repurchases of stock from other investors. On April 18, 2018, Mitsubishi entered into an agreement with Morgan Stanley to sell shares of Morgan Stanley common stock as part of Morgan Stanley's share repurchase program. This agreement, as intended, allowed Mitsubishi to keep its ownership percentage of Morgan Stanley common stock below 24.9%, in order to comply with Mitsubishi's passivity commitments to the Board of Governors of the Federal Reserve System.

Mitsubishi is currently the largest investor in Morgan Stanley, holding 24.5 percent of Morgan Stanley's outstanding common stock. Mitsubishi also currently nominates two directors to Morgan Stanley's board of directors. Morgan Stanley states that, despite its ownership interest, Mitsubishi does not have sufficient control over Morgan Stanley to warrant treatment of Mitsubishi and Morgan Stanley as ''affiliates'' within the meaning of the Applicable Class Exemptions, which are described below.[19]

4. *Relevant ERISA Provisions and Prohibited Transaction Issues.*

Section 406(a) of ERISA proscribes certain ''prohibited transactions'' between plans and ''parties in interest'' with respect to those plans. ERISA Section 406(a) prohibits, among other things, sales, extensions of credit, and the provision of services between a plan (or an entity whose assets are deemed to constitute the assets of the plan) and a ''party in interest'' with respect to the plan, as well as the use of plan assets by or for the benefit of, or a transfer of plan assets to, a ''party in interest.'' Section 3(14) of ERISA defines the term ''party in interest'' to include, among others, a plan fiduciary, the sponsoring employer of a plan, service providers with respect to a plan, and certain related entities. ERISA section 3(14)(H) specifically provides that a 10% or more shareholder of certain entities, including a service provider to a plan, is a ''party in interest'' to that plan.

Pursuant to ERISA section 3(14)(H), Mitsubishi, as an entity that owns 10% or more of Morgan Stanley, is a ''party

[16] For purposes of this proposed exemption reference to specific provisions of Title I of the Act, unless otherwise specified, should be read to refer as well to the corresponding provisions of the Code.

[17] Part III and Part IV of Prohibited Transaction Exemption 75–1 (PTE 75–1 Parts III and IV)(40 FR 50845, October 31, 1975); Prohibited Transaction Exemption 77–3 (PTE 77–3) (42 FR 18734, April 8, 1977); Prohibited Transaction Exemption 77–4 (PTE 77–4) (42 FR 18732, April 8, 1977); Prohibited Transaction Exemption 79–13 (PTE 79–13) (44 FR 25533, May 1, 1979); Prohibited Transaction Exemption 86–128 (PTE 86–128) (51 FR 41686, November 18, 1986), as amended by (67 FR 64137, October 17, 2002); Prohibited Transaction Exemption 2002–12 (PTE 2002–12)(67 FR 9483, March 1, 2002).

[18] The Department notes that availability of this exemption, if granted, is subject to the express condition that the material facts and representations contained in application D–11955 are true and complete, and accurately describe all material terms of the transactions covered by the exemption. If there is any material change in a transaction covered by the exemption, or in a material fact or representation described in the application, the exemption will cease to apply as of the date of such change.

[19] For example, Section I(b) of PTE 86–128 defines an ''affiliate'' as, in relevant part, ''any person directly controlling, controlled by, or under common control with the person . . .'' where ''[t]he term 'control' means the power to exercise a controlling influence over the management or policies of a person other than an individual.''

in interest'' with respect to plans that receive services from Morgan Stanley. As noted above, Section 406(a) of ERISA prohibits a wide range of transactions between plans and ''parties in interest.'' Morgan Stanley is therefore prohibited by Section 406(a) of ERISA from causing plans to engage in a wide range of transactions involving Mitsubishi.

Section 406(b) of ERISA also prohibits fiduciary transactions involving fiduciary self-dealing, fiduciary conflicts of interest, and kickbacks to fiduciaries. Irrespective of whether Mitsubishi's ownership interest in Morgan Stanley gives it the level of control necessary to classify the two entities as affiliates for the purposes of the Applicable Class Exemptions, its degree of interest and influence is substantial, and could affect either party's best judgment as a plan fiduciary, raising issues under Section 406(b) of ERISA.

5. *Relevant Administrative Exemptions.*

The Department has authority under Section 408(a) of ERISA to grant administrative exemptions, on both a class and individual basis, which permit transactions that would otherwise violate the prohibitions of Section 406 of ERISA. Prior to granting an exemption, the Secretary of Labor must first find that such exemption is administratively feasible and in the interest of, and protective of, affected plans.[20]

The Department has granted a wide variety of class exemptions that permit affiliated parties to engage in specified plan-related transactions, provided that certain protective conditions are met. The following seven class exemptions (the Applicable Class Exemptions) are relevant to this proposed exemption:

PTE 75–1, Part III permits a fiduciary to cause a plan to purchase securities from a member of an underwriting syndicate, when the fiduciary is also a member of such syndicate, and the member selling the securities to the plan is not affiliated with the fiduciary. The class exemption defines the term ''fiduciary'' to include ''affiliates'' of the fiduciary.

PTE 75–1, Part IV permits a plan to purchase or sell securities in a principal transaction from a fiduciary that is also a ''market-maker'' with respect to such securities. For purposes of the exemption, the term ''fiduciary'' includes ''affiliates'' of the fiduciary.

PTE 77–3 permits the acquisition or sale of shares of a registered open-end investment company (a mutual fund) by a plan that covers only employees of the mutual fund, the mutual fund's investment adviser, the mutual fund's underwriter, or an affiliate thereof.

PTE 77–4 permits the purchase or sale by a plan of shares of a mutual fund, where the mutual fund's investment adviser is a plan fiduciary, or is affiliated with a plan fiduciary, but is not an employer of employees covered by the plan.

PTE 79–13 permits the purchase, ownership and sale of shares of a closed-end mutual fund by a plan, where such plan covers only employees of the closed-end mutual fund, employees of an investment adviser to the closed-end mutual fund, or employees of an affiliate of the closed-end mutual fund or investment adviser.

PTE 86–128 provides an exemption for certain fiduciaries and their affiliates to receive a fee from a plan or IRA for effecting or executing securities transactions as an agent on behalf of the plan or IRA. It also allows a fiduciary (or an affiliate of a fiduciary) to act as an agent in an ''agency cross transaction'' for both a plan (and IRA) and for another party to the transaction, and to receive reasonable compensation from another party to the transaction.

PTE 2002–12 permits the cross-trading of securities by and between certain index and model-driven funds managed by investment ''managers,'' and among index and model-driven funds, and certain large accounts, which engage such ''managers.'' For purposes of the exemption, the term ''manager'' includes affiliates of the ''manager.''

6. *Exemption Request.*

As described above, the Applicable Class Exemptions permit certain plan-related transactions involving affiliated parties (the Affiliated Transactions). Assuming Morgan Stanley and Mitsubishi are not affiliates for the purposes of the Applicable Class Exemptions, as they indicate, they could not engage in the Affiliated Transactions without violating Section 406 of ERISA. Morgan Stanley therefore requests an exemption that, in general terms, would allow Morgan Stanley and Mitsubishi to treat the other as an ''affiliate'' for purposes of the Applicable Class Exemptions when engaging in transactions that would otherwise mirror the Affiliated Transactions.

Morgan Stanley states that the requested exemption would be beneficial to both its client plans and its own sponsored plans. Morgan Stanley indicates that it would allow Morgan Stanley to invest in open and closed-end mutual funds maintained by Mitsubishi. Morgan Stanley further states that the requested exemption would allow the asset management affiliates of Morgan Stanley and Mitsubishi to engage the other's brokers to execute agency transactions in the same manner, and using the same conditions, as PTE 86–128; allow the cross trading of index and model driven accounts managed by asset manager affiliates of Morgan Stanley or Mitsubishi; allow both entities' asset managers to purchase securities in an underwriting when their affiliates were members of the underwriting syndicate; and allow market making transactions under PTE 75–1, Part IV with affiliates of either Morgan Stanley or Mitsubishi.

Morgan Stanley represents that the proposed exemption would enhance affected plans' investment and service provider options. According to Morgan Stanley, plan participants would have access to more counterparties and investment products in the market. In addition, the plans, as clients of Morgan Stanley and of Mitsubishi and its affiliates, would have access to more efficient and less expensive brokerage services. Morgan Stanley states that this proposed exemption should be granted for the same reasons the Department granted the Applicable Class Exemptions.

7. *Structure of this Proposed Exemption.*

The operative language in this document consists of nine Parts. Parts I through VII detail proposed individual exemptions. Each of the exemptions are modeled after one of the seven Applicable Class Exemptions. While the seven Applicable Class Exemptions permit specific transactions involving entities that are ''affiliated'', the seven proposed exemptions permit those same transactions but as undertaken by a Morgan Stanley entity and a related Mitsubishi entity. In general terms, the proposed individual exemptions permit two broad classes of transactions: (1) Those in which a Morgan Stanley entity acting as a plan fiduciary causes the plan to engage in a covered transaction involving a Mitsubishi entity acting as a non-fiduciary; and/or (2) those in which a Mitsubishi entity acting as a plan fiduciary causes the plan to engage in a covered transaction involving a Morgan Stanley entity acting as a non-fiduciary.[21] The proposed exemptions use the term ''Morgan Stanley/Mitsubishi Entity'' when referring to a Morgan Stanley or Mitsubishi entity that is acting as the plan fiduciary, and the term ''Related Entity'' when referring to the Morgan Stanley or a Mitsubishi

[20] 29 CFR part 2570, subpart B (76 FR 66637, 66644, October 27, 2011).

[21] The exception is PTE 2002–12 and the transactions in this exemption that are modeled after PTE 2002–12, which are described below.

entity that is acting in a non-plan fiduciary role. Accordingly, the terms ''Morgan Stanley/Mitsubishi Entity'' and ''Related Entity'' are used in much the same way as the terms ''fiduciary'' and ''affiliate'' are used in the Applicable Class Exemptions. Examples are provided below.

Part VIII of this proposed exemption contains a set of new conditions that are not found in the Applicable Class Exemptions (the New Conditions). The New Conditions apply to each of the seven exemptions described in this proposal. Otherwise, the conditions in the proposed exemptions are similar to the conditions in the Applicable Class Exemptions. Distinctions between the proposed exemptions and the Applicable Class Exemptions are discussed below.

Part IX of this proposed exemption provides definitions not found in the Applicable Class Exemptions. For example, Part IX defines the term ''Morgan Stanley'' to mean, ''Morgan Stanley & Co. LLC and any person, directly or indirectly, through one or more intermediaries, controlling, controlled by, or under common control with Morgan Stanley & Co;'' and the term ''Mitsubishi'' to mean, ''Mitsubishi UFJ Financial Group, Inc., and any person, directly or indirectly, through one or more intermediaries, controlling, controlled by, or under common control with Mitsubishi UFJ Financial Group, Inc.''

8. *The Seven Proposed Individual Exemptions.*

Part I of this document is a proposed exemption that is based on PTE 75–1, Part III. This proposed exemption permits the purchase or other acquisition of certain securities by a plan during the existence of an underwriting or selling syndicate with respect to such securities, from any person other than a Morgan Stanley/Mitsubishi Entity or Related Entity, when a Morgan Stanley/Mitsubishi Entity is a fiduciary with respect to the plan, and a Related Entity is a member of the syndicate. For example, if the conditions in Parts I and VIII are met, (a) a Morgan Stanley entity, acting as the plan fiduciary, may cause the plan to purchase securities from a member of an underwriting syndicate (but not from Morgan Stanley or Mitsubishi), if Mitsubishi is a member of such syndicate; and/or (b) a Mitsubishi entity, acting as a plan fiduciary, may cause the plan to purchase securities from a member of an underwriting syndicate (but not from Morgan Stanley or Mitsubishi), if a Morgan Stanley entity is a member of the syndicate.

Part II of this document is a proposed exemption that is based on PTE 75–1, Part IV. The proposed exemption permits the purchase or sale of securities by a plan from or to a Related Entity which is a market-maker with respect to such securities, when a Morgan Stanley/Mitsubishi Entity is a plan fiduciary. For example, if the conditions in Parts II and VIII are met, a Morgan Stanley entity, acting as a plan fiduciary, may cause the plan to purchase or sell securities in a principal transaction involving a Mitsubishi entity that is acting as a ''market-maker'' with respect to the securities; and/or a Mitsubishi entity, acting as a plan fiduciary, may cause the plan to purchase or sell securities in a principal transaction involving a Morgan Stanley entity that is acting as a ''market-maker'' with respect to the securities.

Part III of this document is a proposed exemption that is based on PTE 77–3. This proposed exemption permits the purchase or sale by a plan of mutual fund shares, where the mutual fund's investment adviser or principal underwriter is a Related Entity, and the plan that is purchasing or selling the mutual fund shares covers only employees of a Morgan Stanley/Mitsubishi Entity. If the conditions in Parts III and VIII are met, this proposed exemption permits the acquisition or sale of shares of a mutual fund by a plan that covers only employees of (a) a Morgan Stanley entity, where a Mitsubishi entity is the mutual fund's investment adviser or principal underwriter; or (b) a Mitsubishi entity, where a Morgan Stanley entity is the mutual fund's investment adviser or principal underwriter.

Part IV of this document is a proposed exemption that is based on PTE 77–4. This proposed exemption permits the purchase or sale by a plan of mutual fund shares, where the mutual fund's investment adviser is a Related Entity and a Morgan Stanley/Mitsubishi Entity is a fiduciary with respect to the plan, but not an employer of employees covered by the plan. If the conditions of Parts IV and VIII are met, this proposed exemption permits the purchase or sale by a plan of shares of a mutual fund, where (a) a Morgan Stanley entity is the mutual fund's investment adviser and a Mitsubishi entity is a plan fiduciary, but not an employer of employees covered by the plan, and/or (b) a Mitsubishi entity is the mutual fund's investment adviser and a Morgan Stanley entity is a plan fiduciary, but not an employer of employees covered by the plan.

Part V of this document is a proposed exemption that is based on PTE 79–13. The proposed exemption permits the acquisition, ownership, or sale of shares of a closed-end mutual fund (where a Related Entity serves as investment adviser to such closed-end mutual fund) by a plan covering only employees of a Morgan Stanley/Mitsubishi Entity. Thus, if the conditions of Parts V and VIII are met, this proposed exemption would permit (a) the acquisition, ownership or sale of shares of a closed-end mutual fund with a Morgan Stanley entity as its investment adviser, by a plan covering only employees of a Mitsubishi entity, or (b) the acquisition, ownership or sale of shares of a closed-end mutual fund with a Mitsubishi entity as its investment adviser, by a plan covering only employees of a Morgan Stanley entity.

Part VI of this document is a proposed exemption that is based on PTE 86–128. This proposed exemption permits (a) a Morgan Stanley/Mitsubishi Entity, as a plan fiduciary, to use its authority to cause the plan to pay a fee to a Related Entity, for effecting or executing securities transactions on behalf of the plan; (b) a Morgan Stanley/Mitsubishi Entity using its fiduciary authority to cause a plan to enter into an agency cross transaction where (1) a Related Entity acts as the agent to the plan in such agency cross transaction, or (2) a Related Entity acts as the agent to one or more other parties to the agency cross transaction; and (c) the receipt of reasonable compensation by a Related Entity for effecting or executing an agency cross transaction on behalf of a plan with a Morgan Stanley/Mitsubishi Entity as the plan fiduciary that used its authority to cause the transaction, where such reasonable compensation is received from one or more other parties to the agency cross transaction (*i.e.,* not from the plan). If the conditions of Parts VI and Part VIII are met, this proposed exemption permits, among other things: A Morgan Stanley entity that is a plan fiduciary using its authority to cause the plan to pay a fee to a Mitsubishi entity, for effecting or executing securities transactions on behalf of the plan; and/or a Mitsubishi entity that is a plan fiduciary using its authority to cause the plan to pay a fee to a Morgan Stanley entity, for effecting or executing securities transactions on behalf of the plan.

Part VII of this document is a proposed exemption that is based on PTE 2002–12. This proposed exemption permits (a) the purchase and sale of securities among Index and Model Driven Funds (either, a Fund), where one such Fund is managed by a Morgan Stanley entity and the other fund is managed by a Mitsubishi entity; and (b) the purchase and sale of securities

between a Fund and a Large Account, as defined in Part VII, Section IV(e) (or in certain instances, as between two Large Accounts), where one such Fund or Large Account is managed by a Morgan Stanley entity and the other such fund or Large Account is managed by a Mitsubishi entity. If the conditions in Parts VII and VIII are met, this exemption permits the cross-trading of securities by and between: A Fund managed by a Morgan Stanley investment manager and a Fund managed by a Mitsubishi investment manager; and/or a Fund and a Large Account (or in certain instances, by and between two Large Accounts), where one Fund/Large Account is managed by a Morgan Stanley investment manager and the other Fund/Large Account is managed by a Mitsubishi investment manager.

9. *Part VIII. New Conditions and Modifications.*

The proposed individual exemptions contain conditions not otherwise found in the Applicable Class Exemptions (the New Conditions).[22] The first New Condition provides that, if an Applicable Class Exemption is amended, revised or revoked pursuant to the Department's authority under Section 408(a) of ERISA, or if an Applicable Class Exemption is the subject of an interpretation issued by the Department, the relevant Part of this exemption will be subject to the same amendment, revision, revocation or interpretation.

Another New Condition of this exemption requires any Morgan Stanley or Mitsubishi entity engaging in a transaction that is covered by this exemption (with the exception of transactions described in Parts III and V), to provide a written notice to a plan fiduciary who is independent of both Mitsubishi and Morgan Stanley. The required notice must clearly detail in plain English: (a) The ownership relationship between Morgan Stanley and Mitsubishi; (b) the transaction(s) that Morgan Stanley and Mitsubishi will engage in on behalf of the plan under this exemption; and (c) that, as a result of the ownership relationship between Morgan Stanley and Mitsubishi, the previously identified transactions will provide a benefit to Morgan Stanley and/or Mitsubishi, and/or involve a conflict of interest.

Another New Condition requires the Morgan Stanley/Mitsubishi Entity engaging in a transaction covered by this exemption to comply with the following ''Impartial Conduct Standards'': (1) The Morgan Stanley/Mitsubishi Entity, at the time of the transaction, must act in the Best Interest of the plan. In this regard, acting in the Best Interest means acting with the care, skill, prudence, and diligence under the circumstances then prevailing that a prudent person acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with like aims, based on the investment objectives, risk tolerance, financial circumstances, and needs of affected plan, and not place the financial or other interests of the Morgan Stanley/Mitsubishi Entity, Related Entity, or other party ahead of the interests of the affected plan, or subordinate the plan's interests to their own; (2)(A) The compensation received, directly or indirectly, by the Morgan Stanley/Mitsubishi Entity and Related Entities for their services may not exceed reasonable compensation within the meaning of ERISA section 408(b)(2) and Code section 4975(d)(2); and (B) As required by the federal securities laws, the Morgan Stanley/Mitsubishi Entity must obtain the best execution of the investment transaction reasonably available under the circumstances; and (3) The Morgan Stanley/Mitsubishi Entity's statements to the plan about the covered transaction and other relevant matters must not be materially misleading at the time statements are made.

This proposed exemption imposes certain global record retention requirements. In this regard, any applicable Morgan Stanley/Mitsubishi Entity must maintain, or cause to be maintained, for a period of six years, records necessary to determine whether the conditions of this exemption are met.

This proposed exemption requires that each Morgan Stanley/Mitsubishi Entity must develop and implement policies and procedures that are prudently designed to ensure that the conditions in this proposed exemption are met. This proposed exemption specifies that such required policies and procedures must be in place prior to any Morgan Stanley/Mitsubishi Entity engaging in a transaction that relies upon the relief provided hereunder.

10. *Modifications to Specific Exemptions.*

As noted above, PTE 77–4 provides relief for the purchase or sale by a plan of shares of a mutual fund, where the mutual fund's investment adviser is a plan fiduciary, or is affiliated with a plan fiduciary. This class exemption extends relief to ''section 406 of the Act and the taxes imposed by section 4975(a) and (b) of the Code . . . .''[23] Part IV of this proposed exemption permits transactions that are modeled after PTE 77–4, but limits relief to cover only sections 406(a)(1)(B) and 406(b) of ERISA and the corresponding provisions of the Code. Consistent with this, Part IV expressly provides that each Morgan Stanley/Mitsubishi Entity must satisfy section 408(b)(2) of ERISA or section 4975(d)(2) of the Code, as applicable.

As noted above, PTE 86–128 permits a plan fiduciary to effect or execute securities transactions (itself or through its affiliates) for a fee on behalf of a plan. Section I of PTE 86–128 defines certain terms used in the class exemption; Section II lists the specific transactions covered by the class exemption; Section III lists the conditions applicable to those transactions; and Section IV lists certain exceptions to those conditions.[24] One of these exceptions, set forth in Section IV(a) of the class exemption, provides that the conditions set forth in Section III do not apply to the Section II transactions to the extent such transactions are engaged in by individual retirement accounts that meet the conditions of 29 CFR 2510.3–2(d), or plans, other than training programs, that cover no employees within the meaning of 29 CFR 2510.3–3.

Unlike PTE 86–128, this proposed exemption does not carve out an exception for IRAs with respect to compliance with the conditions set forth in Section IV(a). Therefore, with respect to transactions in Part VI of this exemption, individual retirement accounts that meet the conditions of 29 CFR 2510.3–2(d) and plans that cover no employees, within the meaning of 29 CFR 2510.3–3, are subject to the conditions of this exemption on the same basis as plans (as plans are defined in Section 3(3) of ERISA).

Several of the Applicable Class Exemptions contain limitations or caps that are intended to protect affected plans. The parallel conditions in this proposed exemption clarify that these limitations or caps would apply across both the relevant individual exemption and the relevant Applicable Class Exemption. For example, condition (d) of PTE 75–1, Part III provides that the amount of such securities to be purchased or otherwise acquired by a plan does not exceed 3 percent (3%) of

[22] All of the transactions covered by this proposed exemption, if granted, and all of the conditions applicable to those transactions, are listed together at the end of this document.

[23] See 42 FR 18732 at 33.

[24] Section V of PTE 86–128 contains two illustrative examples, and Section VI sets forth effective dates and a transitional rule.

the total amount of such securities being offered. The parallel provision in this document (Part I, condition (d)) clarifies that the amount of such securities to be purchased or otherwise acquired by a plan *pursuant to this exemption and PTE 75–1, Part III,* does not exceed 3 percent (3%) of the total amount of such securities being offered (emphasis added). A similar clarification appears in Part I (e), Part II (b) and Part VI, Section IV, paragraph (c) of this exemption.

*The Department's Findings*

11. The Department granted each Applicable Class Exemption after determining on the record that the exemption was in the interest of and protective of, affected plans, and administratively feasible. Given that the transactions in this exemption are substantially similar to those permitted by the Applicable Class Exemptions, subject to not only essentially the same suite of conditions, but also to the New Conditions and the modifications described above, the Department has tentatively determined that this proposed exemption is in the interest of and protective of affected plans and their participants and beneficiaries, and administratively feasible.

**Proposed Exemption**

Based on the facts and representations, the Department of Labor (the Department) is considering granting an exemption under the authority of section 408(a) of the Employee Retirement Income Security Act of 1978, as amended, (the Act) and section 4975(c)(2) of the Internal Revenue Code of 1982 (the Code) and in accordance with the procedures set forth in 29 CFR part 2570, subpart B (76 FR 66637, 66644, October 27, 2011).

*Part I. Proposed Exemption From the Prohibitions Respecting Certain Classes of Transactions Involving Plans and Certain Underwriters (Modeled After PTE 75–1, Part III)*

The restrictions of section 406 of the Act, and the taxes imposed by reason of section 4975(a) and (b) of the Code, by reason of section 4975(c)(1) of the Code, shall not apply to the purchase or other acquisition of certain securities by a plan during the existence of an underwriting or selling syndicate with respect to such securities, from any person other than Morgan Stanley or Mitsubishi, when a Morgan Stanley/Mitsubishi Entity is a fiduciary with respect to such plan, and a Related Entity is a member of such syndicate, provided that the following conditions are met:

(a) No Morgan Stanley/Mitsubishi Entity or Related Entity which is involved in any way in causing a plan to make the purchase is a manager of such underwriting or selling syndicate. The term ''manager'' means any member of an underwriting or selling syndicate who, either alone or together with other members of the syndicate, is authorized to act on behalf of the members of the syndicate in connection with the sale and distribution of the securities being offered or who receives compensation from the members of the syndicate for its services as a manager of the syndicate.

(b) The securities to be purchased or otherwise acquired are:

(1) Part of an issue registered under the Securities Act of 1933 (the 1933 Act) or, if exempt from such registration requirement, are:

(i) Issued or guaranteed by the United States or by any person controlled or supervised by and acting as an instrumentality of the United States, pursuant to authority granted by the Congress of the United States,

(ii) Issued by a bank,

(iii) Issued by a common or contract carrier, if such issuance is subject to the provisions of section 20a of the Interstate Commerce Act, as amended,

(iv) Exempt from such registration requirement, pursuant to a Federal statute other than the 1933 Act, or are

(v) The subject of a distribution and are of a class which is required to be registered under section 12 of the Securities Exchange Act of 1934 (15 U.S.C. 781) (the 1934 Act), and the issuer of which has been subject to the reporting requirements of section 13 of the 1934 Act (15 U.S.C. 78m) for a period of at least ninety (90) days immediately preceding the sale of securities and has filed all the reports required to be filed thereunder with the SEC during the preceding twelve (12) months.

(2) Purchased at not more than the public offering price prior to the end of the first full business day after the final terms of the securities have been fixed and announced to the public, except that:

(i) If such securities are offered for subscription upon exercise of rights, they are purchased on or before the fourth day preceding the day on which the rights offering terminates; or

(ii) If such securities are debt securities, they may be purchased at a public offering price on a day subsequent to the end of such first full business day, provided that the interest rates on comparable debt securities offered to the public subsequent to such first full business day and prior to the purchase are less than the interest rate of the debt securities being purchased.

(3) Offered pursuant to an underwriting agreement under which the members of the syndicate are committed to purchase all of the securities being offered, except if:

(i) Such securities are purchased by others pursuant to a rights offering; or

(ii) Such securities are offered pursuant to an over-allotment option.

(c) The issuer of such securities has been in continuous operation for not less than three (3) years, including the operations of any predecessors, unless:

(1) Such securities are non-convertible debt securities rated in one of the four (4) highest rating categories by at least one (1) of the Rating Agencies, as defined below in Part IX (e);

(2) Such securities are issued or fully guaranteed by a person described above in subparagraph (b)(1)(i) of this Part I; or

(3) Such securities are fully guaranteed by a person who has issued securities described above in subparagraph (b)(1)(ii), (iii), (iv), or (v) of Part I, and in this subparagraph (c) of Part I.

(d) The amount of such securities to be purchased or otherwise acquired by a plan, pursuant to this exemption and PTE 75–1, Part III, does not exceed 3 percent (3%) of the total amount of such securities being offered.

(e) The consideration to be paid by a plan in purchasing or otherwise acquiring such securities pursuant to this exemption and PTE 75–1, Part III, does not exceed 3 percent (3%) of the fair market value of the total assets of such plan as of the last day of the most recent fiscal quarter of such plan prior to such transaction, provided that if such consideration exceeds $1 million, it does not exceed 1 percent (1%) of such fair market value of the total assets of such plan.

If such securities are purchased by a plan from a party in interest or disqualified person with respect to such plan, such party in interest or disqualified person shall not be subject to the civil penalty which may be assessed under section 502(i) of the Act, or to the taxes imposed by section 4975(a) and (b) of the Code, if the conditions of this exemption are not met. However, if such securities are purchased from a party in interest or disqualified person with respect to a plan, the restrictions of section 406(a) of the Act shall apply to any Morgan Stanley/Mitsubishi Entity acting as fiduciary with respect to such plan, and the taxes imposed by section 4975(a) and (b) of the Code, by reason of section 4975(c)(1)(A) through (D) of the Code,

shall apply to such party in interest or disqualified person, unless the conditions for exemption of PTE 75–1 (40 FR 50845, October 31, 1975), Part II (relating to certain principal transactions) are met.

*Part II. Proposed Exemption From Prohibitions Respecting Certain Classes of Transactions Involving Plans and Market-Makers (Modeled After PTE 75–1, Part IV)*

The restrictions of section 406 of the Act, and the taxes imposed by section 4975(a) and (b) of the Code, by reason of section 4975(c)(1) of the Code, shall not apply to any purchase or sale of any securities by a plan from or to a Related Entity which is a market-maker with respect to such securities, when a Morgan Stanley/Mitsubishi Entity is a fiduciary with respect to such plan, provided that the following conditions are met:

(a) The issuer of such securities has been in continuous operation for not less than three (3) years, including the operations of any predecessors, unless:

(1) Such securities are non-convertible debt securities rated in one of the four (4) highest rating categories by at least one (1) of the Rating Agencies;

(2) Such securities are issued or guaranteed by the United States or by any person controlled or supervised by and acting as an instrumentality of the United States pursuant to authority granted by the Congress of the United States; or

(3) Such securities are fully guaranteed by a person described in this subparagraph (a).

(b) As a result of purchasing such securities:

(1) The fair market value of the aggregate amount of such securities owned, directly or indirectly, by a plan and with respect to which a Morgan Stanley/Mitsubishi Entity is a fiduciary, pursuant to this exemption and PTE 75–1, Part IV, does not exceed 3 percent (3%) of the fair market value of the assets of such plan with respect to which such Morgan Stanley/Mitsubishi Entity is a fiduciary, as of the last day of the most recent fiscal quarter of such plan prior to such transaction, provided that if the fair market value of such securities exceeds $1 million, it does not exceed 1 percent (1%) of the fair market value of such assets of such plan, except that this subparagraph shall not apply to securities described in subparagraph (a)(2) of this Part II; and

(2) The fair market value of the aggregate amount of all securities for which any Related Entity is a market-maker, which are owned, directly or indirectly, by a plan and with respect to which a Morgan Stanley/Mitsubishi Entity is a fiduciary, pursuant to this exemption and PTE 75–1, Part IV, does not exceed 10 percent (10%) of the fair market value of the assets of such plan with respect to which the Morgan Stanley/Mitsubishi Entity is a fiduciary, as of the last day of the most recent fiscal quarter of such plan prior to such transaction, except that this subparagraph shall not apply to securities described in subparagraph (a)(2) of this Part II.

(c) At least one (1) person other than a Related Entity is a market-maker with respect to such securities.

(d) The transaction is executed at a net price to a plan for the number of shares or other units to be purchased or sold in the transaction which is more favorable to such plan than that which the Morgan Stanley/Mitsubishi Entity, acting as fiduciary and acting in good faith, reasonably believes to be available at the time of such transaction from all other market-makers with respect to such securities.

For purposes of this Part II, the term ''market-maker'' shall mean any specialist permitted to act as a dealer, and any dealer who, with respect to a security, holds himself out (by entering quotations in an inter-dealer communications system or otherwise) as being willing to buy and sell such security for his own account on a regular or continuous basis.

*Part III. Proposed Exemption Involving Mutual Fund In-House Plans (Modeled After PTE 77–3)*

The restrictions of sections 406 and 407(a) of the Act and the taxes imposed by section 4975(a) and (b) of the Code, by reason of section 4975(c)(1) of the Code, shall not apply to the acquisition or sale of shares of an open-end investment company registered under the Investment Company Act of 1940 (the 1940 Act), where a Related Entity is an investment adviser or principal underwriter with respect to the open-end investment company, by an benefit plan covering only employees of a Morgan Stanley/Mitsubishi Entity, provided that the following conditions are met (whether or not such investment company, investment adviser, principal underwriter or any affiliated person thereof is a fiduciary with respect to the plan):

(a) The plan does not pay any investment management, investment advisory or similar fee to any Morgan Stanley/Mitsubishi Entity or Related Entity. This condition does not preclude the payment of investment advisory fees by the investment company under the terms of its investment advisory agreement adopted in accordance with section 15 of the 1940 Act.

(b) The plan does not pay a redemption fee in connection with the sale by the plan to the investment company of such shares, unless (1) such redemption fee is paid only to the investment company, and (2) the existence of such redemption fee is disclosed in the investment company prospectus in effect both at the time of the acquisition of such shares and at the time of such sale.

(c) The plan does not pay a sales commission in connection with such acquisition or sale.

(d) All other dealings between the plan and the investment company, the Related Entity, any other investment adviser or principal underwriter for the investment company, or any affiliated person (as defined in section 2(a)(3) of the 1940 Act) of the Related Entity, other investment adviser, or principal underwriter, are on a basis no less favorable to the plan than such dealings are with other shareholders of the investment company.

*Part IV. Proposed Exemption for Certain Transactions Between Investment Companies and Plans (Modeled After PTE 77–4)*

The restrictions of section 406(a)(1)(B) and (D) and 406(b) of the Act and the taxes imposed by section 4975(a) and (b) of the Code, by reason of section 4975(c)(1)(B), (D), (E) and (F) of the Code, shall not apply to the purchase or sale by a plan of shares of an open-end investment company registered under the 1940 Act, where a Related Entity is the investment adviser of the investment company and a Morgan Stanley/Mitsubishi Entity is a fiduciary with respect to the plan, but not an employer of employees covered by the plan, provided that the following conditions are met:

(a) The plan does not pay a sales commission in connection with such purchase or sale.

(b) The plan does not pay a redemption fee in connection with the sale by the plan to the investment company of such shares unless:

(1) The redemption fee is paid only to the investment company, and

(2) The existence of the redemption fee is disclosed in the investment company prospectus in effect both at the time of the purchase of the shares and at the time of the sale.

(c) The plan does not pay an investment management, investment advisory or similar fee with respect to the plan assets invested in the shares for the entire period of the investment. This

condition does not preclude the payment of investment advisory fees by the investment company under the terms of its investment advisory agreement adopted in accordance with section 15 of the 1940 Act. This condition also does not preclude payment of an investment advisory fee by the plan based on total plan assets from which a credit has been subtracted representing the plan's pro rata share of the investment advisory fees paid by the investment company. If, during any fee period for which the plan has prepaid its investment management, investment advisory or similar fee, the plan purchases shares of the investment company, the requirement of this subparagraph (c) shall be deemed met with respect to such prepaid fee if, by a method reasonably designed to accomplish the same, the amount of the prepaid fee that constitutes the fee with respect to the plan assets invested in the investment company shares: (1) Is anticipated and subtracted from the prepaid fee at the time of payment of the fee; (2) is returned to the plan no later than during the immediately following fee period; or (3) is offset against the prepaid fee for the immediately following fee period or for the fee period immediately following thereafter. For purposes of this subparagraph (c), a fee shall be deemed to be prepaid for any fee period if the amount of the fee is calculated as of a date not later than the first day of such period.

(d) A second fiduciary with respect to the plan, who is independent of and unrelated to Morgan Stanley and Mitsubishi, receives a current prospectus issued by the investment company, and full and detailed written disclosure of the investment advisory and other fees charged to or paid by such plan and the investment company, including the nature and extent of any differential between the rates of such fees, the reasons why the Morgan Stanley/Mitsubishi Entity may consider such purchases to be appropriate for the plan, and whether there are any limitations on the Morgan Stanley/Mitsubishi Entity with respect to which plan assets may be invested in shares of the investment company and, if so, the nature of such limitations. For purposes of this subparagraph (d), the second fiduciary will not be deemed to be independent of and unrelated to Morgan Stanley and Mitsubishi if:

(1) The second fiduciary directly or indirectly controls, is controlled by, or is under common control with Morgan Stanley or Mitsubishi;

(2) The second fiduciary, or any officer, director, partner, employee or relative of such second fiduciary is an officer, director, partner, employee or relative of Morgan Stanley or Mitsubishi; or

(3) The second fiduciary directly or indirectly receives any compensation or other consideration for his or her own personal account in connection with any transaction described in this Part IV.

If an officer, director, partner, employee or relative of any Morgan Stanley or Mitsubishi entity is a director of such second fiduciary, and if he or she abstains from participation in:

(i) The choice of the plan's investment adviser,

(ii) The approval of any purchase or sale between the plan and the investment company, and

(iii) The approval of any change of fees charged to or paid by such plan, then subparagraph (d)(2) of this Part IV shall not apply.

For purposes of subparagraph (d)(1) above, the term ''control'' means the power to exercise a controlling influence over the management or policies of a person other than an individual, and the term ''relative'' means a ''relative'' as that term is defined in section 3(15) of the Act (or a ''member of the family'' as that term is defined in section 4975(e)(6) of the Code), or a brother, a sister, or a spouse of a brother or a sister.

(e) On the basis of the prospectus and disclosure referred to in subparagraph (d), the second fiduciary referred to in subparagraph (d) approves such purchases and sales consistent with the responsibilities, obligations, and duties imposed on fiduciaries by Part 4 of Title I of the Act. Such approval may be limited solely to the investment advisory and other fees paid by the mutual fund in relation to the fees paid by such plan and need not relate to any other aspects of such investments. In addition, such approval must be either:

(1) Set forth in such plan's plan documents or in the investment management agreement between such plan and the Morgan Stanley/Mitsubishi Entity,

(2) Indicated in writing prior to each purchase or sale, or

(3) Indicated in writing prior to the commencement of a specified purchase or sale program in the shares of such investment company.

(f) The second fiduciary referred to in subparagraph (d) above, or any successor thereto, is notified of any change in any of the rates and fees referred to in subparagraph (d) and approves in writing the continuation of such purchases or sales and the continued holding of any investment company shares acquired by such plan prior to such change and still held by such plan. Such approval may be limited solely to the investment advisory and other fees paid by the mutual fund in relation to the fees paid by such plan and need not relate to any other aspects of such investment.

(g) Each Morgan Stanley/Mitsubishi Entity and Related Entity must satisfy section 408(b)(2) of ERISA or section 4975(d)(2) of the Code, as applicable.

*Part V. Proposed Exemption Involving Closed-End Investment Company and In-House Plans (Modeled After PTE 79–13)*

The restrictions of sections 406 and 407(a) of the Act, and the taxes imposed by section 4975(a) and (b) of the Code, by reason of section 4975(c)(1) of the Code, shall not apply to the acquisition, ownership, or sale of shares of a closed-end investment company which is registered under the Investment Company Act of 1940 Act (1940 Act) and is not a ''small business investment company,'' as defined in section 103 of the Small Business Investment Company Act of 1958, with respect to which a Related Entity is an investment adviser, by an employee benefit plan covering only employees of a Morgan Stanley/Mitsubishi Entity, provided that the following conditions are met (whether or not such investment company, investment adviser or any affiliated person thereof is a fiduciary with respect to the plan):

(a) The plan does not pay any investment management, investment advisory, or similar fee to any Morgan Stanley/Mitsubishi Entity or Related Entity. This condition does not preclude the payment of investment advisory fees by the investment company under the terms of its investment advisory agreement adopted in accordance with section 15 of the 1940 Act.

(b) The plan does not pay a sales commission in connection with such acquisition or sale to any such investment company, or investment adviser, or any Morgan Stanley/Mitsubishi Entity or Related Entity; and

(c) All other dealings between the plan and such investment company, the investment adviser, or any Morgan Stanley/Mitsubishi Entity or Related Entity, are on a basis no less favorable to the plan than such dealings are with other shareholders of the investment company.

*Part VI. Proposed Exemption for Securities Transactions Involving Plans and Broker-Dealers (Modeled After PTE 86–128)*

Section I: Definition and Special Rules

The following definitions and special rules apply to this Part VI:

(a) The term ''Morgan Stanley/Mitsubishi Entity'' means Morgan Stanley & Co. LLC (MS) or one of its ''affiliates,'' or Mitsubishi UFJ Financial Group, Inc. (Mitsubishi UFJ) or one of its ''affiliates,'' acting as the plan fiduciary authorizing a transaction covered by this Part.

(b) An ''affiliate'' of a Morgan Stanley/Mitsubishi Entity or a Related Entity, which is defined below, includes the following:

(1) Any person directly or indirectly controlling, controlled by, or under common control with, MS or with Mitsubishi UFJ;

(2) Any officer, director, partner, employee, relative (as defined in section 3(15) of the Act), brother, sister, or spouse of a brother or sister, of a Morgan Stanley/Mitsubishi Entity or a Related Entity; and

(3) Any corporation or partnership of which a Morgan Stanley/Mitsubishi Entity or a Related Entity is an officer(s), director(s), or partner(s).

A person is not an affiliate of another person solely because such person has investment discretion over the other's assets. The term ''control'' means the power to exercise a controlling influence over the management or policies of a person other than an individual.

(c) An ''agency cross transaction'' is a securities transaction in which the same Related Entity acts as agent for both any seller and any buyer for the purchase or sale of a security.

(d) The term ''covered transaction'' means an action described in Section II (a), (b), or (c) of this Part VI.

(e) The term ''effecting or executing a securities transaction'' means the execution of a securities transaction as agent for another person and/or the performance of clearance, settlement, custodial, or other functions ancillary thereto.

(f) A plan fiduciary is independent of a Morgan Stanley/Mitsubishi Entity and a Related Entity only if the fiduciary has no relationship to and no interest in MS and no interest in Mitsubishi UFJ that might affect the exercise of such fiduciary's best judgment as a fiduciary.

(g) The term ''profit'' includes all charges relating to effecting or executing securities transactions, less reasonable and necessary expenses including reasonable indirect expenses (such as overhead costs) properly allocated to the performance of these transactions under generally accepted accounting principles.

(h) The term ''securities transaction'' means the purchase or sale of securities.

(i) The term ''nondiscretionary trustee'' of a plan means a trustee or custodian whose powers and duties with respect to any assets of the plan are limited to

(1) The provision of nondiscretionary trust services to the plan, and

(2) Duties imposed on the trustee by any provision or provisions of the Act or the Code. The term ''nondiscretionary trust services'' means custodial services and services ancillary to custodial services, none of which services are discretionary. For purposes of this Part VI, a person does not fail to be a nondiscretionary trustee solely by reason of having been delegated, by the sponsor of a master or prototype plan, the power to amend such plan.

(j) The term ''Related Entity'' means MS or one of its ''affiliates,'' or Mitsubishi UFJ or one of its ''affiliates,'' where the entity is not the plan fiduciary authorizing a transaction covered by this Part.

Section II: Covered Transactions

If each condition in Section III below is either satisfied or not applicable under Section IV, the restrictions of section 406(b) of the Act and the taxes imposed by section 4975(a) and (b) of the Code by reason of section 4975(c)(1)(E) and (F) of the Code shall not apply to:

(a) A Morgan Stanley/Mitsubishi Entity, as a plan fiduciary, using its authority to cause the plan to pay a fee to a Related Entity, for effecting or executing securities transactions on behalf of the plan, but only to the extent that such transactions are not excessive, under the circumstances, in either amount or frequency;

(b) a Related Entity, as the agent in an agency cross transaction, acting on behalf of: (1) A plan with a Morgan Stanley/Mitsubishi Entity as the plan fiduciary that used its authority to cause the transaction; and (2) one or more other parties to the agency cross transaction; and

(c) the receipt of reasonable compensation by a Related Entity for effecting or executing an agency cross transaction on behalf of a plan with a Morgan Stanley/Mitsubishi Entity as the plan fiduciary that used its authority to cause the transaction, where the reasonable compensation is received from one or more other parties to the agency cross transaction.

Section III: Conditions

Except to the extent otherwise provided in Section IV below, Section II applies only if the following conditions are satisfied:

(a) The Morgan Stanley/Mitsubishi Entity or Related Entity engaging in the covered transaction is not an administrator of the plan, or an employer any of whose employees are covered by the plan.

(b) The covered transaction is performed under a written authorization executed in advance by a fiduciary of each plan whose assets are involved in the transaction, which plan fiduciary is independent of MS and Mitsubishi UFJ.

(c) The authorization referred to above in subparagraph (b) of this Section III is terminable at will by the plan, without penalty to the plan, upon receipt by the authorized Morgan Stanley/Mitsubishi Entity of written notice of termination. A form expressly providing an election to terminate the authorization described in subparagraph (b) of this Section III with instructions on the use of the form must be supplied to the authorizing plan fiduciary no less than annually. The instructions for such form must include the following information:

(1) The authorization is terminable at will by the plan, without penalty to the plan, upon receipt by the authorized Morgan Stanley/Mitsubishi Entity of written notice from the authorizing plan fiduciary or other plan official having authority to terminate the authorization; and

(2) Failure to return the form will result in the continued authorization of the authorized Morgan Stanley/Mitsubishi Entity to engage in the covered transactions on behalf of the plan.

(d) Within three (3) months before an authorization is made, the authorizing plan fiduciary is furnished with any reasonably available information that the Morgan Stanley/Mitsubishi Entity seeking authorization reasonably believes to be necessary for the authorizing plan fiduciary to determine whether the authorization should be made, including (but not limited to) a copy of this proposed exemption and the associated granted exemption, the form for termination of authorization described in Section III(c) of this Part VI, a description of the Morgan Stanley/Mitsubishi Entity's brokerage placement practices, and any other reasonably available information regarding the matter that the authorizing plan fiduciary requests.

(e) The authorizing plan fiduciary is furnished with either:

(1) A confirmation slip for each securities transaction underlying a

covered transaction within ten (10) business days of the securities transaction containing the information described in Rule 10b–10(a)(1–7) under the Securities and Exchange Act of 1934 (1934 Act), 17 CFR 240.10b–10; or

(2) At least once every three (3) months and not later than forty-five (45) days following the period to which it relates, a report disclosing:

(i) A compilation of the information that would be provided to a plan pursuant to subparagraph (e)(1) of this Section III during the three-month period covered by the report;

(ii) The total of all securities transaction related charges incurred by the plan during such period in connection with such covered transactions; and

(iii) The amount of the securities transaction-related charges retained by the Related Entity and the amount of such charges paid to other persons for execution or other services.

For purposes of this subparagraph (e), the words ''incurred by the plan'' shall be construed to mean ''incurred by the pooled fund'' with respect to covered transactions engaged in on behalf of a pooled fund in which the plan participates.

(f) The authorizing plan fiduciary is furnished with a summary of the information required under subparagraph (e)(1) of this Section III at least once per year. The summary must be furnished within forty-five (45) days after the end of the period to which it relates, and must contain the following:

(1) The total of all securities transaction-related charges incurred by the plan during the period in connection with covered securities transactions.

(2) The amount of the securities transaction-related charges retained by the authorized Related Entity and the amount of these charges paid to other persons and their affiliates for execution or other services.

(3) A description of the Morgan Stanley/Mitsubishi Entity's brokerage placement practices, if such practices have materially changed during the period covered by the summary.

(4)(i) A portfolio turnover ratio, calculated in a manner which is reasonably designed to provide the authorizing plan fiduciary with the information needed to assist in discharging its duty of prudence. The requirements of this subparagraph (f)(4)(i) will be met if the ''annualized portfolio turnover ratio'', calculated in the manner described in subparagraph (f)(4)(ii), is contained in the summary.

(ii) The ''annualized portfolio turnover ratio'' must be calculated as a percentage of the plan assets consisting of securities or cash over which the authorized Morgan Stanley/Mitsubishi Entity had discretionary investment authority, or with respect to which such Morgan Stanley/Mitsubishi Entity rendered, or had any responsibility to render, investment advice (the portfolio) at any time or times (management period(s)) during the period covered by the report. First, the ''portfolio turnover ratio'' (not annualized) is obtained by dividing:

(A) The lesser of the aggregate dollar amounts of purchases or sales of portfolio securities during the management period(s) by

(B) The monthly average of the market value of the portfolio securities during all management period(s). Such monthly average is calculated by totaling the market values of the portfolio securities as of the beginning and ending of each management period and as of the end of each month that ends within such period(s), and dividing the sum by the number of valuation dates so used. For purposes of this calculation, all debt securities whose maturities at the time of acquisition were one (1) year or less are excluded from both the numerator and the denominator. The ''annualized portfolio turnover ratio'' is then derived by multiplying the ''portfolio turnover ratio'' by an annualizing factor. The annualizing factor is obtained by dividing (C) the number twelve (12) by (D) the aggregate duration of the management period(s) expressed in months (and fractions thereof).

(iii) The information described in this subparagraph (f)(4) is not required to be furnished in any case where the authorized Morgan Stanley/Mitsubishi Entity acting as plan fiduciary has not exercised discretionary authority over trading in the plan's account during the period covered by the report.

For purposes of this subparagraph (f), the words, ''incurred by the plan,'' shall be construed to mean ''incurred by the pooled fund'' with respect to covered transactions engaged in on behalf of a pooled fund in which the plan participates.

(g) For an agency cross transaction with respect to which Section IV(a) of this Part VI does not apply, the following conditions must also be satisfied:

(1) The information required under Section III(d) or Section IV(c)(1)(ii) of this Part VI includes a statement to the effect that with respect to agency cross transactions, the entity effecting or executing the transactions will have a potentially conflicting division of loyalties and responsibilities regarding the parties to the transactions;

(2) The summary required under Section III(f) of this Part VI includes a statement identifying the total number of agency cross transactions during the period covered by the summary and the total amount of all commissions or other remuneration received or to be received from all sources by the Related Entity engaging in the transactions in connection with those transactions during the period;

(3) The Morgan Stanley/Mitsubishi entity has the discretionary authority to act on behalf of, and/or provide investment advice to, either:

(i) One or more sellers, or

(ii) One or more buyers with respect to the transaction, but not both.

(4) The agency cross transaction is a purchase or sale, for no consideration other than cash payment against prompt delivery of a security for which market quotations are readily available; and

(5) The agency cross transaction is executed or effected at a price that is at or between the independent bid and independent ask prices for the security prevailing at the time of the transaction.

(h) A Morgan Stanley/Mitsubishi Entity serving as trustee (other than a nondiscretionary trustee) may only engage in a covered transaction with a plan that has total net assets with a value of at least $50 million. In the case of a pooled fund, the $50 million net asset requirement will be met, if 50 percent or more of the units of beneficial interest in such pooled fund are held by plans each of which has total net assets with a value of at least $50 million.

For purposes of the net asset tests described above, where a group of plans is maintained by a single employer or controlled group of employers, as defined in section 407(d)(7) of the Act, the $50 million net asset requirement may be met by aggregating the assets of such plans, if the assets are pooled for investment purposes in a single master trust.

(i) The Morgan Stanley/Mitsubishi Entity serving as trustee (other than a nondiscretionary trustee) engaging in a covered transaction furnishes, at least annually, to the authorizing plan fiduciary of each plan the following:

(1) The aggregate brokerage commissions, expressed in dollars, paid by the plan to brokerage firms affiliated with such trustee;

(2) The aggregate brokerage commissions, expressed in dollars, paid by the plan to brokerage firms not affiliated with such trustee;

(3) The average brokerage commissions, expressed as cents per

share, paid by the plan to brokerage firms affiliated with such trustee; and

(4) The average brokerage commissions, expressed as cents per share, paid by the plan to brokerage firms not affiliated with such trustee.

For purposes of this subparagraph (i), the words, ''paid by the plan,'' should be construed to mean ''paid by the pooled fund'' when the trustee engages in covered transactions on behalf of a pooled fund in which the plan participates.

Section IV: Exceptions From Conditions

(a) Certain agency cross transactions. Section III of this Part VI does not apply in the case of an agency cross transaction, provided that the Morgan Stanley/Mitsubishi Entity and/or Related Entity:

(1) Does not render investment advice to any plan for a fee within the meaning of section 3(21)(A)(ii) of the Act with respect to the transaction;

(2) Is not otherwise a fiduciary who has investment discretion with respect to any plan assets involved in the transaction, *see* 29 CFR 2510.3–21(d); and

(3) Does not have the authority to engage, retain or discharge any person who is or is proposed to be a fiduciary regarding any such plan assets.

(b) Recapture of profits. Section III(a) of this Part VI does not apply in any case where the entity engaging in a covered transaction returns or credits to the plan all profits earned by the entity in connection with the securities transactions associated with the covered transaction.

(c) Special rules for pooled funds. In the case of a covered transaction involving an account or fund for the collective investment of the assets of more than one plan (pooled fund):

(1) Section III(b), (c), and (d) of this Part VI do not apply if:

(i) The arrangement under which the covered transaction is performed is subject to the prior and continuing authorization, in the manner described in this subparagraph (c)(1), of an authorizing plan fiduciary with respect to each plan whose assets are invested in the pooled fund who is independent of the Morgan Stanley/Mitsubishi Entity and the Related Entity. The requirement that the authorizing plan fiduciary be independent shall not apply in the case of a plan covering only employees of a Morgan Stanley/Mitsubishi Entity, if the requirements of Section IV(c)(2)(i) and (ii) of this Part VI are met.

(ii) The authorizing plan fiduciary is furnished with any reasonably available information that the Morgan Stanley/Mitsubishi Entity engaging or proposing to engage in the covered transactions reasonably believes to be necessary for the authorizing plan fiduciary to determine whether the authorization should be given or continued, not less than thirty (30) days prior to implementation of the arrangement or material change thereto, including (but not limited to) a description of the Morgan Stanley/Mitsubishi Entity's brokerage placement practices, and, where requested, any reasonably available information regarding the matter upon the reasonable request of the authorizing plan fiduciary at any time.

(iii) In the event an authorizing plan fiduciary submits a notice in writing to the Morgan Stanley/Mitsubishi Entity engaging in or proposing to engage in the covered transaction objecting to the implementation of, material change in, or continuation of, the arrangement, the plan on whose behalf the objection was tendered is given the opportunity to terminate its investment in the pooled fund, without penalty to the plan, within such time as may be necessary to effect the withdrawal in an orderly manner that is equitable to all withdrawing plans and to the non-withdrawing plans. In the case of a plan that elects to withdraw under this subparagraph (c)(1)(iii), the withdrawal shall be effected prior to the implementation of, or material change in, the arrangement; but an existing arrangement need not be discontinued by reason of a plan electing to withdraw.

(iv) In the case of a plan whose assets are proposed to be invested in the pooled fund subsequent to the implementation of the arrangement and that has not authorized the arrangement in the manner described in subparagraphs (c)(1)(ii) and (c)(1)(iii) of this Section IV, such plan's investment in the pooled fund is subject to the prior written authorization of an authorizing fiduciary who satisfies the requirements of subparagraph (c)(1)(i).

(2) To the extent that Section III(a) of this Part VI prohibits any Morgan Stanley/Mitsubishi Entity or Related Entity from being the employer of employees covered by a plan investing in a pool managed by the Morgan Stanley/Mitsubishi Entity, Section III(a) of this Part VI does not apply if:

(i) The Morgan Stanley/Mitsubishi Entity is an ''investment manager'' as defined in section 3(38) of the Act, and

(ii) Either

(A) The Morgan Stanley/Mitsubishi Entity returns or credits to the pooled fund all profits earned by the Related Entity in connection with all covered transactions engaged in by the Related Entity on behalf of the fund, or

(B) The pooled fund satisfies the requirements of Section IV(c)(3) of this Part VI.

(3) A pooled fund satisfies the requirements of this subparagraph for a fiscal year of the fund if:

(i) On the first day of such fiscal year, and immediately following each acquisition of an interest in the pooled fund during the fiscal year by any plan covering employees of any Morgan Stanley/Mitsubishi Entity or Related Entity, the aggregate fair market value of the interests in such fund of all plans covering employees of any Morgan Stanley/Mitsubishi Entity and Related Entity, acquired under this exemption and PTE 86–128, does not exceed 20 percent (20%) of the fair market value of the total assets of the fund; and

(ii) The aggregate brokerage commissions received by any Related Entity, in connection with covered transactions engaged under this exemption and PTE 86–128, on behalf of all pooled funds in which a plan covering employees of any Morgan Stanley/Mitsubishi Entity or Related Entity participates, do not exceed 5 percent (5%) of the total brokerage commissions received by any Related Entity from all sources in such fiscal year.

*Part VII. Proposed Exemption for Cross-Trades of Securities by Index and Model-Driven Funds (Modeled After PTE 2002–12)*

Section I. Proposed Exemption for Cross-Trading of Securities by Index and/or Model-Driven Funds

The restrictions of sections 406(a)(1)(A) and 406(b)(2) of the Act, and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) of the Code, shall not apply to the transactions described below, if the applicable conditions set forth in Sections II and III of this exemption, below, are satisfied.

(a) The purchase and sale of securities between an Index Fund or a Model-Driven Fund, as defined in Section IV(a) and (b), below, and another Index Fund or Model-Driven Fund (hereinafter, either, a Fund), at least one of which holds ''plan assets'' subject to the Act; or

(b) The purchase and sale of securities between a Fund and a Large Account, as defined in Section IV(e) of this Part VII, at least one of which holds ''plan assets'' subject to the Act, pursuant to a portfolio restructuring program, as defined in Section IV(f) of this Part VII, of the Large Account, where a Morgan

Stanley entity is the Manager on one side of the cross-trade and a Mitsubishi entity is the Manager on the other side of the cross-trade. Each Manager must comply with each condition below and is deemed a Morgan Stanley/Mitsubishi Entity for purposes of Parts VIII and IX below.

Notwithstanding the foregoing, this Part VII shall apply to cross-trades between two (2) or more Large Accounts pursuant to a portfolio restructuring program, if such cross-trades occur as part of a single cross-trading program involving both Funds and Large Accounts for which securities are cross-traded solely as a result of the objective operation of the program.

Section II. Specific Conditions

(a) The cross-trade is executed at the closing price, as defined below in Section IV(h) of this Part VII.

(b) Any cross-trade of securities by a Fund occurs as a direct result of a ''triggering event,'' as defined in Section IV(d), and is executed no later than the close of the third business day following such ''triggering event.''

(c) If the cross-trade involves a Model-Driven Fund, the cross-trade does not take place within three (3) business days following any change made by the Manager to the model underlying the Fund.

(d) The Manager has allocated the opportunity for all Funds or Large Accounts to engage in the cross-trade on an objective basis which has been previously disclosed to the authorizing fiduciaries of plan investors, and which does not permit the exercise of discretion by the Manager (*e.g.,* a pro rata allocation system).

(e) No more than 20 percent (20%) of the assets of the Fund or Large Account at the time of the cross-trade is comprised of assets of plans maintained by the Manager for its own employees (the Manager Plan(s)) for which the Manager exercises investment discretion.

(f)(1) Cross-trades of equity securities involve only securities that are widely-held, actively-traded, and for which market quotations are readily available from independent sources that are engaged in the ordinary course of business of providing financial news and pricing information to institutional investors and/or to the general public, and are widely recognized as accurate and reliable sources for such information. For purposes of this requirement, the terms, ''widely-held'' and ''actively-traded,'' shall be deemed to include any security listed in an Index, as defined in Section IV(c); and

(2) Cross-trades of fixed-income securities involve only securities for which market quotations are readily available from independent sources that are engaged in the ordinary course of business of providing financial news and pricing information to institutional investors and/or to the general public, and are widely recognized as accurate and reliable sources for such information.

(g) The Manager receives no brokerage fees or commissions as a result of the cross-trade.

(h) A plan's participation in the cross-trading program of a Manager, as a result of investments made in any Index or Model-Driven Fund that holds plan assets is subject to a written authorization executed in advance of such investment by a fiduciary of such plan which is independent of Morgan Stanley and Mitsubishi (the independent plan fiduciary).

For purposes of this Part VII, the requirement that the authorizing fiduciary be independent of the Manager shall not apply in the case of a Manager Plan.

(i) With respect to existing plan investors in any Index or Model-Driven Fund that holds plan assets as of the date this proposed exemption is granted, the independent fiduciary is furnished with a written notice, not less than forty-five (45) days prior to the implementation of the cross-trading program, that describes the Fund's participation in the cross-trading program of the Manager, provided that:

(1) Such notice allows each plan an opportunity to object to such plan's participation in the cross-trading program as a Fund investor by providing such plan with a special termination form;

(2) The notice instructs the independent plan fiduciary that failure to return the termination form to the Manager, by a specified date (which shall be at least thirty (30) days following such plan's receipt of the form) shall be deemed to be an approval by such plan of its participation in the Manager's cross-trading program as a Fund investor; and

(3) If the independent plan fiduciary objects to a plan's participation in the cross-trading program as a Fund investor by returning the termination form to the Manager by the specified date, such plan is given the opportunity to withdraw from each Index or Model-Driven Fund without penalty prior to the implementation of the cross-trading program, within such time as may be reasonably necessary to effectuate the withdrawal in an orderly manner.

(j) Prior to obtaining the authorization described in Section II(h) of this Part VII, and in the notice described in Section II(i) of this Part VII, the following statement must be provided by the Manager to the independent plan fiduciary:

Investment decisions for the Fund (including decisions regarding which securities to buy or sell, how much of a security to buy or sell, and when to execute a sale or purchase of securities for the Fund) will not be based in whole or in part by the Manager on the availability of cross-trade opportunities and will be made prior to the identification and determination of any cross-trade opportunities. In addition, all cross-trades by a Fund will be based solely upon a ''triggering event'' set forth in this Part VII. Records documenting each cross-trade transaction will be retained by the Manager.

(k) Prior to any authorization set forth in Section II(h) of this Part VII, and at the time of any notice described in Section II(i) of this Part VII, the independent plan fiduciary must be furnished with any reasonably available information necessary for the fiduciary to determine whether the authorization should be given, including (but not limited to) a copy of this proposed exemption and the final exemption, if granted, an explanation of how the authorization may be terminated, detailed disclosure of the procedures to be implemented under the Manager's cross-trading practices (including the ''triggering events'' that will create the cross-trading opportunities, the independent pricing services that will be used by the Manager to price the cross-traded securities, and the methods that will be used for determining closing price), and any other reasonably available information regarding the matter that the authorizing plan fiduciary requests. The independent plan fiduciary must also be provided with a statement that the Manager will have a potentially conflicting division of loyalties and responsibilities to the parties to any cross-trade transaction and must explain how the Manager's cross-trading practices and procedures will mitigate such conflicts.

With respect to Funds that are added to the Manager's cross-trading program or changes to, or additions of, triggering events regarding Funds, following the authorizations described in Section II(h) or Section II(i) of this Part VII, the Manager shall provide a notice to each relevant independent plan fiduciary of each plan invested in the affected Funds prior to, or within ten (10) days following, such addition of Funds or

change to, or addition of, triggering events, which contains a description of such Fund(s) or triggering event(s). Such notice will also include a statement that such plan has the right to terminate its participation in the cross-trading program and its investment in any Index Fund or Model-Driven Fund without penalty at any time, as soon as is necessary to effectuate the withdrawal in an orderly manner.

(l) At least annually, the Manager notifies the independent fiduciary for each plan that has previously authorized participation in the Manager's cross-trading program as a Fund investor, that such plan has the right to terminate its participation in the cross-trading program and its investment in any Index Fund or Model-Driven Fund that holds plan assets without penalty at any time, as soon as is necessary to effectuate the withdrawal in an orderly manner. This notice shall also provide each independent plan fiduciary with a special termination form and instruct the fiduciary that failure to return the form to the Manager by a specified date (which shall be at least thirty (30) days following such plan's receipt of the form) shall be deemed an approval of the subject plan's continued participation in the cross-trading program as a Fund investor. In lieu of providing a special termination form, the notice may permit the independent plan fiduciary to utilize another written instrument by the specified date to terminate a plan's participation in the cross-trading program; provided that in such case the notification explicitly discloses that a termination form may be obtained from the Manager upon request. Such annual re-authorization must provide information to the relevant independent plan fiduciary regarding each Fund in which a plan is invested, as well as explicit notification that such plan fiduciary may request and obtain disclosures regarding any new Funds in which such plan is not invested that are added to the cross-trading program, or any new triggering events (as defined in Section IV(d) of this Part VII) that may have been added to any existing Funds in which such plan is not invested, since the time of the initial authorization described in Section II(h) of this Part VII, or the time of the notification described in Section II(i) of this Part VII.

(m) With respect to a cross-trade involving a Large Account:

(1) The cross-trade is executed in connection with a portfolio restructuring program, as defined in Section IV(f) of this Part VII, with respect to all or a portion of the Large Account's investments which an independent fiduciary of the Large Account (other than in the case of any assets of a Manager Plan) has authorized the Manager to carry out or to act as a ''trading adviser,'' as defined in Section IV(g) of this Part VII, in carrying out a Large Account-initiated liquidation or restructuring of its portfolio;

(2) Prior to the cross-trade, a fiduciary of the Large Account who is independent of Morgan Stanley and Mitsubishi (other than in the case of any assets of a Manager Plan) [25] has been fully informed of the Manager's cross-trading program, has been provided with the information required in Section II(k) of this Part VII, and has provided the Manager with advance written authorization to engage in cross-trading in connection with the restructuring, provided that:

(i) Such authorization may be terminated at will by the Large Account upon receipt by the Manager of written notice of termination.

(ii) A form expressly providing an election to terminate the authorization, with instructions on the use of the form, is supplied to the authorizing Large Account fiduciary concurrent with the receipt of the written information describing the cross-trading program. The instructions for such form must specify that the authorization may be terminated at will by the Large Account, without penalty to the Large Account, upon receipt by the Manager of written notice from the authorizing Large Account fiduciary;

(3) All cross-trades made in connection with the portfolio restructuring program must be completed by the Manager within sixty (60) days of the initial authorization (or initial receipt of assets associated with the restructuring, if later) to engage in such restructuring by the Large Account's independent fiduciary, unless such fiduciary agrees in writing to extend this period for another thirty (30) days; and,

(4) No later than thirty (30) days following the completion of the Large Account's portfolio restructuring program, the Large Account's independent fiduciary must be fully apprised in writing of all cross-trades executed in connection with the restructuring. Such writing shall include a notice that the Large Account's independent fiduciary may obtain, upon request, the information described in Section III(a) of this Part VII, subject to the limitations described in Section III(b) of this Part VII. However, if the program takes longer than sixty (60) days to complete, interim reports containing the transaction results must be provided to the Large Account fiduciary no later than fifteen (15) days following the end of the initial sixty (60) day period and the succeeding thirty (30) day period.

Section III. General Conditions

(a) The Manager maintains or causes to be maintained for a period of six (6) years from the date of each cross-trade the records necessary to enable the persons described below in subparagraph (b) of this Section III to determine whether the conditions of this Part VII have been met, including records which identify:

(1) On a Fund by Fund basis, the specific triggering events which result in the creation of the model prescribed output or trade list of specific securities to be cross-traded;

(2) On a Fund by Fund basis, the model prescribed output or trade list which describes:

(i) Which securities to buy or sell; and

(ii) How much of each security to buy or sell; in detail sufficient to allow an independent plan fiduciary to verify that each of the above decisions for the Fund was made in response to specific triggering events; and

(3) On a Fund by Fund basis, the actual trades executed by the Fund on a particular day and which of those trades resulted from triggering events.

Such records must be readily available to assure accessibility and maintained so that an independent fiduciary, or other persons identified below in subparagraph (b) of this Section III, may obtain them within a reasonable period of time. However, a prohibited transaction will not be considered to have occurred if, due to circumstances beyond the control of the Manager, the records are lost or destroyed prior to the end of the six-year period, and no party in interest other than the Manager shall be subject to the civil penalty that may be assessed under section 502(i) of the Act or to the taxes imposed by section 4975(a) and (b) of the Code if the records are not maintained or are not available for examination as required by subparagraph (b) below of this Section III.

(b)(1) Except as provided below in subparagraph (b)(2) of this Section III and notwithstanding any provisions of sections 504(a)(2) and (b) of the Act, the records referred to in subparagraph (a) of this Section III are unconditionally

[25] However, proper disclosures must be made to, and written authorization must be made by, an appropriate plan fiduciary for the Manager Plan in order for the Manager Plan to participate in a specific portfolio restructuring program as part of a Large Account.

available at their customary location for examination during normal business hours by:

(i) Any duly authorized employee or representative of the Department or the IRS,

(ii) Any fiduciary of a plan participating in a cross-trading program who has the authority to acquire or dispose of the assets of such plan, or any duly authorized employee or representative of such fiduciary,

(iii) Any contributing employer with respect to any plan participating in a cross-trading program or any duly authorized employee or representative of such employer, and

(iv) Any participant or beneficiary of any Manager Plan participating in a cross-trading program, or any duly authorized employee or representative of such participant or beneficiary.

(2) If, in the course of seeking to inspect records maintained by a Manager pursuant to this Section III, any person described below in subparagraph (b)(1)(ii) through (iv) of this Section III seeks to examine trade secrets, or commercial or financial information of the Manager that is privileged or confidential, and the Manager is otherwise permitted by law to withhold such information from such person, the Manager may refuse to disclose such information provided that, by the close of the thirtieth (30th) day following the request, the Manager gives a written notice to such person advising the person of the reasons for the refusal and that the Department of Labor may request such information.

(3) The information required to be disclosed to persons described above in subparagraph (b)(1)(ii) through (iv) of this Section III shall be limited to information that pertains to cross-trades involving a Fund or Large Account in which they have an interest.

Section IV. Definitions

The following definitions apply for purposes of this Part VII:

(a) ''Index Fund''—Any investment fund, account or portfolio sponsored, maintained, trusteed, or managed by a Manager or an Affiliate, in which one or more investors invest, and:

(1) Which is designed to track the rate of return, risk profile and other characteristics of an Index, as defined in Section IV(c) of this Part VII, by either

(i) Replicating the same combination of securities which compose such Index, or

(ii) Sampling the securities which compose such Index based on objective criteria and data;

(2) For which the Manager does not use its discretion, or data within its control, to affect the identity or amount of securities to be purchased or sold;

(3) That either contains ''plan assets'' subject to the Act, is an investment company registered under the 1940 Act, or contains assets of one or more institutional investors, which may include, but not be limited to, such entities as an insurance company separate account or general account, a governmental plan, a university endowment fund, a charitable foundation fund, a trust, or other fund which is exempt from taxation under section 501(a) of the Code; and,

(4) That involves no agreement, arrangement, or understanding regarding the design or operation of the Index Fund which is intended to benefit a Manager or an Affiliate, or any party in which a Manager or an Affiliate may have an interest.

(b) ''Model-Driven Fund''—Any investment fund, account or portfolio sponsored, maintained, trusteed, or managed by the Manager or an Affiliate in which one or more investors invest, and:

(1) Which is composed of securities the identity of which and the amount of which are selected by a computer model that is based on prescribed objective criteria using independent third party data, not within the control of the Manager, to transform an Index, as defined in Section IV(c) of this Part VII;

(2) Which either contains ''plan assets'' subject to the Act, is an investment company registered under the 1940 Act, or contains assets of one or more institutional investors, which may include, but not be limited to, such entities as an insurance company separate account or general account, a governmental plan, a university endowment fund, a charitable foundation fund, a trust, or other fund which is exempt from taxation under section 501(a) of the Code; and

(3) That involves no agreement, arrangement, or understanding regarding the design or operation of the Model-Driven Fund or the utilization of any specific objective criteria which is intended to benefit a Manager or an Affiliate, or any party in which a Manager or an Affiliate may have an interest.

(c) ''Index''—A securities index that represents the investment performance of a specific segment of the public market for equity or debt securities in the United States and/or foreign countries, but only if—

(1) The organization creating and maintaining the index is:

(i) Engaged in the business of providing financial information, evaluation, advice, or securities brokerage services to institutional clients,

(ii) A publisher of financial news or information, or

(iii) A public securities exchange or association of securities dealers; and,

(2) The index is created and maintained by an organization independent of the Manager, as defined in Section IV(i) of this Part VII; and,

(3) The index is a generally accepted standardized index of securities which is not specifically tailored for the use of the Manager.

(d) ''Triggering Event'':

(1) A change in the composition or weighting of the Index underlying a Fund by the independent organization creating and maintaining the Index;

(2) A material amount of net change in the overall level of assets in a Fund, as a result of investments in and withdrawals from the Fund, provided that:

(i) Such material amount has either been identified in advance as a specified amount of net change relating to such Fund and disclosed in writing as a ''triggering event'' to an independent fiduciary of each plan having assets held in the Fund prior to, or within ten (10) days following, its inclusion as a ''triggering event'' for such Fund or the Manager has otherwise disclosed in the description of its cross-trading practices, pursuant to Section II(k) of this Part VII, the parameters for determining a material amount of net change, including any amount of discretion retained by the Manager that may affect such net change, in sufficient detail to allow the independent fiduciary to determine whether the authorization to engage in cross-trading should be given; and

(ii) Investments or withdrawals as a result of the Manager's discretion to invest or withdraw assets of a Manager Plan, other than a Manager Plan which is a defined contribution plan under which participants direct the investment of their accounts among various investment options, including such Fund, will not be taken into account in determining the specified amount of net change;

(3) An accumulation in the Fund of a material amount of either:

(i) Cash which is attributable to interest or dividends on, and/or tender offers for, portfolio securities; or

(ii) Stock attributable to dividends on portfolio securities; provided that such material amount has either been identified in advance as a specified amount relating to such Fund and disclosed in writing as a ''triggering event'' to an independent fiduciary of each plan having assets held in the

Fund prior to, or within ten (10) days after, its inclusion as a ''triggering event'' for such Fund, or the Manager has otherwise disclosed in the description of its cross-trading practices, pursuant to Section II(k) of this Part VII the parameters for determining a material amount of accumulated cash or securities, including any amount of discretion retained by the Manager that may affect such accumulated amount, in sufficient detail to allow the independent fiduciary to determine whether the authorization to engage in cross-trading should be given;

(4) A change in the composition of the portfolio of a Model-Driven Fund mandated solely by operation of the formulae contained in the computer model underlying the Model-Driven Fund where the basic factors for making such changes (and any fixed frequency for operating the computer model) have been disclosed in writing to an independent fiduciary of each plan having assets held in the Model-Driven Fund, prior to, or within ten (10) days after, its inclusion as a ''triggering event'' for such Model-Driven Fund; or

(5) A change in the composition or weighting of a portfolio for an Index Fund or a Model-Driven Fund which results from an independent fiduciary's direction to exclude certain securities or types of securities from the Fund, notwithstanding that such securities are part of the index used by the Fund.

(e) ''Large Account''—Any investment fund, account or portfolio that is not an Index Fund or a Model-Driven Fund sponsored, maintained, trusteed (other than a Fund for which the Manager is a nondiscretionary trustee), or managed by the Manager, which holds assets of either:

(1) An employee benefit plan within the meaning of section 3(3) of the Act that has $50 million or more in total assets (for purposes of this requirement, the assets of one or more employee benefit plans maintained by the same employer, or controlled group of employers, may be aggregated provided that such assets are pooled for investment purposes in a single master trust);

(2) An institutional investor that has total assets in excess of $50 million, such as an insurance company separate account or general account, a governmental plan, a university endowment fund, a charitable foundation fund, a trust, or other fund which is exempt from taxation under section 501(a) of the Code; or

(3) An investment company registered under the 1940 Act (*e.g.,* a mutual fund) other than an investment company advised or sponsored by the Manager; provided that the Manager has been authorized to restructure all or a portion of the portfolio for such Large Account or to act as a ''trading adviser'' (as defined in Section IV(g) of this Part VII in connection with a portfolio restructuring program (as defined in Section IV(f) of this Part VII for the Large Account.

(f) ''Portfolio restructuring program''—Buying and selling the securities on behalf of a Large Account in order to produce a portfolio of securities which will be an Index Fund or a Model-Driven Fund managed by the Manager or by another investment manager, or in order to produce a portfolio of securities the composition of which is designated by a party independent of the Manager, without regard to the requirements of Section IV(a)(3) or (b)(2) of this Part VII, or to carry out a liquidation of a specified portfolio of securities for the Large Account.

(g) ''Trading adviser''—A Morgan Stanley or Mitsubishi entity whose role is limited with respect to a Large Account to the disposition of a securities portfolio in connection with a portfolio restructuring program that is a Large Account-initiated liquidation or restructuring within a stated period of time in order to minimize transaction costs. The Morgan Stanley or Mitsubishi Entity does not have discretionary authority or control with respect to any underlying asset allocation, restructuring or liquidation decisions for the account in connection with such transactions and does not render investment advice [within the meaning of 29 CFR 2510.3–21(c)] with respect to such transactions.

(h) ''Closing price''—The price for a security on the date of the transaction, as determined by objective procedures disclosed to investors in advance and consistently applied with respect to securities traded in the same market, which procedures shall indicate the independent pricing source (and alternates, if the designated pricing source is unavailable) used to establish the closing price and the time frame after the close of the market in which the closing price will be determined.

(i) ''Manager''—A Morgan Stanley entity acting as manager of a Fund or Large Account involved in one side of a cross-trade transaction involving a Mitsubishi entity acting as manager of a Fund or Large Account involved in the other side of the same cross-trade transaction; or a Mitsubishi entity acting as manager of a Fund or Large Account involved in one side of a cross-trade transaction involving a Morgan Stanley entity acting as manager of a Fund or Large Account involved in the other side of the same cross-trade transaction, where the Morgan Stanley entity and the Mitsubishi entity is:

(1) A bank or trust company, or any Affiliate thereof, which is supervised by a state or federal agency; or

(2) An investment adviser or any Affiliate thereof which is registered under the Investment Advisers Act of 1940.

(j) ''Affiliate''—An affiliate of a Manager is:

(1) Any person, directly or indirectly, through one or more intermediaries, controlling, controlled by or under common control with the Manager:

(2) Any officer, director, employee, or relative of such Manager, or partner of any such Manager; or

(3) Any corporation or partnership of which such Manager is an officer, director, partner, or employee.

(k) ''Control''—The power to exercise a controlling influence over the management or policies of a person other than an individual.

(l) ''Relative''—A relative is a person that is defined in section 3(15) of the Act (or a ''member of the family'' as that term is defined in section 4975(e)(6) of the Code), or a brother, a sister, or a spouse of a brother or sister.

(m) ''Nondiscretionary trustee''—A plan trustee whose powers and duties with respect to any assets of a plan are limited to

(1) The provision of nondiscretionary trust services to such plan, and

(2) Duties imposed on the trustee by any provision or provisions of the Act or the Code. The term ''nondiscretionary trust services'' means custodial services and services ancillary to custodial services, none of which services are discretionary. For purposes of this Part VII, a person who is otherwise a nondiscretionary trustee will not fail to be a nondiscretionary trustee solely by reason of having been delegated, by the sponsor of a master or prototype plan, the power to amend such plan.

*Part VIII. New Global Conditions Applicable to All Transactions Covered by This Exemption*

(a) Notwithstanding the requirements above, the applicable Morgan Stanley/Mitsubishi Entity maintain(s) or cause(s) to be maintained for a period of six (6) years from the date of any transaction described herein, such records as are necessary to enable the persons described below in subparagraph (b) to determine whether the conditions of this proposed exemption were met, except that:

(1) If the records necessary to enable the persons described below in

subparagraph (b)(1)(i)–(iv) to determine whether the conditions of the proposed exemption have been met are lost or destroyed, due to circumstances beyond the control of the Morgan Stanley/Mitsubishi Entity, then no prohibited transaction will be considered to have occurred solely on the basis of the unavailability of those records; and

(2) No party in interest with respect to a plan which engages in the covered transactions, other than Morgan Stanley and Mitsubishi, shall be subject to the civil penalty that may be assessed under section 502(i) of the Act or to the taxes imposed by section 4975(a) and (b) of the Code if the records have not been maintained or are not available for examination as required by subparagraph (b) below.

(b)(1) Except as provided below in subparagraph (b)(2), and notwithstanding the provisions of subsections (a)(2) and (b) of section 504 of the Act, the records referred to above in subparagraph (a) are unconditionally available for examination during normal business hours at their customary location to the following persons or an authorized representative thereof:

(i) Any duly authorized employee or representative of the Department, the Internal Revenue Service (IRS), or the SEC; or

(ii) Any fiduciary of any plan that engages in the covered transactions, or any duly authorized employee or representative of such fiduciary; or

(iii) Any employer of participants and beneficiaries and any employee organization whose members are covered by any plan that engages in the transactions covered herein, or any authorized employee or representative of these entities; or

(iv) Any participant or beneficiary of any plan that engages in the transactions covered herein, or duly authorized representative of such participant or beneficiary;

(2) None of the persons described above in subparagraph (b)(1)(ii)–(iv) shall be authorized to examine the trade secrets of a Morgan Stanley/Mitsubishi Entity, or commercial or financial information, which is privileged or confidential; and

(3) Should a Morgan Stanley/Mitsubishi entity refuse to disclose information on the basis that such information is exempt from disclosure, pursuant to subparagraph (b)(2) above such Morgan Stanley/Mitsubishi Entity shall, by the thirtieth (30th) day following the request, provide a written notice advising that person of the reasons for the refusal and that the Department may request such information.

(c) If an Applicable Class Exemption is amended, revised or revoked, or is subject to a new interpretation by the Department following the grant of this exemption, such change or interpretation will apply to the relevant transactions, conditions and/or terms in the relevant exemption herein.

(d) *Disclosure of Conflicts:* The Morgan Stanley/Mitsubishi Entity engaging in a transaction covered by any Part of this exemption (with the exception of transactions described in Parts III and V) must provide a written notice to a fiduciary of that plan that is independent of both Mitsubishi and Morgan Stanley. The notice must clearly, and in plain English: Describe the ownership relationship between Morgan Stanley and Mitsubishi; describe the transactions that Morgan Stanley and Mitsubishi will engage in under this exemption on behalf of the plan or IRA; and alert the independent plan fiduciary that, as a result of the ownership relationship between Morgan Stanley and Mitsubishi, the previously identified transactions will provide a benefit to Morgan Stanley or Mitsubishi (*i.e.,* the party that is not exercising discretion over the assets involved in the transaction) and/or involve a conflict of interest;

(e) When relying on the relief in any Part of this exemption, the Morgan Stanley/Mitsubishi Entity must comply with the following ''Impartial Conduct Standards'': (1) The Morgan Stanley/Mitsubishi Entity, at the time of the transaction, must act in the Best Interest of the plan. In this regard, acting in the Best Interest means acting with the care, skill, prudence, and diligence under the circumstances then prevailing that a prudent person acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with like aims, based on the investment objectives, risk tolerance, financial circumstances, and needs of affected plan, and not place the financial or other interests of the Morgan Stanley/Mitsubishi Entity, Related Entity, or other party ahead of the interests of the affected plan, or subordinate the plan's interests to their own; (2)(A) The compensation received, directly or indirectly, by the Morgan Stanley/Mitsubishi Entity and Related Entities for their services may not exceed reasonable compensation within the meaning of ERISA section 408(b)(2) and Code section 4975(d)(2); and (B) As required by the federal securities laws, the Morgan Stanley/Mitsubishi Entity must obtain the best execution of the investment transaction reasonably available under the circumstances; and (3) The Morgan Stanley/Mitsubishi Entity's statements to the plan about the covered transaction and other relevant matters must not be materially misleading at the time statements are made.

(f) All Morgan Stanley/Mitsubishi Entities utilizing the exemption will have policies and procedures in place that are prudently designed to ensure that the conditions of the exemption are met. The policies and procedures must be in place prior to the occurrence of the transaction that is the subject of the relevant relief.

*Part IX. General Definitions*

(a) The term ''Morgan Stanley/Mitsubishi Entity'' means an entity acting as a plan fiduciary in a transaction described in Parts I through VII:

(1) That meets the definition of Morgan Stanley, as defined below; or

(2) That meets the definition of Mitsubishi, as defined below; or

(b) The term ''Related Entity'' means an entity that meets the definition of ''Morgan Stanley/Mitsubishi Entity,'' except that the entity is not acting as a fiduciary with respect to the transaction that is the subject of the exemptive relief described in Parts I through VII of the exemption, if granted.

(c) The term ''Morgan Stanley'' means Morgan Stanley & Co. LLC and any person, directly or indirectly, through one or more intermediaries, controlling, controlled by, or under common control with Morgan Stanley & Co.

(d) The term ''Mitsubishi'' means Mitsubishi UFJ Financial Group, Inc., and any person, directly or indirectly, through one or more intermediaries, controlling, controlled by, or under common control with Mitsubishi UFJ Financial Group, Inc.

(e) For purposes of Part IX(c) and (d) above, the term ''control'' means the power to exercise a controlling influence over the management or policies of a person other than an individual.

(f) The term ''Rating Agency'' or collectively, ''Rating Agencies'' means a credit rating agency that:

(1) Is currently recognized by the Securities and Exchange Commission (SEC) as a nationally recognized statistical ratings organization (NRSRO);

(2) Has indicated on its most recently filed SEC Form NRSRO that it rates ''issuers of asset-backed securities;'' and

(3) Has had, within a period not exceeding twelve (12) months prior to the initial issuance of the securities, at least three (3) ''qualified ratings engagements.'' A ''qualified ratings engagement'' is one:

(i) Requested by an issuer or underwriter of securities in connection with the initial offering of the securities;

(ii) For which the credit rating agency is compensated for providing ratings;

(iii) Which is made public to investors generally; and

(iv) Which involves the offering of securities of the type that would be granted relief by the certain underwriter exemptions (the Underwriter Exemptions).[26]

(g) The term ''Applicable Class Exemption'' means PTE 75–1, Part III; PTE 75–1, Part IV; PTE 77–3; PTE 77–4; PTE 79–13; PTE 86–128; or PTE 2002–12.

*Effective Date:* The exemption, if granted, will be effective as of the date the final exemption is published in the **Federal Register**.

**Notice to Interested Persons**

Notice of the proposed exemption will be provided to all interested persons within 30 days of the publication of the notice of proposed exemption in the **Federal Register**. The notice will be provided to all interested persons in the manner agreed upon by the Applicant and the Department and will contain a copy of the notice of proposed exemption as published in the **Federal Register** and a supplemental statement, as required pursuant to 29 CFR 2570.43(a)(2). The supplemental statement will inform interested persons of their right to comment on and to request a hearing with respect to the pending exemption. All written comments and/or requests for a hearing must be received by the Department within sixty days of the date of publication of this proposed exemption in the **Federal Register**.

All comments will be made available to the public. *Warning:* If you submit a comment, EBSA recommends that you include your name and other contact information in the body of your comment, but DO NOT submit information that you consider to be confidential, or otherwise protected (such as a Social Security number or an unlisted phone number) or confidential business information that you do not want publicly disclosed. All comments may be posted on the internet and can be retrieved by most internet search engines.

**FOR FURTHER INFORMATION CONTACT:** Mr. Joseph Brennan of the Department, telephone (202) 693–8456. (This is not a toll-free number.)

**General Information**

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and/or section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person from certain other provisions of the Act and/or the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which, among other things, require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) Before an exemption may be granted under section 408(a) of the Act and/or section 4975(c)(2) of the Code, the Department must find that the exemption is administratively feasible, in the interests of the plan and of its participants and beneficiaries, and protective of the rights of participants and beneficiaries of the plan;

(3) The proposed exemptions, if granted, will be supplemental to, and not in derogation of, any other provisions of the Act and/or the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction; and

(4) The proposed exemptions, if granted, will be subject to the express condition that the material facts and representations contained in each application are true and complete, and that each application accurately describes all material terms of the transaction which is the subject of the exemption.

Signed at Washington, DC.

**George Christopher Cosby,**

*Acting Director, Office of Exemption Determinations, Employee Benefits Security Administration, U.S. Department of Labor.*

[FR Doc. 2021–25139 Filed 11–17–21; 8:45 am]

BILLING CODE 4510–29–P

[26] The Underwriter Exemptions are a group of individual exemptions granted by the Department to provide relief for the origination and operation of certain asset pool investment trusts and the acquisition, holding, and disposition by plans of certain asset-backed pass-through certificates representing undivided interests in those investment trusts. The most recent amendment to the Underwriter Exemptions is the Amendment to Prohibited Transaction Exemption 2007–05, 72 FR 13130 (March 20, 2007), Involving Prudential Securities Incorporated, et al., To Amend the Definition of ''Rating Agency,'' [Prohibited Transaction Exemption 2012–08, 78 FR 41090 (July 9, 2013); Exemption Application No. D–11718].

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Part IV

## Department of Justice

Drug Enforcement Administration

Pronto Pharmacy, LLC; Decision and Order; Notice

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**[Docket No. 19–42]**

### Pronto Pharmacy, LLC; Decision and Order

On August 23, 2019, a former Acting Administrator of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause and Immediate Suspension of Registration (hereinafter, OSC) to Pronto Pharmacy, LLC (hereinafter, Respondent). Administrative Law Judge Exhibit (hereinafter, ALJ Ex.) 1, (OSC) at 1.[*A] The OSC informed Respondent of the immediate suspension of its DEA Certificate of Registration Number FP2302076 (hereinafter, registration or COR) and proposed its revocation, the denial of any pending applications for renewal or modification of such registration, and the denial of any pending applications for additional DEA registrations pursuant to 21 U.S.C. 824(a)(4) and 823(f), because Respondent's ''continued registration is inconsistent with the public interest.'' *Id.* (citing 21 U.S.C. 824(a)(4) and 823(f)).

In response to the OSC, Respondent timely requested a hearing before an Administrative Law Judge. ALJ Ex. 3. The hearing in this matter was conducted from January 28–29, 2020, in Tampa, Florida. On May 5, 2020, Administrative Law Judge Mark M. Dowd (hereinafter, ALJ) issued his Recommended Rulings, Findings of Fact, Conclusions of Law and Decision (hereinafter, Recommended Decision or RD). On May 26, 2020, the Government and Respondent filed exceptions to the Recommended Decision (hereinafter, Gov Exceptions and Resp Exceptions, respectively). Having reviewed the entire record, I find Respondent's Exceptions without merit and I adopt the ALJ's Recommended Decision with minor modifications, as noted herein.[*B] I have addressed each of Respondent's Exceptions and I issue my final Order in this case following the Recommended Decision.

**Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge** [*C 1 2 3]

The issue ultimately to be adjudicated by the Administrator, with the assistance of this Recommended Decision, is whether the record as a whole establishes by a preponderance of the evidence that the DEA Certificate of Registration, No. FP2302076, issued to the Respondent should be revoked, and any pending applications for modification or renewal of the existing registration be denied, and any applications for additional registrations be denied, because its continued registration would be inconsistent with the public interest under 21 U.S.C. 823(f) and 824(a)(4).

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**

1. The Respondent repeatedly issued prescriptions in violation of the minimum practice standards that govern the practice of pharmacy in Florida. ALJ Ex. 1 at ¶ 4. Specifically, from at least January 2018 through at least May 2019, the Respondent repeatedly filled prescriptions for Schedule II narcotics in the face of obvious red flags of drug abuse and diversion. *Id.* Filling these prescriptions violated federal and Florida law, including 21 CFR 1306.04(a) and 1306.06, and Fla. Admin. Code r. 64B16–27.810.

2. In addition, the Respondent engaged in the ''manufacture'' of controlled substances, as the Controlled Substances Act defines that term. ALJ Ex. 1 at ¶ 5. The Respondent is not registered with the DEA as a manufacturer. *Id.* Manufacturing controlled substances without the appropriate registration is a violation of federal law, including 21 U.S.C. 841(a)(1) and 21 CFR 1301.13(e). *Id.*

*Improper Dispensing*

Between January 9, 2018, and May 7, 2019, the Respondent repeatedly issued prescriptions in violation of the minimum practice standards that govern the practice of pharmacy in Florida. ALJ Ex. 1 at ¶ 11. These prescriptions presented numerous red flags of drug abuse and diversion, including drug cocktails, early refills, excessive dispensing of high-strength controlled substances, travelling long distances, and cash payments. *Id.* at ¶¶ 12–15, 18–19. Filling these prescriptions violated federal and state law, including 21 U.S.C. 842(a)(1), 21 CFR 1306.04(a), and Florida Administrative Code r. 64B16–27.810. *Id.* at ¶ 19. The OSC/ISO provided the following specific examples of prescriptions that raised these red flags:

Drug Cocktails

3. Patient A.G.: On at least nine occasions between January 25, 2018, and April 12, 2019, the Respondent filled prescriptions issued by the same prescriber for patient A.G. for alprazolam and oxycodone or hydromorphone on the same date. ALJ Ex. 1, ¶ 12(a). Specifically, the Respondent filled prescriptions for hydromorphone and alprazolam for A.G. on the following four occasions: January 25, 2018; March 1, 2018; April 12, 2018; and May 8, 2018. *Id.* The Respondent filled prescriptions for oxycodone and alprazolam for A.G. on the following five occasions: December 20, 2018; January 17, 2019; February 14, 2019; March 20, 2019; and April 12, 2019. *Id.*

4. Patient B.S.: On at least five occasions between January 29, 2018, and April 22, 2019, the Respondent filled prescriptions issued by the same prescriber for patient B.S. for alprazolam and oxycodone or hydromorphone on the same date. ALJ Ex. 1, ¶ 12(b). Specifically, the Respondent filled prescriptions for hydromorphone and alprazolam for B.S. on the following two occasions: January 29, 2018, and May 22, 2018. *Id.* The Respondent filled prescriptions for oxycodone and alprazolam for B.S. on the following three occasions: December 20, 2018; February 28, 2019; and March 26, 2019. *Id.*

5. Patient N.B.: On at least three occasions between September 14, 2018, and January 16, 2019, the Respondent filled prescriptions issued by the same prescriber for patient N.B. for alprazolam and oxycodone or hydromorphone on the same date. ALJ Ex. 1, ¶ 12(c). Specifically, the Respondent filled prescriptions for hydromorphone and alprazolam for N.B. on September 14, 2018. *Id.* The Respondent filled prescriptions for oxycodone and alprazolam for N.B. on the following two occasions: December 20, 2018, and January 16, 2019. *Id.*

[*A] According to Agency records, DEA removed all controlled substances from Respondent's possession on August 29, 2019, when the OSC was served, pursuant to the Immediate Suspension Order.

[*B] I have made minor, nonsubstantive, grammatical changes to the RD and nonsubstantive conforming edits. Where I have made substantive changes, omitted language for brevity or relevance, or where I have added to or modified the ALJ's opinion, I have noted the edits in brackets, and I have included specific descriptions of the modifications in brackets or in footnotes marked with an asterisk and a letter. Within those brackets and footnotes, the use of the personal pronoun ''I'' refers to myself—the Administrator.

[*C] I have omitted the RD's discussion of the procedural history to avoid repetition with my introduction.

[1] [Footnote omitted, *see supra* n.*C.]

[2] [Footnote omitted, *see supra* n.*C.]

[3] [Footnote omitted, *see supra* n.*C.]

6. Patient C.R.: On at least three occasions between March 6, 2018, and July 12, 2018, the Respondent filled prescriptions issued by the same prescriber for patient C.R. for alprazolam and oxycodone on the same date. ALJ. Ex. at ¶ 12(d). Specifically, the Respondent filled prescriptions for oxycodone and alprazolam for C.R. on March 6, 2018; April, 19, 2018; and July 12, 2018. *Id.*

7. Patient J.M.: On at least five occasions between January 25, 2018, and May 16, 2018, the Respondent filled prescriptions issued by the same prescriber for patient J.M. for alprazolam and oxycodone on the same date. *Id.* Specifically, the Respondent filled prescriptions for oxycodone and alprazolam for J.M. on January 25, 2018; March 1, 2018; April 4, 2018; April 19, 2018; and May 16, 2018. *Id.*

Early Refills

8. Patient A.H.: On January 22, 2019, the Respondent filled a prescription for patient A.H. for a 30-day supply of hydromorphone 8 mg tablets. ALJ Ex. 1, ¶ 13(a). The Respondent filled additional prescriptions for A.H. for 30-day supplies of hydromorphone 8 mg tablets on February 15, 2019 (six days early); February 27, 2019 (18 days early); and March 14, 2019 (15 days early). *Id.*

9. Patient M.M.: On January 3, 2019, the Respondent filled a prescription for patient M.M. for a 28-day supply of hydromorphone 8 mg tablets. ALJ Ex. 1, ¶ 13(b). The Respondent filled additional prescriptions for M.M. for 30-day supplies of hydromorphone 8 mg tablets on January 24, 2019 (seven days early); February 19, 2019 (four days early); and a 28-day supply on March 15, 2019 (six days early). *Id.*

10. Patient J.D.: On May 10, 2018, the Respondent filled a prescription for patient J.D. for a 30-day supply of hydromorphone HCL powder. ALJ Ex. 1, ¶ 13(c). The Respondent filled additional prescriptions for J.D. for 30-day supplies of hydromorphone HCL powder on May 30, 2018 (10 days early); June 15, 2018 (14 days early); and June 30, 2018 (15 days early). *Id.*

11. Patient R.G.: On January 29, 2018, the Respondent filled prescriptions for patient R.G. for a 30-day supply of oxycodone HCL powder and a 30-day supply of alprazolam 2 mg tablets. ALJ Ex. 1, ¶ 13(d). The Respondent filled additional prescriptions for 30-day supplies of oxycodone HCL powder and alprazolam 2 mg tablets for R.G. on February 21, 2018 (seven days early); March 19, 2018 (four days early); April 17, 2018 (one day early); and May 8, 2018 (nine days early). *Id.*

12. Patient R.L.: On February 1, 2018, the Respondent filled a prescription for patient R.L. for a 30-day supply of hydromorphone HCL powder. ALJ Ex. 1, ¶ 13(e). The Respondent filled additional prescriptions for 30-day supplies of hydromorphone HCL powder for R.L. on February 26, 2018 (five days early); a 29-day supply on March 22, 2018 (six days early); a 30-day supply on April 17, 2018 (three days early); and a 30-day supply on May 11, 2018 (six days early). *Id.*

High-Strength Controlled Substances

13. During the relevant time period, virtually all of the prescriptions for oxycodone and hydrocodone that the Respondent ''compounded'' were for oxycodone 30 mg immediate release and hydromorphone 8 mg immediate release, the highest strengths of these controlled substances. ALJ Ex. 1, ¶ 14. Furthermore, between January 11, 2018, and July 17, 2018, 100 percent of the oxycodone tablet prescriptions and 87 percent of the hydromorphone tablet prescriptions (approximately 44 prescriptions total) issued by a particular prescriber were for the highest strength available for those controlled substances. *Id.*

Long Distances

14. Between September 10, 2018, and May 6, 2019, the Respondent filled:

a. 86 prescriptions for patients with addresses in Cape Coral, Florida, which is approximately 140 miles from the Respondent;

b. 145 prescriptions for patients with addresses in Fort Myers, Florida, which is approximately 130 miles from the Respondent;

c. 41 prescriptions for patients with addresses in Lehigh Acres, Florida, which is approximately 140 miles from the Respondent;

d. 15 prescriptions for patients with addresses in Immokalee, Florida, which is approximately 150 miles from the Respondent;

e. 15 prescriptions for patients with addresses in Naples, Florida, which is approximately 170 miles from the Respondent;

f. 11 prescriptions for patients with addresses in Opa-locka, Florida, which is approximately 270 miles from the Respondent. ALJ Ex. 1, ¶¶ 15(a)–(f).

15. In addition, between September 10, 2018, and May 6, 2019, over 75 percent of the prescriptions for controlled substances filled by the Respondent were issued by prescribers whose medical practices are located more than 150 miles away from the Respondent. ALJ Ex. 1, ¶ 16.

Cash Payments

16. During the relevant time period, over 90 percent of the prescriptions for oxycodone 30 mg and hydromorphone 8 mg filled by the Respondent were paid for with cash. ALJ Ex. 1, ¶ 18. In contrast, in 2018 ''approximately 11 percent of all prescriptions filled by independently owned pharmacies . . . were paid for with cash.'' *Id.*

*Illegal Manufacturing*

17. Between January 2018 and May 2019, the Respondent was engaged in manufacturing controlled substances, as that term is defined in the CSA, without a separate DEA registration authorizing it to manufacture controlled substances, in violation of 21 U.S.C. 841(a)(1) and 21 CFR 1301.13(e). ALJ Ex. 1, ¶ 20–28.

**The Hearing**

*Government's Opening Statement*

In its Opening Statement, Tr. 14–17, the Government stated that through its investigation of the Respondent, the DEA obtained the Respondent's dispensing records and patient profiles, a pharmacy expert reviewed those records, and that review revealed suspicious patterns. Tr. 14. Those suspicious patterns included the fact that 99 percent of the Respondent's prescriptions were paid for in cash; over 90 percent of the Respondent's patients travelled more than 100 miles to fill their prescriptions; and that the Respondent dispensed a disproportionately high volume of opioids. *Id.* The DEA's expert reviewed the Respondent's records related to 11 specific patients and found that the prescriptions filled by these patients presented numerous red flags that could not have been resolved by a pharmacist acting in the usual course of professional practice. Tr. 14–15. The expert further opined that based on his review of the Respondent's records, the Respondent made no attempt to resolve the red flags presented by these prescriptions. *Id.*

In addition, the Government previewed that its evidence would show that the Respondent unlawfully manufactured controlled substances, specifically oxycodone and hydromorphone, without a manufacturer's registration. Tr. 15–17. To support this allegation, the Government intended to show that in May 2012 the Respondent's owner, Mr. Norman J. Clement, Sr., told DEA investigators that he compounded oxycodone and hydromorphone because it was cheaper than obtaining them from distributors. Tr. 14–15. In conclusion,

the Government requested that the Respondent's registration be revoked and any pending applications be denied because its continued registration presents a threat to the public. Tr. 17.

*Respondent's Opening Statement*

In the Respondent's opening statement, Tr. 503–06, the Respondent stated that the DEA initiated this case without objectively evaluating the evidence. Tr. 503. The DEA did not interview any patients identified in the OSC/ISO or the doctors who issued the prescriptions involved in this case. *Id.* The DEA also did not subpoena the medical records of the patients at issue. *Id.*

The Respondent argued that the Government's evidence would fail to show that any patients involved in this case suffered adverse consequences from the prescriptions filled by the Respondent. Tr. 504. Furthermore, the Respondent argued that the Government's evidence would fail to meet its burden to revoke the Respondent's registration. *Id.* In the Respondent's view, the Government's case is based on the faulty assumption that the patients must have been drug abusers because they received treatment for chronic pain. *Id.* The Respondent characterized this assumption as ''inherently unfair and inappropriate.'' *Id.*

The Respondent argued that the Government's assumption ignores the Respondent's combined 90-years of pharmacy experience possessed by the Respondent's pharmacists, as well as their professional education and training. Tr. 505. The Respondent's evidence is expected to prove that its pharmacists exercised appropriate professional judgment and resolved red flags. *Id.* The Respondent highlighted that the Government's evidence on red flags comes from a witness who has never practiced in Florida. *Id.* Furthermore, the Respondent argued that its evidence will show that its pharmacists' professional judgment complied with the Florida standard of care, and that the Florida standard of care is established by state statutes rather than an ''ivory tower aspirational goal.'' *Id.*

**Government's Case-in-Chief**

The Government presented its case-in-chief through the testimony of three witnesses. First, the Government presented the testimony of Diversion Investigator Richard Albert. Tr. 24–180. Second, the Government presented the testimony of Task Force Officer Jeffrey Shearer. Tr. 181–94. Finally, the Government presented the testimony of its expert, Dr. Donald Sullivan. Tr. 195–502.

*Diversion Investigator (DI) Richard J. Albert, Jr.*

DI Albert has been a Diversion Investigator for more than seven years. Tr. 24–25. He is currently stationed in Tampa, Florida. Previously, he was stationed in Nashville, Tennessee. Tr. 24. To become a Diversion Investigator, DI Albert received training at the 12-week basic diversion school in Quantico, Virginia. *Tr. 25.*

DI Albert became involved in the investigation of the Respondent in May 2017, when he received a call from the Department of Health regarding a pharmacy that was compounding hydromorphone and oxycodone. Tr. 26. DI Albert and his supervisor then met with the Health Department investigator at Respondent. *Id.* The Respondent's owner, Mr. Norman J. Clement, Sr., was not present at the pharmacy, but his daughter and wife were present. Tr. 26–27. The investigators presented a Notice of Inspection to Mr. Clement, Sr.'s, daughter, who allowed the investigators to inspect the pharmacy. *Id.* Approximately 15-minutes into the inspection, Mrs. Clement asked the investigators to leave. *Id.* The investigators complied. Tr. 27.

In September 2017, the DEA served a subpoena on the Respondent requesting Schedule II controlled substance prescriptions, receiving records, and batch records. Tr. 27. Government Exhibit 2 is a receiving record sent from Auburn Pharmaceutical to the Respondent. Tr. 28; GX 2. The DEA received this document in response to the September 2017 subpoena. *Id.*

Government Exhibit 3 is a receiving record for hydromorphone [4] sent from B&B Pharmaceuticals to the Respondent. Tr. 29; GX 3. The DEA received this document in response to the September 2017 subpoena. *Id.*

Government Exhibit 4 is a receiving record for oxycodone sent from Fagron, Inc., to the Respondent. Tr. 31; GX 4. The DEA received this document in response to the September 2017 subpoena. Tr. 32.

Government Exhibit 5 contains batch records for hydromorphone 8 mg. Tr. 32–33; GX 5. A batch record documents the production of a controlled substance and lists the ingredients in the controlled substance. Tr. 33. The batch record is created by the person who makes the substance. *Id.* The batch records indicate how many capsules were used in the production of a particular batch. Tr. 38, 40–41. Government Exhibit 5 documents the production of hydromorphone 8 mg. Tr. 33. The initials ''N.C.,'' who DI Albert presumed to be the Respondent's owner, Norman J. Clement, Sr., appear in the columns labelled ''Manufactured By,'' ''Checked By,'' and ''Final Product Checked By.'' [5] Tr. 35–37; GX 5.

Government Exhibit 6 contains batch records for oxycodone 30 mg. Tr. 38–39; GX 6. The DEA received this document in response to the September 2017 subpoena. Tr. 39.

Upon reviewing the batch records received in response to the September 2017 subpoena, DI Albert noticed that the records listed lactose as the only non-controlled substance ingredient. Tr. 42–43. When he reviewed the prescriptions received in response to the subpoena, he noticed that patients were travelling long distances to the pharmacy. Tr. 43, 129–30.

Government Exhibit 10 is a printout of the prescription drug monitoring program (''PDMP'') for the Respondent's dispensing from September 2016 to June 2018. Tr. 46, 159, 162; GX 10, pp. 1, 20. This document represents the total number of controlled substance prescriptions that the Respondent dispensed during that 21-month time period. Tr. 162–63. The document lists 2,360 prescriptions. Tr. 162–63. DI Albert reviewed the Respondent's PDMP records during his investigation. Tr. 43–44. Government Exhibits 8 and 9 also contain PDMP printouts of the Respondent's dispensing. Tr. 49–52; GX 8–9.

DI Albert returned to Respondent in September 2018 to serve an administrative inspection warrant (''AIW'') and subpoena. Tr. 52. Government Exhibit 67 is the subpoena, dated September 5, 2018, that DI Albert served on the Respondent's counsel at the time of executing the AIW. Tr. 52–53; GX 67. The second page of the subpoena is a list of patient names. Tr. 53; GX 67, p. 2. DI Albert did not speak with any patients who presented at the pharmacy while the AIW was being executed. Tr. 168. He also did not speak with any of the Respondent's staff, including Mr. Norman J. Clement, Sr., who was instructed by counsel to not answer any questions. Tr. 168, 173, 177.

During service of the AIW, digital forensic specialists captured mirror

[4] Hydromorphone is a Schedule II controlled substance. Tr. 29.

[5] During cross-examination, the Respondent's counsel directed DI Albert's attention to page 7 and 11 of Government Exhibit 6, which shows illegible initials in the ''Manufactured By'' column (page 7) and the ''Checked By'' column (page 11). Tr. 150; GX 6, pp. 7, 11. DI Albert was also unable to identify the signature on page 13 of Government Exhibit 6. Tr. 151; GX 6, p. 13.

images of the Respondent's computer system. Tr. 54, 62, 91, 93, 134. The Respondent used Rx30 pharmacy software. Tr. 135. DI Albert received the information that was captured from the Respondent's system in Excel format, but he did not know the process that the digital forensic team used to convert that information into the format he received. Tr. 136. DI Albert was unable to determine whether errors were made in converting the captured images of the Respondent's system into Excel. Tr. 136–37.

During execution of the AIW, DI Albert observed Mr. Clement, Sr., conduct a closing inventory of the controlled substances that the Respondent had on-hand at the time. Tr. 54, 56, 165–66. Mr. Clement, Sr., signed the closing inventory. Tr. 56, 58; GX 7. The closing inventory lists 470 tablets of hydromorphone 8mg, 3,546 capsules of hydromorphone 8 mg, hydromorphone powder, 204 tablets of oxycodone 30 mg, 574 capsules of oxycodone 30 mg, and oxycodone powder. Tr. 59, 61; GX 7. Medications from distributors are in the form of tablets. When medications are compounded from powder in batch at a pharmacy, the dosage units are contained in capsules. Tr. 60.

Government Exhibit 11 is saved on a DVD. Tr. 63–64; GX 11. Government Exhibit 11 contains records electronically downloaded from the Respondent's computer system during execution of the AIW. Tr. 63.

Government Exhibit 12 is a report of the Respondent's dispensing over a three-month period from November 2015 through January 2016. Tr. 68; GX 12. This document was obtained electronically during execution of the AIW in September 2018. Tr. 69. Government Exhibit 13 was also obtained during service of the AIW. Tr. 70; GX 13.

Government Exhibit 14 is a PDMP dispensing record for patient A.G. Tr. 71–72; GX 14. Government Exhibit 15 is a record kept by the Respondent for patient A.G. with information about the patient as well as notes. Tr. 73–74; GX 15. It was electronically downloaded from the Respondent's computer system during the AIW search. Tr. 75. The DEA also obtained Government Exhibits 16 and 17 during the AIW search. Tr. 76–81, 140; GX 16–17. Government Exhibits 16 and 17 are dispensing records for patient A.G. maintained by the Respondent and obtained from the pharmacy. *Id.*

Government Exhibit 19 is a PDMP dispensing record for patient A.H. Tr. 81–82; GX 19. The Government moved for the admission of Exhibits 19 through 43 and 46 through 52 as a group. Tr. 85–87. These exhibits were either obtained from the Respondent during the AIW search in September 2018 or printed from the PDMP. *Id.* They relate to the specific patients identified in the OSC/ISO. *Id.*

After executing the AIW at the pharmacy in September 2018, DI Albert sent the records he obtained to a pharmacy expert, Dr. Donald Sullivan, for review. Tr. 88. DI Albert served another subpoena on the Respondent in May 2019. Tr. 88–89; GX 68. Attached to the subpoena is a list of seven patients. Tr. 89; GX 68, p. 2. This subpoena requested that the Respondent produce five categories of documents, to include (1) patient profiles for the patients identified in the attachment; (2) other records documenting the steps taken to avoid or resolve any issues or red flags with prescriptions; (3) original prescriptions and fill stickers of all prescriptions filled for patients listed in the attachment from September 10, 2018, to May 10, 2019; (4) any pharmacist notes evaluating potential red flags with prescriptions; (5) and any other documentation related to the specific patients identified, such as dispensing records, billing records, PDMP records, and medical records. Tr. 89–90; GX 68.

DI Albert received additional documents from the Respondent in response to the May 2019 subpoena. Tr. 94. The documents that DI Albert received related to patients A.G. and R.B. are contained in Government Exhibits 18 and 44. Tr. 94–98; GX 18, 44. DI Albert sent the documents that he received in response to the May 2019 subpoena to the expert witness for review. Tr. 118. He then began preparing the OSC/ISO. Tr. 118–19.

In his investigation of the Respondent, DI Albert calculated the approximate distances from the cities where patients lived to the Respondent pharmacy. Tr. 99–105, 130. DI Albert made these calculations by using Google Maps to determine the distance from the cities of residence to the Respondent's address. Tr. 99–101. The approximate distances on Google Maps are contained in Government Exhibit 54.[6] Tr. 99; GX 54.

DI Albert also searched for specific addresses in Google Maps. Tr. 105–12. Each of the specific addresses that DI Albert searched relate to a specific patient. Tr. 106, 108–09, 111–12. The one-way distances from those addresses to the Respondent are in Government Exhibits 55 through 60 and 62 through 65. Tr. 105–12; GX 55–60, 62–65.

Government Exhibit 55 shows a distance of 131 miles.[7] Tr. 106; GX 55, p. 1. Government Exhibit 56 shows a distance of 132 miles. Tr. 109; GX 56, p. 1. Government Exhibit 57 shows a distance of 148 miles. Tr. 110; GX 57, p. 1. Government Exhibit 58 shows a distance of 134 miles. GX 58, p. 1. Government Exhibit 59 shows a distance of 130 miles. GX 59, p. 1. Government Exhibit 60 shows a distance of 144 miles. GX 60, p. 1.

Government Exhibit 62 shows a distance of 137 miles. GX 62, p. 1. Government Exhibit 63 shows a distance of 138 miles. GX 63, p. 1. Government Exhibit 64 shows a distance of 131 miles. GX 64, p. 1. Government Exhibit 65 shows a distance of 138 miles. GX 65, p. 1.

Government Exhibit 61 shows the roundtrip distance from patient M.M.'s home, to the doctor's office, to the Respondent, and then back home. Tr. 112–18, 131, 172; GX 61. The total roundtrip distance from M.M.'s home to the doctor's office and the Respondent, and then back home, is 327 miles. Tr. 117, 131; GX 61, p. 1. Although DI Albert searched for the roundtrip distance between M.M.'s home, doctor's office, and the Respondent, he did not check to see whether M.M. filled any prescriptions at the Respondent in Tampa on the same day that he obtained them from the doctor in Fort Myers. Tr. 133, 171. DI Albert is therefore not sure whether M.M. ever made the roundtrip drive that is depicted in Government Exhibit 61. *Id.* If M.M. had travelled from her home to the doctor's office and the Respondent on separate days, however, the total travel distance would be similar to the roundtrip distance travelled on one day.[8] Tr. 173.

[6] Although Google Maps includes estimated travel times as well as mileage, due to the high variability of travel times, only the mileage is being considered herein.

[7] The Google Maps printouts list three routes with different distances and travel times. When speaking of the distances between patients' homes and the Respondent, I will refer to the route with the shortest mileage.

[8] The distance from M.M.'s home to her doctor's office is 134 miles. GX 61, p. 3. Thus, the total distance travelled if M.M. went to the doctor and returned home on the same day would be 268 miles. The distance from M.M.'s home to the Respondent is 38 miles. Tr. 134; GX 61, p. 6. Thus, the total distance travelled if M.M. went to the Respondent and returned home on the same day would be 76 miles. Added together, these distances total 344 miles. Thus, if M.M. travelled to her doctor's office to obtain a prescription on one day and returned home, and then travelled to the Respondent on another day to fill the prescription and returned home, the total distance travelled to obtain and fill that prescription would be slightly higher (344 miles) than if she had made the roundtrip drive from home, to the doctor's office, to the pharmacy, and back home, all in one day (327 miles). However, during the hearing, counsel

Continued

DI Albert was candid in conceding there were matters and facts of which he was unaware. For example, during his investigation, DI Albert readily conceded he did not talk to any of the 11 patients named in the OSC/ISO. Tr. 123–24, 155. He also conceded that he did not contact the subject prescribing doctors. Tr. 125–26, 128, 173–74, 178–80. DI Albert also conceded that he was unfamiliar with the FDA guidelines on compounding and that he did not receive training on compounding during DI training. Tr. 152. He also admitted that he did not familiarize himself with the Florida laws governing pharmacies, and that he only applied federal law in his investigation. Tr. 152–53. DI Albert also candidly acknowledged that he did not know the significance of the citations to Florida law in the subpoenas that he served. Tr. 153–54. In addition, DI Albert acknowledged that he had not done a comparison of the Respondent's daily, weekly, and monthly dispensing volume to other nearby pharmacies. Tr. 167–68.

DI Albert's willingness to concede these points, excepting in these areas, bolsters his credibility. DI Albert's testimony focused primarily on identifying exhibits and describing his investigation. Based on my close observation of DI Albert at the hearing, my careful review of his testimony in the transcript, and in conjunction with other credible evidence, I find DI Albert to be a credible witness. DI Albert presented as an impartial investigator with no direct stake in the outcome of the case, and his testimony was straightforward, professional, and candid. Furthermore, his testimony was also detailed and internally consistent. For these reasons, I fully credit DI Albert's testimony and find that his testimony merits considerable weight in this Recommended Decision.

*Task Force Officer (TFO) Jeffrey Shearer*

TFO Shearer has been running a private investigation business for the past five years. Tr. 182. Before that, he was a police officer with the Tampa Police Department for 16 years. *Id.* He spent the last five-and-a-half years of his career with the Tampa Police Department as a task force officer working out of the DEA's Tampa District Office. Tr. 182–83. As a TFO, Mr. Shearer worked with the DEA in the Tactical Diversion Squad on investigations related to the diversion of controlled substances. Tr. 182.

TFO Shearer worked on an investigation of the Respondent. Tr. 183. In May 2012, during execution of an AIW at the Respondent pharmacy, TFO Shearer interviewed Mr. Clement, Sr., the Respondent's owner. *Id.* Mr. Clement, Sr., was cooperative during execution of the AIW. Tr. 192. Mr. Clement, Sr., was not in custody at the time and was free to leave. Tr. 183. In the interview, Mr. Clement, Sr., told TFO Shearer about his process for manufacturing oxycodone and hydromorphone in capsules. Tr. 183–84. Mr. Clement, Sr., told TFO Shearer that he could buy a 100 gram bottle of oxycodone powder for $1,100, enough to manufacture about 6,000 dosage units. Tr. 185. Tablets of oxycodone purchased from commercial distributors cost roughly $2-$10 per pill. *Id.* Mr. Clement, Sr., told TFO Shearer that he manufactured thousands of capsules per batch because it was cost effective.[9] Tr. 184–85. The batch records that TFO Shearer reviewed in 2012 documented that Mr. Clement, Sr., produced thousands of pills in each batch. *Id.* Mr. Clement, Sr., was not charged with a crime. Tr. 190.

Based on listening to him testify at the hearing, and reviewing the transcript of his testimony, I find TFO Shearer to be a credible witness who testified in a candid, professional, and straightforward manner. TFO Shearer testified regarding events that had occurred approximately seven years prior to the hearing. He seemed fully capable of recalling the majority of those events with ease, but it is not surprising that some of his answers lacked detail. Any lack of detail, however, did not detract from his credibility or the usefulness of his testimony. He was honest about what he could not recall and he presented as an impartial individual without a direct stake in the outcome of the case. For these reasons, TFO Shearer's testimony is credible and merits significant weight in this Recommended Decision.

*Dr. Donald L. Sullivan* [10]

Dr. Sullivan is presently employed as a professor of Clinical Pharmacy at Ohio State University College of Pharmacy, and has been for five years. Tr. 196–97. *See* GX 53. Previously, he was employed at Ohio Northern University for 17 years. Tr. 197. He obtained his Bachelor's degree in 1990. Tr. 198. In 1991, he obtained his Master's in pharmacy administration, and his doctorate in pharmacy administration in 1996. Tr. 198. At Ohio State, in addition to performing research, he teaches pharmacy practice law to all four years of students. He teaches two courses on pharmacy operations, financial analysis, marketing, and human resource issues. Tr. 197. His courses cover professional standards for pharmacy personnel, including: Dispensing; record keeping; documentation; drug utilization review; patient education and counseling; compounding from a pharmacy practice perspective, as well as state and federal statutes governing the practice of pharmacy. The study of federal law comprises about 50-percent of the legal curriculum. Tr. 197–98, 203.

He has lectured to independent pharmacies on behalf of wholesalers, including Cardinal Health, AmerisourceBergen, HD Smith, as well as several pharmacy organizations. Tr. 199. For the past four years, he has presented a two-hour Continuing Education program to Florida pharmacists on controlled substance dispensing. Tr. 199. Within the past two-to-three years, Florida has increased the professional requirements for pharmacists, to include validating controlled substance prescriptions, understanding different types of diversion, red flags for diversion, how to resolve red flags, naloxone availability, and state and federal laws governing dispensing controlled substances and related record keeping. Tr. 200. Dr. Sullivan has authored five publications, consumer drug reference books, as well as several peer-reviewed publications. Tr. 200. He has completed a research study into community pharmacists, the resources they use in identifying red flags, and their willingness to identify red flags of diversion. Tr. 202. He presents training for government investigators and attorneys. Tr. 203. He has been qualified as an expert in a California criminal trial and in four DEA show cause hearings similar to the instant hearing. Tr. 201, 354–55, 359.

He is a registered pharmacist in Ohio and in Florida. Tr. 198. He has worked as a pharmacist in Ohio, but not in Florida. Tr. 198. However, he has not worked in retail pharmacy for 20 years. Tr. 414. His background is primarily in community pharmacy, which relates to typical private pharmacies and chain pharmacies. Tr. 199. He has also had experience at a pharmacy located within a mental health clinic, and in a mail order pharmacy. *Id.*

Dr. Sullivan described a recent problematic trend in medication reimbursement in which the pharmacies are sometimes being reimbursed less than their actual costs to purchase the

for the Government conceded, and Dr. Sullivan confirmed, it was the distance from the patient's home to her physician's office which represented the red flag of long distance. Tr. 294.

[9] [Footnote omitted for relevance.]

[10] [I agree with the ALJ's discretionary decision to allow the Government to ask leading questions of its expert witness, over objection by Respondent's counsel. *See* RD, at n.10.]

medications. Tr. 430–31. This trend has caused small independent pharmacies to seek niche markets. Tr. 431.

Through his education, training, and experience, Dr. Sullivan is familiar with compounding in retail pharmacy, as well as issues related to abuse and diversion of controlled substances, and with the responsibilities of a retail pharmacist in the detection and prevention of such abuse and diversion. Tr. 203. Dr. Sullivan is also familiar with a pharmacist's corresponding responsibility under federal law, and the standard of care and professional obligations of a pharmacist in the state of Florida. Tr. 204. Dr. Sullivan was qualified as an expert in the field of pharmacy and the standard of care for the practice of pharmacy in the state of Florida. Tr. 204–05, 490.*[D]

Dr. Sullivan described the duties of a pharmacist in filling a controlled substance prescription. Tr. 206. First, the pharmacist must ensure the prescription is a ''valid prescription for a legitimate medical purpose.'' *Id.* That is, the pharmacist must determine if it is issued ''in the normal course of professional practice,'' that the pharmacist believes the patient can safely take it, that the medication is for an actual medical purpose, and is not being abused, misused, or diverted. *Id.* These requirements are codified in both federal and Florida law. Fla. Admin. Code r. 64B16–27.800, .810, and .831.

In reviewing a prescription, a pharmacist must first determine if the prescription appears legal on its face; that all the information necessary appears on the face of the prescription. Tr. 208. Then, applying clinical expertise, the pharmacist must consider possible over-utilization and under-utilization, where the patient is taking more or less medication than prescribed; consider possible abuse or misuse; whether it is serving a legitimate medical purpose; and whether it exposes the patient to potential undue risk of side-effects, adverse effects, or overdose. Tr. 208–09. The Florida standard of care requires pharmacists to document their resolution of any potential issues discovered in the pharmacist's review of a prescription. Tr. 210, 437, 489.

Dr. Sullivan was unaware that Florida had codified a definition of ''standard of care'' for healthcare workers. Tr. 438; Fla. Stat 766.102.[11] He was unaware of the Florida Patient Bill of Rights. Tr. 462. Dr. Sullivan initially conceded there was no federal or Florida regulation mandating where or how the resolution of red flags must be documented. Tr. 435–37. In particular, Dr. Sullivan agreed that Florida Administrative Code r. 64B16–27.831, Standards of Practice for the Filling of Controlled Substance Prescriptions, subpart three, is silent as to whether a pharmacist must document the steps a pharmacist takes to validate a prescription. Tr. 449–50, 453–54. [However, Florida Administrative Code r. 64B16–27.831 requires pharmacists to record ''[p]harmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug,'' which Dr. Sullivan agreed would generally include the information that is needed to resolve red flags. Tr. 488–89.]

In conjunction with the precautionary evaluation described, the pharmacist is required to maintain a ''patient profile'' for each patient, which includes: The patient's full name, address and telephone number, age or date of birth, gender, a list of all new and refilled prescriptions obtained by the patient at the pharmacy, and any notes or comments by the pharmacist particular to that patient, such as drug allergies or contraindications. Tr. 209–10.

Dr. Sullivan explained that under federal law, the pharmacist has a corresponding responsibility, an equal responsibility with the prescribing physician, to determine if a prescription has been written for a legitimate medical purpose. Tr. 210–11. That a prescription is written by a physician does not absolve the pharmacist from ensuring that it is for a legitimate medical purpose. Tr. 211. Common potential concerns for a pharmacist are referred to as ''red flags.'' Red flags include potential for diversion or abuse, patients traveling long distances to see their physicians, or to the pharmacy[12] [13] ''drug cocktails commonly abused, large dosage units, payment in cash for all or part of a patient's prescriptions,[14] over-prescribing of immediate release pain killers, and patients traveling in groups. Tr. 213–15, 240–41[15], 473–76. Traveling long distances to a pharmacy creates the suspicion that pharmacies closer to the patient have declined to fill that particular prescription. Tr. 220. Drug cocktails, or drug combinations known for abuse, such as the combination opioid/benzodiazepine, represent a ''red flag.'' Tr. 220–21; GX 66. Indeed, the FDA issued a ''black box'' warning in August 2016, highlighting the potential danger to the patient of this combination of medications. Tr. 221–23. Cash payment for medications is a red flag as medications are typically expensive and normally patients will defer those costs to their health insurance. Tr. 224–25. Dr. Sullivan testified that ''[t]he theory behind [cash payments] is that patients are selling [the drugs] and that's where they're getting all the cash from.'' *Id.* at 225. Early refills, or early fills of new prescriptions, are suspicious as they may suggest the patient is not taking the medication as prescribed. Tr. 224–25. Florida initiated annual CME four years previously involving ''validation and appropriate use of controlled substances.'' Tr. 235. Florida pharmacists are taught to identify the

*[D] Throughout the case, the Government's expert and all parties appear to have used the phrases ''standard of care,'' ''corresponding responsibility,'' and ''usual course of professional practice'' interchangeably. Dr. Sullivan testified that in the practice of pharmacy the phrases ''standard of care'' and ''usual course of professional practice'' are the same. Tr. 321–22. Dr. Sullivan's testimony regarding the requirement to resolve red flags clearly related to Respondent's corresponding responsibility under 21 CFR 1306.04. The interchangeable use of this terminology does not impact my ultimate finding that Respondent failed to resolve red flags in contravention of Respondent's corresponding responsibility under 21 CFR 1306.04 and outside the usual course of professional practice in violation of 21 CFR 1306.06. For consistency purposes, I will use the language regarding standard of care to encompass corresponding responsibility herein.

[11] The ''prevailing professional standard of care,'' is defined under Florida law as ''that level of care, skill, and treatment which, in light of all relevant surrounding circumstances, is recognized as acceptable and appropriate by reasonably prudent similar heath care providers.'' Fla. Stat. § 766.102.

[12] Dr. Sullivan noted 90% of prescriptions filled at the Respondent involved patients living more than 100 miles from the pharmacy. Tr. 235.

[13] Dr. Sullivan conceded that he was not aware of any federal or Florida regulation limiting the distance traveled to fill a prescription. Tr. 462.

[14] Dr. Sullivan conceded that he was not aware of any federal or Florida laws that prohibit pharmacies from accepting cash as payment for prescriptions. Tr. 444.

[15] The Government offered various statistical evidence regarding average national prices for controlled substances, average miles driven to the pharmacy by patients nationally, a high percentage of Respondent's patients traveling long distances to the Respondent's pharmacy, the relatively high percentage of the Respondent's patients paying by cash, the high percentage of the Respondent's controlled substance dispensations versus non-controlled, the extremely high percentage of compounded hydromorphone 8 mg dispensed versus the commercially available hydromorphone 8 mg tablet dispensed by the Respondent, the extremely high percentage of oxycodone 30 mg, and Alprazolam 2 mg (the highest dosage units commercially produced) prescriptions issued as compared with lower dosage units dispensed, that the Respondent dispensed almost twice as many oxycodone 30 mg capsules as tablets. Tr. 235–38, 241, 244–46, 250–51. This evidence was admitted as it related to the prompting and evaluation of various red flags. It was not admitted, and will not be considered, as probative evidence that specific prescriptions were filled contrary to the standard of care in Florida, which determination requires individualized proof and individualized analysis.

above red flags, to resolve them, and to document the resolution. Tr. 235–36.

To resolve red flags, a pharmacist should discuss the matter with the patient, and attempt to get to know each patient. Tr. 239, 445–49; *see* Fla. Admin. Code r. 64B16–27.831. The pharmacist should also discuss the matter with the prescribing physician, which would provide another source of input for the pharmacist. Tr. 229. However, the prescribing physician can never be the only source of information obtained. Tr. 229. Next, the pharmacist would review the patient's drug record, the PDMP, to determine other medications and the strengths of those medications, and conduct a ''prospective drug utilization review,'' to make an independent clinical evaluation whether the subject prescription was written for a legitimate medical purpose. Tr. 211, 227. Once the pharmacist makes his independent clinical evaluation, the standard of care requires the pharmacist to document his evaluation. Tr. at 210, 228, 488–89; *see also* Tr. 236.

If a pharmacist is unable to resolve the red flags he should decline to fill the prescription. Tr. 228, 488. *[Omitted for relevance.]

*[Dr. Sullivan testified that a pharmacist does not look at individual red flags in isolation; rather, he looks at them ''as a collective whole based on what's going on with that prescription at that time.'' Tr. 482, 498. When asked whether you can evaluate a prescription based on isolated red flags alone, Dr. Sullivan testified that ''[i]t's like pieces in a puzzle, you look at everything related to that prescription and patient.'' Tr. 498.

Dr. Sullivan testified that there are some red flags that, ''when taken as a collective whole[,] . . . cannot be resolved.'' Tr. 481. Dr. Sullivan testified that in these circumstances, ''no matter what the patient tells me, what the doctor tells me, any of that, I'm still not filling the prescription.'' Tr. 282. Dr. Sullivan testified that an individual red flag (such as long distances traveled or cash payments) may become unresolvable if it is combined with multiple additional red flags. Tr. 473 (testifying that there is nothing that the patients could have told Respondent to resolve the distance red flag in conjunction with the other red flags); Tr. 475 (testifying that Respondent's lack of contracts for commercial insurance does not resolve the red flag of cash payment ''when taken into account with the other red flags on these prescriptions''); *see also* Tr. 409–11 (testifying that when there are ''so many [red flags],'' a pharmacist can make the decision not to fill a prescription without calling the prescribing physician).]

Dr. Sullivan testified that [it is often difficult to determine whether any individual red flag is unresolvable, because] red flags should be evaluated in combination. Tr. 480–86, 498. However, he testified that a single red flag could be so egregious that it was unresolvable. Tr. 497–99.

Dr. Sullivan explained compounding, in which a pharmacist ''makes a drug . . . from scratch . . . to meet the unique therapeutic needs of a patient.'' Tr. 230. Typical justification for compounding may include a patient's allergies to certain ingredients within commercially manufactured medications, or the unavailability of a particular medication, or strength of medication required for treatment among commercially available medications. Tr. 230–32, 336–38. Both oxycodone 30 mg, and hydromorphone 8 mg, are commercially available. Tr. 232. [Dr. Sullivan testified that compounding would typically be a ''very very small'' percentage of a pharmacy's business because it is ''very time and labor intensive. Tr. 232.]

Dr. Sullivan reviewed materials sent to him by DI Albert related to Respondent's dispensing. Tr. 233, 349, 405–06. These materials included the Respondent's pharmacy prescription log covering approximately three months [GX 11], PDMP data over an eighteen-month period [GX 8–10], and the Respondent's Prehearing Statement, which included witness summaries. Tr. 341–43, 347–48. Dr. Sullivan did not speak with the pharmacy customers at issue. Tr. 407, 416–18. Dr. Sullivan did not review copies of the actual prescriptions. Tr. 348, 416, 500. Dr. Sullivan agreed that the average 4–5 prescriptions filled at the Respondent's pharmacy per day were much fewer than the average community pharmacy of 190 prescriptions. Tr. 420.

Dr. Sullivan reviewed a list of prescriptions issued by Dr. L. Tr. 251; ALJ Ex. 42 [16], p. 8. Dr. L.'s prescriptions for the highest strength available opioid was a potential red flag for diversion or abuse. Tr. 251–52. As to Dr. P., whose prescribing history revealed he prescribed 65,000 doses of hydromorphone 8 mg to only 135 doses of hydromorphone 4mg, Dr. Sullivan opined that a prudent pharmacist would not fill Dr. P.'s prescriptions for the highest dosage of hydromorphone. Tr. 253, 496. Similarly, Dr. Sullivan opined a reasonable pharmacist would not fill Dr. P.'s prescriptions for oxycodone 30 mg, as Dr. P. prescribed over 24,000 dosage units of oxycodone 30 mg, to only 200 of the lower dosage units. Tr. 253–54.

Turning to specific patients, Dr. Sullivan opined the distance traveled by Patient A.G. from his home to the Respondent's pharmacy was a red flag. Tr. 254; GX 55; ALJ Ex. 42, p. 10. In reviewing A.G.'s prescription history, he was always prescribed the highest dose of hydromorphone and of oxycodone, and except for one instance, the highest dose of alprazolam. Tr. 254–55; GX 17; ALJ Ex. 42, p. 11. The combination of opioid and benzodiazepine, coming even after the FDA's black box warning, is a well-known red flag of diversion and abuse. Tr. 255–56. A review of the PDMP report revealed the dangerous combination of the highest dosage unit of opioid along with a benzodiazepine, in addition to early fills on April 12, 2019, representing unresolvable red flags. Tr. 256–57, 267; GX 14; ALJ Ex. 42, p. 12.

A review of Patient A.G.'s patient profile in RX30, and of the prescriptions and fill stickers, failed to resolve the red flags noted or to justify the compounding done. Tr. 259, 267; GX 17; ALJ Ex. 42, p. 11. In the patient memo, it simply stated, ''Doctor OK to receive medication in compound capsule form,'' which Dr. Sullivan testified is insufficient to justify compounding that medication, which requires an individualized therapeutic need. Tr. 257–59; GX 15; ALJ Ex. 42, p. 13. *See* 21 U.S.C. 802(10), (15). In addition, Dr. Sullivan noted that A.G. was prescribed both capsules and tablets of oxycodone 30 mg between November 8, 2017, and January 25, 2018, demonstrating there was no therapeutic need for compounding the oxycodone 30 mg. Tr. 256.

Dr. Sullivan was suspicious of the patient questionnaire used by Respondent. Tr. 259–60; GX 18. The questionnaire questioned whether the patient lived more than 100 miles from the pharmacy. Dr. Sullivan interpreted the questionnaire as cover for filling prescriptions for distant patients, rather than an effort to disclose or resolve red flags. Tr. 259–61; GX 18. A follow-up question to the distant traveling patients asked, ''why do you travel this distance,'' and in this case, the patient responded, ''quick and good service.'' Tr. 262. Dr. Sullivan opined that this reason was insufficient to resolve the red flags. The questionnaire contained a certification to be made by the patient, certifying that ''I am taking all of my medication prescribed.'' Tr. 262. Dr. Sullivan deemed this certification ineffectual in resolving the red flags of

[16] The Government's demonstrative exhibit will be marked as ALJ Exhibit 42.

early fills and of diversion. A further statement by the patient that, ''I am not selling any of my medication,'' did not alleviate any concerns that the patient may have been diverting his medication. Tr. 262. Indeed, Dr. Sullivan suspected the question exposed a subterfuge by the pharmacy, revealing the pharmacy believed patients were selling their medications, and the question was designed to relieve the pharmacy of any liability. Tr. 263. If a pharmacist believes a patient is selling his medications, the pharmacist should not fill any further prescriptions of that patient. Tr. 264.[17] Dr. Sullivan was directed to the ''Pharmacy Comment'' at the bottom of the prescriptions for A.G. Tr. 265–66; GX 18, p. 6. The notation, ''non acute pain Uninsured Patient'' suggested to Dr. Sullivan that whoever made the notations was trying to signal that this medication therapy was ongoing and to provide some justification for cash payment. Tr. 266.

As to Patient A.H., Dr. Sullivan opined the 132 miles from A.H.'s home to the Respondent pharmacy represented a red flag. Tr. 268; GX 56; ALJ Ex. 42, p. 14. The prescriptions from January to August, 2018 contained several red flags including, highest dosage of short acting pain-relievers, hydromorphone 8 mg and oxycodone 30 mg, and of alprazolam 2 mg; capsules of hydromorphone being dispensed without required therapeutic justification; and the combination of short-acting opioids with a benzodiazepine. Dr. Sullivan deemed these unresolvable red flags. Tr. 269. Later prescriptions for A.H. revealed significantly early fill dates for four consecutive months. Tr. 269–71; GX 19; ALJ Ex. 42, p. 16. Dr. Sullivan viewed this pattern of early fills as evidence of diversion or abuse, warranting action by the pharmacist such as refusing to fill these prescriptions. Tr. 271–72. The fact that the prescribing physician wrote the prescriptions early does not relieve the pharmacist's responsibility to resolve the red flag of early fills. Tr. 272. A review of this patient's file received by Dr. Sullivan failed to reveal any effort by the Respondent to resolve the red flags relating to Patient A.H. Tr. 272–73. Dr. Sullivan opined that, for the reasons discussed above, the relevant standard of care would have caused a reasonable pharmacist operating within the usual course of professional practice to decline filling the prescriptions for A.H. Tr. 272–73; GX 19, 21; ALJ Ex. 42, p. 15–16.

As to Patient B.S., Dr. Sullivan opined the 132 mile distance from B.S.'s home to Respondent represented a red flag. Tr. 273; GX 57; ALJ Ex. 42, p. 18. The prescriptions from August 2017 to August 2018 contained several red flags including, highest dosage of short-acting pain-relievers, hydromorphone 8 mg and oxycodone 30 mg, and of alprazolam 2 mg; capsules of hydromorphone being dispensed without required therapeutic justification; and the combination of short-acting opioids with a benzodiazepine. Dr. Sullivan deemed these unresolvable red flags. Tr. 274, 276. Dr. Sullivan noted the anti-inflammatory ibuprofen 400 mg prescription, which he found inconsistent in combination with the high dose of pain medication. He opined that a once a day ibuprofen dose would have no effect in combination with such a high dose of pain medication. Dr. Sullivan interpreted the ibuprofen as an attempt to demonstrate that the doctor was trying an alternate therapy as opposed to prescribing controlled substances without a legitimate medical purpose, which Dr. Sullivan viewed as a red flag. Tr. 275. Later prescriptions for B.S. revealed significantly early fill dates. Tr. 275–76; GX 22; ALJ Ex. 42, p. 20. Dr. Sullivan viewed this pattern of early fills as evidence of diversion or abuse, warranting action by the pharmacist such as refusing to fill these prescriptions. Tr. 276–78. A review of this patient's file received by Dr. Sullivan failed to reveal any effort by the Respondent to resolve the red flags relating to patient B.S. Tr. 277. Dr. Sullivan opined that, for the reasons discussed above, he relevant standard of care would have caused a reasonable pharmacist operating within the usual course of professional practice would have declined to fill the prescriptions for B.S. GX 22, 24; ALJ Ex. 42, p. 19–20.

As to Patient C.R., Dr. Sullivan opined the 134 miles from C.R.'s home to Respondent represented a red flag. Tr. 279; GX 58; ALJ Ex. 42, p. 22. The prescriptions from July 2017 to August 2018 contained several red flags including, highest dosage of short-acting pain-reliever, oxycodone 30 mg, capsules of oxycodone 30 mg being dispensed without required therapeutic justification; and the combination of short-acting opioids with a benzodiazepine, and the muscle relaxant tizanidine. A July 12, 2018 prescription for morphine sulphate 60 mg per day further heightened the danger to the patient. Tr. 280. Dr. Sullivan deemed these unresolvable red flags. Tr. 279–82; GX 27; ALJ Ex. 42, p. 23. A review of this patient's profile by Dr. Sullivan failed to reveal any effort by the Respondent to resolve the red flags relating to patient C.R. Tr. 281. Dr. Sullivan opined that, for the reasons discussed above, the relevant standard of care would have caused a reasonable pharmacist operating within the usual course of professional practice to decline filling the prescriptions for C.R. Tr. 281–83; GX 27; ALJ Ex. 42, p. 23.

As to Patient J.D., Dr. Sullivan opined that the 130 miles from J.D.'s home to the Respondent pharmacy represented a red flag. Tr. 283; GX 59; ALJ Ex. 42, p. 23. The prescriptions from January 2018 to September 2019 contained several red flags including, highest dosage of short-acting pain-reliever, hydromorphone 8 mg, capsules of hydromorphone 8 mg being dispensed without required therapeutic justification; and the combination of two short-acting pain-relievers, hydromorphone and methadone 10 mg, resulting in an ''extreme risk of overdose.'' Tr. 283–84, 468; GX 30; ALJ Ex. 42, p. 26. Dr. Sullivan deemed these red flags unresolvable and testified that a reasonable pharmacist operating within the usual course of professional practice would not have filled these prescriptions. Tr. 284, 288–89. Several prescriptions filled in mid-2018 revealed unjustified early fills. Tr. 284–87; GX 30; ALJ Ex. 42, p. 27. The pharmacist noted in J.D.'s patient profile, ''NEXT FILL DATE 7/5/18!!! WATCH FILL DATES!!!!!!,'' demonstrating the Respondent knew of J.D.'s issues with early fills. Such note is insufficient to justify filling J.D.'s prescriptions early. Tr. 287–88; GX 29; ALJ Ex. 42, p. 28.

As to Patient J.M., Dr. Sullivan opined that the 144 miles from J.M.'s home to Respondent represented a red flag. Tr. 289; GX 60; ALJ Ex. 42, p. 29. The prescriptions from June 2017 to September 2018 contained several red flags including, highest dosage of short-acting pain-relievers, hydromorphone 8 mg and oxycodone 30 mg, and of alprazolam 2 mg; capsules of oxycodone and hydromorphone being dispensed without required therapeutic justification; and the combination of short-acting opioids with a benzodiazepine, and a muscle relaxer. Dr. Sullivan deemed these unresolvable red flags. Tr. 290–91. Dr. Sullivan noted that J.M. was prescribed both capsules and tablets of oxycodone 30 mg between April 2018 and May 2018 demonstrating

[17] Dr. Sullivan also questioned the prescribing protocol for A.G., in that he was prescribed alternate monthly doses of 30 mg oxycodone and 10 mg of oxycodone. Tr. 264; GX 18, p. 6. However, I believe Dr. Sullivan misread the 30 mg oxycodone prescription of October 30, 2018, as a 10 mg dosage due to a poor copy. So, his conclusions in this regard will not be considered.

there was no therapeutic need for compounding the oxycodone 30 mg. Tr. 290. A review of this patient's file received by Dr. Sullivan failed to reveal any effort by the Respondent to resolve the red flags relating to patient J.M. *Id.* Dr. Sullivan opined that, for the reasons discussed above, the relevant standard of care would have caused a reasonable pharmacist acting within the usual course of professional practice to decline to fill the prescriptions for J.M. Tr. 291; GX 33; ALJ Ex. 42, p. 30.

As to Patient M.M., Dr. Sullivan opined the distance between M.M.'s home and the prescribing physician's office, south of Ft. Myers, Florida, represented a red flag. Tr. 294; ALJ Ex. 42, p. 32. In reviewing M.M.'s dispensing log, Dr. Sullivan identified many of the same red flags as revealed by the other patient's records: high-strength hydromorphone prescribed and dispensed; and capsules of hydromorphone dispensed without individualized therapeutic justification. Tr. 295; GX 36; ALJ Ex. 42, p. 33. Dr. Sullivan was also suspicious of the .4 mg of folic acid, which he suspected was intended to mask the opioid prescriptions. Tr. 295–96. In reviewing the prescriptions filled from January 2019 to April 2019, Dr. Sullivan noted that the Respondent filled both capsules and tablets of hydromorphone, thus negating any prospect that the patient had an individualized therapeutic need for compounded medication. Tr. 297–98; GX 34; ALJ Ex. 42, p. 34. Dr. Sullivan was also concerned regarding a significant break in therapy, from July 18, 2018, and January 3, 2019. Tr. 297. Despite an almost six-month lapse in opioid therapy, the Respondent filled a prescription for hydromorphone 8 mg, the highest commercially available dosage. Tr. 298. If the patient had become opioid naïve during this lapse, there is a heightened risk of overdose. Tr. 298. Dr. Sullivan also recognized some red flags in the form of early fills. Tr. 299; GX 34; ALJ Ex. 42, p. 34. Dr. Sullivan deemed the above red flags unresolvable, and testified that no reasonable pharmacist acting within the usual course of professional practice would have filled the subject prescriptions. Tr. 299–301.

As to Patient N.B., Dr. Sullivan opined the 137 miles from N.B.'s home to the Respondent pharmacy represented a red flag. Tr. 301; GX 62; ALJ Ex. 42, p. 36. The prescriptions from June 2017 to August 2018 contained several red flags, including highest dosage of short-acting pain-reliever, hydromorphone 8 mg, capsules of hydromorphone 8 mg being dispensed without required therapeutic justification; two separate prescriptions for alprazolam with two separate dosage units; and the combination of an opioid and benzodiazepine. Dr. Sullivan noted the anti-inflammatory ibuprofen 400 mg prescription, which he found inconsistent in combination with the high dose of pain medication. A once a day low ibuprofen dose would have no effect in combination with such a high dose of pain medication. Dr. Sullivan found these red flags unresolvable. Tr. 302–03, 305–06; GX 39; ALJ Ex. 42, p. 37. The PDMP data revealed several prescriptions filled unjustifiably early. Tr. 303–04; GX 37; ALJ Ex. 42, p. 38. Dr. Sullivan found no evidence of an attempt to resolve these red flags. Tr. 306–07; GX 37, 39; ALJ Ex. 42, pp. 38–39. Dr. Sullivan was concerned by the two-month gap in opioid treatment from September 14, 2018, and December 20, 2018, potentially producing opioid naïveté in the patient. Tr. 304. In the patient memo, it simply stated, ''Doctor ok patient to receive medication in compound capsule form,'' which, according to Dr. Sullivan, is insufficient to justify compounding that medication, which requires an individualized therapeutic need. Tr. 306, 471; GX 38; ALJ Ex. 42, p. 39.

As to Patient R.B., Dr. Sullivan opined the 138 miles from R.B.'s home to Respondent represented a red flag. Tr. 307; GX 63; ALJ Ex. 42, p. 40. Dr. Sullivan further asserted that the number of patients traveling from the Ft. Myers area to Respondent represented a red flag itself. Tr. 308. The coincidence of patients traveling over 100 miles to the Respondent's pharmacy from the same proximate area represents a pattern that the standard of care would require a pharmacist to notice and to investigate. Tr. 309–10.

The prescriptions from June 2017 to August 2018 contained several red flags, including highest dosage of short-acting pain-reliever, hydromorphone 8 mg, capsules of hydromorphone 8 mg being dispensed without required therapeutic justification; prescriptions for alprazolam at the highest dosage strength; and the combination of an opioid and benzodiazepine. Dr. Sullivan found these red flags were not resolvable according to the standard of care in Florida. Tr. 311, 313, 321; GX 43; ALJ Ex. 42, p. 41. The PDMP data revealed several prescriptions filled unjustifiably early. Tr. 311–12; GX 40; ALJ Ex. 42, p. 42. Dr. Sullivan was concerned by the two-month gap in opioid treatment from September 12, 2018, to January 22, 2019, potentially producing opioid naïveté in the patient. Tr. 312, 471. Dr. Sullivan found no evidence of an attempt to resolve these red flags. Tr. 313; GX 41; ALJ Ex. 42, p. 41. In R.B.'s Patient Questionnaire, R.B. gave conflicting information as to the year of her injury. Tr. 313–14. Furthermore, R.B.'s justification for traveling more than 100 miles to the Respondent's pharmacy, ''it's cheaper and they're good people,'' does not resolve the red flag of long-distance travel. Tr. 315; GX 44. Nor does R.B.'s declaration that she is not selling her medications resolve concerns of diversion. Tr. 315. Patient R.B.'s PDMP report reveals she filled prescriptions at five different pharmacies, including the Respondent's pharmacy. Tr. 316–17; GX 44, p. 5. Dr. Sullivan views this as clear evidence of pharmacy shopping. Another suspicious entry in the PDMP record is the payment source for an April 6, 2016 prescription for oxycodone acetaminophen, and two August 22, 2017 prescriptions for hydrocodone, which were paid for using commercial insurance. Tr. 317–18; GX 44, p. 4. A patient alternately paying cash and using commercial insurance is a red flag of diversion or abuse. Tr. 318–19.

Dr. Sullivan noted prescriptions for R.B. in which it appeared the pharmacist, by permission of the prescribing physician, changed the prescribed ''tablet'' form of medication to compounded capsule. Tr. 319–20; GX 44, pp. 6, 8. As the ''tablet'' form was initially prescribed, changing to compounded capsule does not appear to have been done on the basis of an individualized therapeutic purpose. Tr. 321.

As to Patient R.G., Dr. Sullivan opined the 131 miles from R.G.'s home to the Respondent pharmacy represented a red flag. Tr. 322; GX 64; ALJ Ex. 42, p. 44. The prescriptions from June 2017 to September 2018 contained several red flags, including highest dosage of short-acting pain-reliever, capsules of oxycodone 30 mg being dispensed without required therapeutic justification; the highest strength for alprazolam; and the combination of an opioid and benzodiazepine. Dr. Sullivan noted the ongoing prescribing at the highest opioid dosage suggested a red flag for the lack of individualized treatment, with patients consistently receiving the highest dosage. Tr. 322–24, 329–30. A further indication that there was no therapeutic justification for the compounded capsules of oxycodone 30 mg was the two fills on August 10, 2018, for oxycodone. Tr. 324; GX 49; ALJ Ex. 42, p. 45. R.G. was dispensed 68 tablets and 70 capsules on that same day. Tr. 324–26. Dr. Sullivan found these red flags unresolvable. Tr. 322–23, 326,

328–29; GX 49; ALJ Ex. 42, p. 45. The PDMP data revealed several prescriptions filled unjustifiably early. Tr. 326–28; GX 49; ALJ Ex. 42, p. 46. The pharmacist noted in R.G.'s patient profile, ''WATCH FILL DATES!!!!!!,'' demonstrating the Respondent knew of R.G.'s issues with early fills. Such note is insufficient to justify filling R.G.'s prescriptions early. Tr. 328; GX 47; ALJ Ex. 42, p. 47. Dr. Sullivan found no evidence of the resolution of these red flags. Tr. 329; GX 49; ALJ Ex. 42, p. 45.

As to Patient R.L., Dr. Sullivan opined the 138 miles from R.L.'s home to the Respondent pharmacy represented a red flag. Tr. 330; GX 65; ALJ Ex. 42, p. 48. The prescriptions from June 2017 to September 2018 contained several red flags, including highest dosage of short-acting pain-relievers, hydrocodone 8 mg and oxycodone 30 mg; capsules of hydromorphone 8 mg being dispensed without required therapeutic justification; the highest strength of alprazolam; and the combination of an opioid and benzodiazepine. Dr. Sullivan was concerned by the promethazine 25 mg prescription, as it acts as a muscle relaxant with sedative qualities, thus increasing potential side effects in combination with the opioid and benzodiazepine medications. Dr. Sullivan noted the ongoing prescribing at the highest opioid dosage suggested a red flag for the lack of individualized treatment, with patients consistently receiving the highest dosage. Tr. 331–32, 329–30. Dr. Sullivan found these red flags unresolvable. Tr. 332; GX 52; ALJ Ex. 42, p. 49.

The PDMP data revealed several prescriptions filled unjustifiably early. Tr. 333–35; GX 52; ALJ Ex. 42, p. 51. The pharmacist noted in R.L.'s patient profile, ''NEXT FILL 6/10/18–10 DAYS EARLY MARCH & APRIL–TOLD HIM THIS 5/11/18GD,'' demonstrating the Respondent knew of R.L.'s issues with early fills. Such note is insufficient to justify filling R.L.'s prescriptions early. Tr. 334–35; GX 51; ALJ Ex. 42, p. 52. Dr. Sullivan found no evidence of the resolution of these red flags. Tr. 335–36; GX 50, 52; ALJ Ex. 42, pp. 49–52.

Finally, Dr. Sullivan opined that the compounding done in this case was not legitimate, as it was outside the standard of practice. Tr. 336–38. Dr. Sullivan explained that the FDA wants pharmacists to have the ability to compound to address the rare cases of patients with special needs, such as allergies. Tr. 337–38. If a patient had an allergy that required compounding, Dr. Sullivan would expect that to be documented in the patient profile. Tr. 339. However, compounding is also the subject of licensing and regulation. Tr. 339–40. *See* 21 U.S.C. 353a; Fla. Admin. Code r. 64B16–27.700, .797. Manufacturing is not permitted under a standard community retail pharmacy license. Tr. 340. It requires specific licensing. *Id.*

Dr. Sullivan noted that 95 or 96 percent of the subject hydromorphone medication was compounded. Dr. Sullivan concluded the extreme volume alone as proof positive that the Respondent's compounding was not limited to patients with individualized therapeutic needs. Tr. 337. Although the Patient Profiles reviewed contained a category for ''allergy,'' no allergies were documented, either within the Patient Profiles or in any of the other records reviewed. Tr. 339; *see* Fla. Admin. Code r. 64B16–27.800(2). Dr. Sullivan found no evidence that any of the subject patients receiving compounded medications were subject to medication allergies. Tr. 339.

Expert Opinion

[Omitted for brevity.]

Dr. Sullivan was qualified as an expert in the field of pharmacy and the standard of care for the practice of pharmacy in the State of Florida. He gave his opinion regarding the relevant standards of care in Florida for the practice of pharmacy, including the existence of red flags, or generally suspicious circumstances. He also gave his opinion regarding the parameters of lawful pharmacy compounding in light of federal statutes and regulations governing compounding and manufacturing. The relevant standard of care may be established by an expert witness through his experience in the field, and through his reliance upon and application of state and federal professional standards.

[Omitted for brevity.]

Dr. Sullivan demonstrated a commanding grasp of pharmacy practice and of the distinctions between pharmacy compounding and manufacturing. However, there were several matters for which he had diminished credibility. For one, he was unaware that Florida had codified the standard of care for medical personnel. Although I later determined the statute in question did not apply to pharmacists, it was somewhat surprising he was unaware of it, as he teaches Florida pharmacy law.[18] [Text omitted.] *E [19]

[Text omitted.] *F

[18] However, under Florida Statute 766.102, pharmacists are not considered ''healthcare providers.'' This Florida law defines ''healthcare providers'' as:

. . . any hospital or ambulatory surgical center as defined and licensed under chapter 395; a birth center licensed under chapter 383; any person licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, part I of chapter 464, chapter 466, chapter 467, part XIV of chapter 468, or chapter 486; a health maintenance organization certificated under part I of chapter 641; a blood bank; a plasma center; an industrial clinic; a renal dialysis facility; or a professional association partnership, corporation, joint venture, or other association for professional activity by health care providers.

Fla. Stat. 766.202(4). Pharmacists are administered under chapter 465.

*E I have omitted the RD's statement that Dr. Sullivan agreed that this statute (which does not apply to pharmacists) was consistent with his understanding of the Florida standard of care for pharmacists. RD, at 39. I have also deleted the RD's statement that Dr. Sullivan ''arguably conceded an alternate generalized standard of care for pharmacists in Florida, which is not consistent with Florida law or regulation.'' *Id.* at 39–40. When Respondent's counsel asked Dr. Sullivan whether he was aware of the statute, and whether he agreed with the definition of the standard of care outlined in the statute, Dr. Sullivan replied, ''Is that out of the pharmacy statutes? I'm not familiar with that.'' Tr. 438. Respondent's counsel stated that the definition comes from Florida statute 766.102, and it applies to healthcare providers. *Id.* Dr. Sullivan replied, ''I'll take your word for it that that's what it says.'' *Id.* Their exchange continued:

Q: Okay. Do you agree that, that's the definition—the appropriate definition of the standard of care in Florida?

A: In a broad sense, yes.

Q: Okay. And it talks about reasonably prudent healthcare providers, correct?

A: Can you read that statement in there where it says that again, please?

Q: Sure, I would be happy to. I'll read you the whole thing just to make sure you have it all. ''The prevailing professional standard of care for a given healthcare provider shall be that level of care, skill, and treatment which, in light of all relevant surrounding circumstances, is recognized as acceptable and appropriate by reasonably prudent similar healthcare providers.

A: And what was the question again, please?

Q: Do you agree that that's an accurate statement of the standard of care that applies in Florida?

A: If that's what the statute says, yes.

Tr. 438–39. During this exchange, Dr. Sullivan did not testify that this statute outlines the standard of care for pharmacists. Dr. Sullivan agreed—when asked whether the statute outlined ''the appropriate definition of the standard of care in Florida''—that it captured the standard of care in a ''[i]n a broad sense.'' *Id.* Dr. Sullivan repeated several times that he was not aware of this statute, but he would ''take [counsel's] word for it'' that he was accurately reciting the definition from the statute. *Id.* I do not find that this testimony diminishes Dr. Sullivan's credibility as an expert in the standard of care for Florida pharmacists.

[19] [Text omitted where footnote was included.]

*F I have omitted the RD's assertion that Dr. Sullivan offered inconsistent testimony regarding unresolvable red flags. RD, at 40. I find that Dr. Sullivan's testimony on this issue was consistent, reliable, and supported by prior Agency Decisions. The RD found that Dr. Sullivan's testimony was

Continued

Dr. Sullivan deemed the questionnaire used by the Respondent as essentially a subterfuge, designed not to reveal red flags and enable the Respondent to assess them, but as cover for red flags already known to exist by the Respondent. This conclusion was developed on the basis of Dr. Sullivan's experience in reviewing pharmacies, which were found to be operating in violation of pharmacy standards. It seemed more in the nature of an observation of coincident patterns. This conclusion assumes the questionnaires were never intended to assist the Respondent in assessing red flags versus being a good faith effort to identify red flags, which was never fulfilled. If the questionnaires were designed to provide cover to the Respondent's illegal behavior, they fail to do so. I did not see the questionnaires as providing any cover to the Respondent's improper filling of prescriptions. If anything, the completed questionnaires highlighted and documented red flags of long-distance travel. The completed questionnaires are damning, not exculpatory. Although not dispositive of this issue, the Government has not alleged intentional diversion. I find Dr. Sullivan's subject conclusion more in the nature of speculation. I don't believe the record provides sufficient factual foundation to support this expert opinion.[20] I also find it inconsistent with the facts of the case. Accordingly, on the basis of the instant record, I find Dr. Sullivan's subject conclusion unjustified.

Dr. Sullivan made a similar conclusion regarding the prescribing of non-controlled substances and of controlled substances not subject to abuse or diversion. Again, he deemed such prescriptions as an apparent subterfuge on the part of the prescriber, designed to mask the improper prescribing of controlled substances highly subject to abuse and diversion, and creating a red flag, which went unaddressed by the Respondent. I question the sufficiency of the factual foundation for Dr. Sullivan's expert opinion that the above prescriptions were an apparent attempt to mask scores of improper opioid prescriptions. [Omitted for brevity].*G [21] This finding does not affect the probity of Dr. Sullivan's opinions as to the therapeutic effect of the subject medications, their contraindication with other prescribed medications, or the justification of their prescription.

The Respondent made the point that Dr. Sullivan did not confer with the subject patients or with their prescribing physicians. Dr. Sullivan conceded that a diligent pharmacist would, as circumstances require, attempt to resolve any red flags by discussing them with the patient and with the prescribing physician. The Respondent argues that the fact Dr. Sullivan did not discuss any red flags with the patients or with the prescribers renders Dr. Sullivan's conclusions regarding red flags questionable as Dr. Sullivan did not attempt to resolve the subject red flags.

Although certainly the extent of Dr. Sullivan's review of relevant material is critical to the conclusions he draws, the focus of Dr. Sullivan's opinions relate to whether the Respondent complied with his corresponding responsibility to resolve red flags prior to dispensing the subject medications, and to documenting any resolution within the file. It is neither here nor there that Dr. Sullivan could have resolved his own concerns regarding the subject red flags by speaking to the patients and prescribers years later. Nor is it dispositive that Dr. Sullivan could have determined that the subject red flags were resolvable at the time they were dispensed, if the Respondent failed to satisfy his corresponding responsibility to resolve them. So, with the exception of his opinion regarding the apparent red flag created by the prescribing of non-controlled substances (discussed immediately above), I don't view the fact that Dr. Sullivan did not speak with the subject patients or prescribers as diminishing the probity of his relevant opinions as to the Respondent's acts or omissions at all.

The Respondent makes the similar point regarding the fact that Dr. Sullivan did not review copies of the physical prescriptions, as there is evidence Respondent may have made notations relevant to resolving red flags directly onto the prescriptions. Dr. Sullivan freely conceded he had not been provided with copies of the prescriptions to review. [Omitted for Relevance.] [However, because Dr. Sullivan credibly testified that the red flags for each patient could not have been resolved by a pharmacist acting within the usual course of professional practice, it was unnecessary for Dr. Sullivan to review the prescriptions.] Here, Dr. Sullivan was provided sufficient materials to develop his opinions, which assist the factfinder to understand or to determine facts in issue. [Citation omitted.]

[The RD does not make an explicit credibility finding on Dr. Sullivan's testimony, aside from stating that Dr. Sullivan was provided sufficient materials to develop his opinions and that he demonstrated a commanding grasp of pharmacy practice and the distinctions between pharmacy compounding and manufacturing. Based on these statements, and based on the controlling weight that the ALJ accorded Dr. Sullivan's unrebutted expert testimony in his legal analysis, it is evident that the ALJ found Dr. Sullivan's opinions to be generally consistent, reliable, and credible. I agree with that conclusion.]

**Respondent's Case-in-Chief**

The Respondent presented its case-in-chief through the testimony of a single witness, Norman L. Clement, Jr. Tr. 506–57.

*Norman L. Clement, Jr.*

Mr. Clement, Jr., is the son of Mr. Norman Clement, Sr., the Respondent's

inconsistent because he ''described several red flags as unresolvable,'' but later ''conceded that those same red flags could be resolved. *Id.* Additionally, the RD states that Dr. Sullivan ''at one point suggested no single red flag was unresolvable, rather it was the combination of red flags which made them unresolvable.'' *Id.* The RD does not cite to specific portions of the record here, but an earlier section of the RD discusses portions of Dr. Sullivan's testimony that the ALJ found confusing. RD, at 24.

The ALJ primarily seemed to be concerned with Dr. Sullivan's testimony about prescribing two immediate-release opioids concurrently. The ALJ asked Dr. Sullivan for an example of an unresolvable combination of red flags, and Dr. Sullivan testified that it would be unresolvable if a patient ''brought in a prescription for two immediate release narcotic pain killers *in very high doses.*'' Tr. 228 (emphasis added). The following day, the ALJ said to Dr. Sullivan, ''Yesterday you testified that the prescribing of two fast-acting opioids can never be permitted,'' and Dr. Sullivan replied, ''I'm sorry, Your Honor. If I said that, I misspoke.'' Tr. 481. Dr. Sullivan's testimony, however, had been that the prescribing of two immediate-release opioids *in very high doses* was unresolvable. *Id.* at 228. Dr. Sullivan clarified that there were instances were two immediate-release opioids could be used together. Tr. 481. Dr. Sullivan also testified that this red flag ''didn't apply to this case here.'' *Id.* at 482. I do not find that Dr. Sullivan's testimony about immediate-release opioids undermines his testimony about unresolvable red flags. Throughout the hearing, Dr. Sullivan consistently testified that a pharmacist should analyze all of the red flags with a prescription as a ''collective whole,'' rather than analyzing each red flag in isolation, and that certain combinations of red flags may not be resolvable ''when taken as a collective whole.'' Tr. 282, 409–11, 473, 475, 481–82, 498. Dr. Sullivan further testified that the red flags presented by each prescription in this case were unresolvable. As discussed in more detail below, Dr. Sullivan's testimony finds support in prior Agency decisions, which have consistently held—based on the credible testimony of pharmacy experts—that prescriptions may raise red flags that are so strongly indicative of diversion that they cannot be resolved by a pharmacist acting within the usual course of professional practice.

[20] [Omitted for clarity.]

*G I agree with the ALJ's conclusions about Dr. Sullivan's testimony regarding the physicians' motivations for prescribing non-controlled substances, so I am disregarding this testimony.

[21] [Omitted for clarity.]

owner. Tr. 506–07. Mr. Clement, Jr., has held a pharmacy tech license in Florida since 2014. Tr. 507. He has worked for the Respondent since 2014. Tr. 507, 521. Mr. Clement, Jr., reported the Respondent employs approximately four pharmacists-in-charge. *Id.* He described the Respondent as a family operation. *Id.*

The Respondent gets few patient customers per day. Tr. 508. Typically, the pharmacy would only see two to three patients a day, sometimes none. *Id.* Four patients in one day would make for a busy day at the pharmacy. *Id.* The fact that the Respondent only saw a few patients per day meant that the staff could spend more time talking with the patients and getting to know them. *Id.*

Mr. Clement, Jr., testified that the Respondent's staff always recorded the information it collected from the patients. Tr. 509, 543. The types of information the Respondent collected from patients included ''personal life information,'' how treatment was progressing, and dietary information. Tr. 509. The Respondent recorded this information in the patient's profile. Tr. 543. Sometimes it recorded the information on the hard-copy prescriptions. *Id.*

When a new patient presents at the pharmacy, the Respondent gathers information about the patient to assist the pharmacist in making a decision about whether to dispense to that patient. Tr. 509, 537–38, 540. The Respondent charges new patients $25 for an initial consultation. Tr. 542. As part of this information-gathering process, the Respondent asks patients to complete a questionnaire. Tr. 511, 537–38, 542. The questionnaire solicits information regarding the reason the patient is visiting the Respondent, how the patient feels, and what caused the patient's ailment or injury. Tr. 511–12, 538, 540. Sometimes a patient has been rejected by three to six other pharmacies before visiting the Respondent. Tr. 538. The Respondent creates a patient profile for all new patients and places a copy of the questionnaire in the profile. Tr. 546–48. Notes regarding the resolution of red flags would be contained in the patient's profile. Tr. 553. Mr. Clement, Jr., testified that the Respondent ''look[ed] at every aspect'' of a prescription before filling it, and that if ''everything checks out,'' the patient is cleared to fill the prescription. Tr. 540–41. The Respondent places a check mark on a prescription to verify it is cleared for dispensing. Tr. 554–55.

Mr. Clement, Jr., testified that the questionnaire asks the patients to provide details about their injury; simply claiming that ''my back pain hurts'' will not suffice. Tr. 512. The Respondent also makes a copy of the patient's driver's license. Tr. 513, 538. Mr. Clement, Jr., testified that the pharmacy checked the medical legitimacy of prescriptions [22] and called the prescribing doctor for all controlled substance prescriptions. Tr. 538–40, 542–43, 545. Initially, Mr. Clement, Jr., testified that the Respondent would write down what the doctor says in the patient's profile. Tr. 543–44. Government counsel later asked if the lack of notes about calling the doctor meant the doctor was never called. Tr. 550. Mr. Clement, Jr., responded, ''Not necessarily,'' and explained that sometimes the Respondent would write those notes on the hard-copy prescription. Tr. 550–51. The Respondent would write, ''M.D. okay'' on the prescription to verify the doctor had been called. Tr. 550–52.

After reviewing the questionnaire, a staff member searches for the patient in the PDMP to see if the patient is visiting other pharmacies. Tr. 512–13, 538. Typically, the Respondent attaches a copy of the PDMP reports to the patient's file. Tr. 513. The software system that the Respondent used also produced a ''Narx'' score that informed the pharmacy about a patient's risk of addiction. Tr. 518–19. The Respondent and its staff used the ''Narx'' score feature when deciding whether to fill prescriptions. *Id.* Sometimes after conducting this process the Respondent has turned patients away. Tr. 512, 538, 542.

Mr. Clement, Jr.'s, primary duties at the Respondent are working with the computer system and records. Tr. 515, 522. The Respondent uses Rx30 software. Tr. 514. When the DEA served the OSC/ISO on the Respondent in August 2019, it also executed a search warrant and seized two of the Respondent's computers. Tr. 514–15, 530–31. The Respondent also kept files on a back-up system, which was also seized by the DEA. Tr. 534–35. When the computers were eventually returned, they did not work and the scanned copies of prescriptions had been erased.[23] Tr. 514–15, 530–31. Mr. Clement, Jr., worked with an IT consultant and Rx30's technical support to try to recover the prescription image files from the computers seized by DEA. Tr. 517–18. Those recovery efforts were unsuccessful. *Id.*

The DEA also seized a touch-screen computer monitor. Tr. 516. When DEA returned the monitor, the screen had been shattered and it no longer worked.[24] Tr. 516–17, 531. The DEA also seized most of the hard-copy prescriptions that were kept at the pharmacy.[25] Tr. 516.

In general, I found Mr. Clement, Jr.'s, testimony to be somewhat subjective. As essentially a party to the litigation, he had a clear personal and family interest in the outcome. The Respondent's position that the Agency has treated the Respondent unfairly was reflected in Mr. Clement, Jr.'s, testimony. His emotional description of the manner of the seizure of Respondent's equipment and records, and their destruction and loss in the hands of the Agency, manifests his partiality in this matter. However, having a personal interest in the litigation, or manifesting an emotional commitment to your cause, are not bars to credibility. They are simply factors to be considered. I had some concerns with aspects of his testimony, however, which detracted from his credibility on certain topics. For the most part, these concerns were situations where Mr. Clement, Jr., provided conclusory testimony, and then followed-up with more detail when pressed by counsel.

There were also instances of inconsistency. For example, Mr. Clement, Jr., initially testified that the Respondent's computer system worked normally after the DEA made mirror images of the Respondent's computer hard-drive. Tr. 522, 525. He then clarified that the Respondent's computers did not work normally. Tr. 525–26. The computer system started working normally again about 3–4 months after the DEA made mirror images of it. Tr. 527.

[22] [Omitted for clarity.]

[23] Although Mr. Clement, Jr.'s, testimony about how files were backed-up was sometimes difficult to follow, Tr. 531–36, he seemed to indicate that the Respondent had the capability of retrieving lost files from Rx30's system. Tr. 535–36.

[24] [I have omitted, for brevity and relevance, the RD's discussion of unfair, unequal, or uneven treatment. Respondent did not raise any claims of unfair treatment in its Posthearing brief, and I do not find sufficient evidence on the record to suggest that Respondent was treated unfairly. Respondent raised concerns prehearing that it had not received access to all of the evidence that DEA had seized when it executed the OSC on August 29, 2019. However, those concerns appear to have been addressed before the hearing. Respondent also raised concerns that certain equipment that was seized by DEA had been damaged. However, the evidence on the record provides no indication of any sort of unequal treatment, or any improper motive in commencing the investigation. In fact, the evidence demonstrates that such an investigation was routine. DEA began investigating Respondent after receiving a tip from the Florida Department of Health in May 2017.]

[25] Mr. Clement, Jr., testified that the Respondent has not received back the hard-copy prescriptions seized by the DEA. Tr. 520. After testifying to this, the Respondent's counsel informed the Tribunal, on the record, that the DEA had provided copies of the prescriptions to counsel's office. *Id.*

Another example concerns the Respondent's efforts to call patients' past pharmacies. At the beginning of direct examination, Mr. Clement, Jr., testified that as part of its intake process for new patients, the Respondent would call a new patient's past pharmacy only if the Respondent had questions of that pharmacy. Tr. 512. Government counsel later asked, ''Sometimes you call their past pharmacist?'' Tr. 546. He answered, ''Yes.'' *Id.* Just moments later, Mr. Clement, Jr., testified that the Respondent always called pharmacies for every new patient. Tr. 547, 549. This testimony paints an unclear picture of whether the Respondent always called a patient's previous pharmacy or whether it only called in certain situations.

Another example concerned the extent to which the Respondent verified prescriptions' medical legitimacy. Mr. Clement, Jr., explained that neither he nor the Respondent's pharmacists were qualified to read an MRI report (or any other laboratory test). Tr. 539–40.[26] He said that some patients would provide a copy of their MRI report, but ''no pharmacist needs to look at an MRI.'' *Id.* This testimony seems to conflict with his testimony that the Respondent got to know its new patients by looking into their history, background, ''pain ailments, what they're going through, [and] sometimes treatment plans.'' Tr. 508. If the Respondent checked a patient's background, and confirmed medical legitimacy of the prescription, then it seems that the Respondent merely took the patient (and his or her doctor) at their word, since checking commonly-procured objective medical findings, such as an MRI report, was outside the Respondent's scope of review. The fact that the Respondent may have merely taken doctors, patients, and pharmacies at their word is supported by Mr. Clement, Jr.'s, later testimony that a patient is cleared to receive controlled substances if the doctor says ''yes'' and the patient's previous pharmacy says the patient is ''okay.'' Tr. 542.

There was another instance where Mr. Clement, Jr., came across as more of an advocate for the Respondent rather than an objective witness. In this instance, the Respondent's counsel asked Mr. Clement, Jr., whether the Respondent had developed a niche business in the types of patients it sees. Tr. 509–10. This seemed to be a straightforward, unambiguous question. Mr. Clement, Jr., responded, however, by describing, at length, the process of checking the patient's identification, and checking the PDMP and NarcFacts. Tr. 510–11. The Respondent's counsel then followed-up with a leading question, asking Mr. Clement, Jr., whether the Respondent ''dispense[d] primarily to patients who are suffering from chronic non-malignant pain?'' Tr. 511. Mr. Clement, Jr., answered in the affirmative. *Id.* Mr. Clement, Jr.'s, non-responsive answer demonstrated an eagerness to advocate the Respondent's safety measures for screening patients and preventing diversion, rather than answering the question about what types of clients the Respondent serviced.

Having listened to Mr. Clement, Jr.'s, testimony at the hearing, and having closely reviewed the transcript of his testimony, I find him to be generally credible, with the few exceptions noted above. He generally presented as a professional, knowledgeable, and honest witness. I will give his testimony weight to the extent it is internally consistent, and to the extent it is consistent with other evidence and testimony of record.

**The Government's Rebuttal Case**

After each party presented its case-in-chief, the Government presented the rebuttal testimony of DI Albert. Tr. 557–68.

*DI Albert*

The Government introduced DI Albert's rebuttal testimony to rebut Mr. Clement, Jr.'s, testimony about the resolution of red flags. Tr. 559–60, 563–64. DI Albert testified about a blog post authored by Mr. Clement, Sr.[27] Tr. 559, 561. DI Albert downloaded this blog post from the internet. Tr. 562. The blog post identifies its author as ''Norman J. Clement, R.Ph, DDS.'' Tr. 563. DI Albert also downloaded an attachment from the blog post. Tr. 564–65. The attachment is a copy of the Government's prehearing statement in this case. Tr. 565. There are notes written on the prehearing statement, to include the following note on page 23:

> The question of the red flag issue is not an issue to [me] because I don't challenge the physician for diagnosing and writing prescriptions for the patients because I'm not authorized or qualified to challenge a physician's diagnosis and treatment of his or her patients. Therefore, on the red flag issues, the question is, are they challenging me for filling the prescription or are they challenging the physician who wrote the prescription?

Tr. 566. Neither the hard-copied blog post nor attachment were admitted into evidence; only the oral testimony of DI Albert reading the above-quoted paragraph. Tr. 567.

During this brief rebuttal testimony, DI Albert presented, as he did in the Government's case-in-chief, as an honest, professional, and impartial investigator who had no stake in the case's outcome. DI Albert presented his rebuttal testimony in a credible and reliable manner. Although I fully credit DI Albert's rebuttal testimony, I will only consider his rebuttal testimony to the extent that the paragraph he read into the record rebuts Mr. Clement, Jr.'s, testimony that the Respondent resolved red flags.

**The Facts**

*Stipulations of Fact*

The Government and the Respondent did not agree to any stipulations of fact.

*Findings of Fact*

The factual findings 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. The findings of fact are based primarily on those proposed by the Government in its post-hearing brief. I have also considered the findings of fact proposed by the Respondent and found that many of those proposed findings related to matters proposed by the Government or related to matters addressed elsewhere in this Recommended Decision. If a proposed finding of fact is not included in this section and is also not addressed elsewhere in this Decision, it is because that proposed finding was not relevant to deciding this case.

1. Respondent is registered with the DEA to handle controlled substances in Schedules II through V under Certificate of Registration No. FP2302076. Respondent's registered address is 1461 West Busch Boulevard, Tampa, Florida 33612. Respondent's DEA Certificate of Registration expires by its own terms on March 31, 2022. GX 1.

2. Oxycodone is a Schedule II controlled substance. 21 CFR 1308.12(b)(1).

3. Hydromorphone is a Schedule II controlled substance. 21 CFR 1308.12(b)(1).

4. Alprazolam is a Schedule IV controlled substance. 21 CFR 1308.14(c).

5. Morphine Sulfate is a Schedule II controlled substance. 21 CFR 1308.12(b)(1).

[26] Mr. Clement, Jr's., testimony would make sense if he was referring to the actual x-ray or MRI, which require special training to interpret, such as that of a radiologist, who reduces his findings to a written report, which might then be appropriate for a pharmacist to review.

[27] Although the Government offered the title of the blog post, ''DEA's Kourt of the Kangaroo,'' the title was only admitted for authentication purposes.

6. Methadone is a Schedule II controlled substance. 21 CFR 1308.12(c).

7. Hydromorphone 8 mg is a commercially available drug. Tr. 232. Hydromorphone 8 mg is the highest strength of hydromorphone that is commercially available. Tr. 248.

8. Oxycodone 30 mg is a commercially available drug. Tr. 232.

DEA's Investigation

9. After receiving a tip from the Florida Department of Health in May 2017, DEA investigators traveled to Respondent's registered address and presented a Notice of Inspection to the pharmacist present, who consented to the inspection. Approximately ten to fifteen minutes later, Respondent's owner, Norman Clement, Sr., indirectly asked the DEA investigators to leave, which they did. Tr. 26–27.

10. In September 2017, DEA investigators served an administrative subpoena on Respondent seeking, among other things, original Schedule II controlled substances prescriptions, receiving records, and ''batch records.'' Tr. 27. Government Exhibits 2 through 6 were produced by Respondent to DEA in response to the September 2017 subpoena and were admitted into evidence in this matter. Tr. at 27–34.

11. On September 10, 2018, DEA investigators executed an Administrative Inspection Warrant (''AIW'') at Respondent's registered address. Tr. 52.

12. DI Albert and Respondent's owner conducted an inventory of the Schedule II controlled substances contained in the safe located at Respondent's address. Tr. 56. On September 10, 2018, there were 3,546 compounded capsules of hydromorphone 8 mg; 470 commercially-produced tablets of hydromorphone 8 mg; 574 compounded capsules of oxycodone 30 mg; and 204 commercially-produced oxycodone 30 mg tablets in the safe. GX 7. There were also 155.2 grams of hydromorphone powder and 26 grams of oxycodone powder. *Id.* There were no other Schedule II controlled substances contained in the safe. Tr. 59.

13. During the AIW, DEA investigators attempted to inspect and copy certain records. Tr. 56. At the time, Respondent's owner was not able to tell the investigators where these records were located. Tr. 56–57. As a result, one of Respondent's owner's sons (Norman Clement, Jr.) was reached by video-teleconference on a series of mobile devices and was able to direct the investigators to the location of various records. Tr. 61–62; *see also* Tr. 521–23.

14. During the execution of the AIW, DEA investigators also served an administrative subpoena, seeking complete copies of the ''patient record system'' for certain specific patients. Tr. 53; GX 67.

15. During the execution of the AIW, a technician from DEA's Digital Evidence Laboratory (SFL–9) was able to obtain copies of electronic records from Respondent's system by ''mirroring'' the hard drive. Tr. 62. The records obtained by the SFL–9 investigator included information relating to patients not involved in this proceeding.[28] Tr. 90–93. The SFL–9 provided DI Albert with electronic copies of the records obtained during the execution of the AIW. Tr. 62–63, 94.

16. Government Exhibit 11 is a complete and accurate copy of Respondent's dispensing log for June 1, 2017, to September 7, 2018, which was obtained during the execution of the AIW in September 2018. Tr. 63–66. Government Exhibits 12–13; 15–17; 20–21; 23–24; 26–27; 29–30; 32–33; 35–36; 38–39; 41–43; 47–49, and 51 are correct and accurate copies of documents that were obtained from Respondent's electronic record system by the SFL–9 technician during the execution of the AIW. Tr. 68–86.

17. During the course of the investigation, DI Albert queried the Florida Prescription Drug Monitoring Database (E–FORCSE or PDMP) and obtained information regarding Respondent's dispensing of controlled substance as it was reported to the State of Florida. Tr. 44. Government Exhibits 8–10 are accurate copies of the data obtained from the E–FORSCE database for the dates listed. Tr. 48–51. Government Exhibits 14, 19, 22, 25, 28, 31, 34, 37, 40, 46, and 50 are complete and accurate copies of E–FORSCE information for certain specific enumerated patients. Tr. 68–86. There is no evidence in the record to indicate that the information reported by Respondent to the E–FORSCE database is inaccurate or unreliable.

18. In May 2018, DI Albert served an additional subpoena on Respondent seeking the complete patient record system maintained by Respondent for certain specific patients, as well as any ''other documentation kept by [Respondent] in connection with the filling of prescriptions . . . for these individuals.'' Tr. 88–89; GX 68.

19. Government Exhibit 18 includes all documents and information produced in response to the May 2018 subpoena regarding Patient A.G. Tr. 96; GX 18. Government Exhibit 44 includes all documents and information produced in response to the May 2018 subpoena regarding Patient R.B. Tr. 97–98; GX 44.

20. The Respondent dispensed four to five prescriptions per day on average. Tr. 419.

*The Standard of Professional Pharmacy Practice in Florida*

21. Dr. Sullivan testified that the standard of professional practice in Florida requires that a pharmacist make sure each prescription is valid and has been issued for a legitimate medical purpose prior to dispensing controlled substances. Tr. 206. As part of this evaluation, Dr. Sullivan testified that a pharmacist must first determine whether the prescription is facially legitimate—whether it includes all of the required information. *Id.* at 208. Then, Dr. Sullivan testified that the pharmacist must attempt to determine whether there is over-utilization or under-utilization; clinical abuse or misuse going on; whether the prescription was issued for a legitimate medical purpose; and whether the prescription puts the patient at ''any potential undue risk of side effects, adverse effects, and/or potentially overdose situations.'' *Id.* at 207–08; *see also* Fla. Admin. Code r. 64B16–27.810 (stating that ''a pharmacist shall review the patient record and each new and refill prescription'' to identify potential concerns such as ''[o]ver-utilization or under-utilization,'' and ''take appropriate steps to avoid or resolve the potential problems''); Fla. Admin. Code r. 64B16–27.831(2)(c) (''When validating a prescription, if at any time the pharmacist determines that in his or her professional judgment, concerns with the validity of the prescription cannot be resolved, the pharmacist shall refuse to fill or dispense the prescription.'')

22. [Omitted Florida law regarding the maintenance of a patient profile, because I do not think it is relevant to the facts in this case.]

23. Dr. Sullivan testified that a ''red flag'' is a ''warning sign'' that ''there's something potentially wrong with the prescription.'' Tr. 211. Specifically, it is a sign that ''the patient may be either abusing or diverting it.'' *Id.* at 212. Dr. Sullivan testified that these ''red flags'' are well-documented in the pharmacy

[28] I do not agree that DI Albert's testimony supports a finding that the SFL–9 investigator obtained a complete copy of the Respondent's electronic records, as the Government proposed in its post-hearing brief. Gov't PHB, p. 4, ¶ 16 (citing Tr. 90–93). DI Albert's testimony supports a finding that the information ''mirrored'' from the hard-drive included patients other than the eleven involved here, but his testimony does not support the conclusion that the information obtained was a ''complete copy'' of all of the Respondent's records. Tr. 90–93.

community and are known to pharmacists in the State of Florida. *Id.* at 211–14; 235–36.

24. Dr. Sullivan testified that some of these red flags include (1) patients travelling long distances to the pharmacy; (2) certain drug cocktails; (3) high dosages of immediate release pain killers; and (4) cash-paying customers. *Id.* at 214.

25. Dr. Sullivan testified that the prescribing of an opioid pain reliever and benzodiazepine at the same time is a significant red flag. *Id.* at 220–21. Dr. Sullivan noted that the FDA had issued a warning in 2016 regarding the serious health risks posed by the combination of those two medications. *Id.* at 220–21; GX 66. Dr. Sullivan testified that a reasonable pharmacist acting within the usual course of professional practice in Florida would be ''very very reluctant to dispense that combination of drugs'' after the FDA safety warning. Tr. 223.

26. Dr. Sullivan testified that filling a controlled substance prescription early is a red flag. *Id.* at 225–27. He testified that the standard of care required a pharmacist not to fill a Schedule II controlled substance prescription until ''the day of or day before the medication from a previous prescription is supposed to run out.'' Tr. 270–71. While there may be legitimate reasons for a particular prescription to be filled early in ''extreme'' and ''unusual'' cases, there is no legitimate reason for a pharmacist to fill a Schedule II controlled substance prescription early in multiple consecutive months. Tr. 270–71.

27. When a pharmacist identifies one or more red flags, he must undertake an investigation into the prescription before he can fill it. Tr. 227. This may include speaking with the patient and/or speaking with the prescriber. A pharmacist would also be expected to look at the patient profile as well as apply his clinical expertise to the drug, quantity, and strength prescribed. *Id.* The standard of care requires that the pharmacist document these conversations and analyses.[29] Tr. 227–28. [Dr. Sullivan testified that a pharmacist does not look at individual red flags in isolation; rather, he looks at them ''as a collective whole based on what's going on with that prescription at that time.'' Tr. 482, 498. Dr. Sullivan testified that there are some red flags that, ''when taken as a collective whole[,] . . . cannot be resolved.'' Tr. 481. Dr. Sullivan testified that in these circumstances, ''no matter what the patient tells me, what the doctor tells me, any of that, I'm still not filling the prescription.'' Tr. 282. Dr. Sullivan testified that an individual red flag (such as long distances traveled or cash payments) may become unresolvable if it is combined with multiple additional red flags. *Id.* at 473, 475; *see also id.* at 409–11.]

Respondent's Dispensing

Patient A.G.

28. At all times relevant to this matter, Patient A.G. resided at 411 NE 25th Ave., Cape Coral, Florida 33909. GX 15. Patient A.G.'s residence is approximately 130 miles (one-way) from Respondent's registered address. GX 55.

29. All of the prescriptions filled by Patient A.G. at Respondent were paid for in cash. GX 14, 17.

30. Dr. Sullivan examined the dispensing data and the patient profile for Patient A.G. and identified multiple ''red flags.'' Specifically, Dr. Sullivan concluded that the distance travelled by Patient A.G. was a ''red flag,'' as was the fact that Patient A.G. was prescribed a ''cocktail of benzodiazepine and opioid'' at the highest strengths of both medications. Tr. 254–55. Dr. Sullivan also observed that Patient A.G. filled multiple prescriptions early. Tr. 257–59.

31. Between June 26, 2017, and August 30, 2018, Respondent filled 30 prescriptions for controlled substances for Patient A.G., including 10 prescriptions for hydromorphone 8 mg; 10 prescriptions for oxycodone 30 mg; 9 prescriptions for alprazolam 2 mg; and 1 prescription for alprazolam 1 mg. Information regarding the controlled substances dispensed to Patient A.G. is accurately set forth in Government Exhibit 17.

32. Between December 20, 2018, and April 12, 2019, Respondent filled 10 prescriptions for controlled substances for Patient A.G., including 5 prescriptions for oxycodone 30 mg and 5 prescriptions for alprazolam 1 mg. Information regarding the controlled substances dispensed to Patient A.G. is accurately set forth in Government Exhibit 14.

33. Respondent maintained a patient profile for Patient A.G. The only pharmacist note in the profile for Patient A.G. stated: ''Doctor OK to Receive Medication in Compound Capsule Form.'' Govt. Ex. 15.

34. Dr. Sullivan testified that the notes contained the Patient A.G.'s patient profile were insufficient to resolve (or to suggest an attempt to resolve) any of the red flags that he identified.*[H] Tr. 258.

35. Dr. Sullivan further testified that the answers provided on the Medical Questionnaire were not sufficient to resolve any of the specific red flags that he identified. Tr. 260–63. [Dr. Sullivan testified that the red flags raised by Patient A.G.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 256–57, 267–68.]

Patient A.H.

36. At all times relevant to this matter, Patient A.H. resided at 1001 NE 6th Place, Cape Coral, Florida 33909. GX 20. Patient A.H.'s residence is approximately 130 miles (one-way) from Respondent's registered address. GX 56.

37. All of the prescriptions filled by Patient A.H. at Respondent were paid for in cash. GX 19, 21.

38. Dr. Sullivan examined the dispensing data and the patient profile for Patient A.H. and identified multiple ''red flags.'' Specifically, Dr. Sullivan concluded that the distance travelled by Patient was a ''red flag,'' as was the fact that Patient A.G. was prescribed a ''cocktail of benzodiazepine and opioid'' at the highest strengths of both medications. Tr. 268–69.

39. Between January 4, 2018, and August 16, 2018, Respondent filled 11 prescriptions for controlled substances for Patient A.H., including six prescriptions for hydromorphone 8 mg and five prescriptions for alprazolam 2 mg. Information regarding the controlled substances dispensed to Patient A.H. is accurately set forth in Government Exhibit 21.

40. Between September 11, 2018, and April 18, 2019, Respondent filled at least seven prescriptions for controlled substances for Patient A.H., including seven prescriptions for hydromorphone 8 mg. Information regarding the controlled substances dispensed to Patient A.H. is accurately set forth in Government Exhibit 19.

41. Respondent maintained a patient profile for Patient A.H. The patient profile for Patient A.H. contained no pharmacist notes or comments. GX 20. In Dr. Sullivan's opinion, Patient A.H.'s patient profile was insufficient to resolve any of the red flags that he identified. Tr. 272. [Dr. Sullivan testified that the red flags raised by Patient A.H.'s prescriptions were not

[29] [Footnote omitted.]

*[H] The Findings of Fact Section discusses Respondent's efforts to document the resolution of red flags. This discussion has minimal relevance to my Decision, because I have concluded that the combination of red flags presented by each prescription in this case could not have been resolved by a pharmacist operating within the usual course of professional practice based on the credible and unrebutted testimony of the Government's expert. However, I have retained this discussion to provide context for Respondent's dispensing to each patient.

resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 269, 273.]

Patient B.S.

42. At all times relevant to this matter, Patient B.S. resided at 117 Zobora Circle, Fort Myers, Florida 33913. GX 23. Patient B.S.'s residence is approximately 150 miles (one-way) from Respondent's registered address. GX 57.

43. All of the prescriptions filled by Patient B.S. at Respondent were paid for in cash. GX 22, 24.

44. Dr. Sullivan examined the dispensing data and the patient profile for Patient B.S. and identified multiple ''red flags.'' Specifically, Dr. Sullivan concluded that the distance travelled by Patient B.S. was a ''red flag,'' as was the fact that Patient B.S. was prescribed a cocktail of benzodiazepine and opioid at the highest strengths of both medications. Tr. 274–75.

45. Between August 22, 2017, and August 23, 2018, Respondent filled 19 prescriptions for controlled substances for Patient B.S., including 12 prescriptions for hydromorphone 8 mg; six prescriptions for alprazolam 2 mg; and one prescription for alprazolam 1 mg. Information regarding the controlled substances dispensed to Patient B.S. is accurately set forth in Government Exhibit 24.

46. Between December 20, 2018, and April 22, 2019, Respondent filled at least nine prescriptions for controlled substances for Patient B.S., including two prescriptions for hydromorphone 8 mg, four prescriptions for oxycodone 30 mg, and three prescriptions for alprazolam 1 mg. Information regarding the controlled substances dispensed to Patient B.S. is accurately set forth in Government Exhibit 22.

47. Respondent maintained a patient profile for Patient B.S. The patient profile for Patient B.S. contained no pharmacist notes or comments. GX 23.

48. Dr. Sullivan testified that the notes contained in Patient B.S.'s patient profile were insufficient to resolve (or to suggest an attempt to resolve) any of the red flags that he identified. Tr. 277. [Dr. Sullivan testified that the red flags raised by Patient B.S.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 274, 276–77.]

Patient C.R.

49. At all times relevant to this matter, Patient C.R. resided at 2907 Jackson Street, Fort Myers, Florida 33901. GX 26. Patient C.R.'s residence is approximately 130 miles (one-way) from Respondent's registered address. GX 58.

50. All of the prescriptions filled by Patient C.R. at Respondent were paid for in cash. GX 25, 27.

51. Dr. Sullivan examined the dispensing data and the patient profile for Patient C.R. and identified multiple ''red flags.'' Specifically, Dr. Sullivan concluded that the distance travelled by Patient C.R. was a ''red flag,'' as was the fact that Patient C.R. was prescribed a cocktail of benzodiazepine and opioid with the opioid prescribed at the highest strength. Tr. 279–80.

52. Between July 19, 2017, and August 30, 2018, Respondent filled 13 prescriptions for controlled substances for Patient C.R., including six prescriptions for oxycodone 30 mg, six prescriptions for alprazolam 1 mg, and one prescription for morphine sulfate 30 mg. Information regarding the controlled substances dispensed to Patient C.R. is accurately set forth in Government Exhibit 27.

53. Respondent maintained a patient profile for Patient C.R. The only pharmacist note in the profile for Patient C.R. stated: ''Script has wrong birthdate on it. Dr[.] has now update[.]'' GX 26.

54. Dr. Sullivan testified that the notes contained the Patient C.R.'s patient profile were insufficient to resolve (or to suggest an attempt to resolve) any of the red flags that he identified. Tr. at 281.

Patient J.D.

55. At all times relevant to this matter, Patient J.D. resided at 229 NW 15th Place, Cape Coral, Florida 33993. GX 29. Patient J.D.'s residence is approximately 130 miles (one-way) from Respondent's registered address. GX 59.

56. All of the prescriptions filled by Patient J.D. at Respondent were paid for in cash. GX 28, 30.

57. Dr. Sullivan examined the dispensing data and the patient profile for Patient A.H. and identified multiple ''red flags.'' Specifically, Dr. Sullivan concluded that the distance travelled by Patient A.H. was a ''red flag,'' as was the fact that Patient A.G. was prescribed the highest strengths of hydromorphone. Tr. 283.

58. Between January 15, 2018, and September 4, 2018, Respondent filled ten prescriptions for controlled substances for Patient J.D., including nine prescriptions for hydromorphone 8 mg and one prescription for methadone 10 mg. Information regarding the controlled substances dispensed to Patient J.D. is accurately set forth in Government Exhibit 30.

59. In addition, Dr. Sullivan noted that Respondent dispensed two immediate release narcotic pain relievers (hydromorphone 8 mg and methadone 10 mg) to Patient J.D. on March 24, 2018. Dr. Sullivan testified that dispensing two immediate release narcotic pain relievers on the same day was ''a red flag in and of itself.'' Tr. 283–84.

60. Respondent maintained a patient profile for Patient J.D. The only pharmacist note in the profile for Patient J.D. stated: ''Next Fill 7/5/18!!! Watch fill dates!!!!!!'' GX 29.

61. Dr. Sullivan testified that the notes contained in Patient J.D.'s patient profile were insufficient to resolve (or to suggest an attempt to resolve) any of the red flags that he identified. Tr. 287–88. [Dr. Sullivan testified that the red flags raised by Patient J.D.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 284, 288–89.]

Patient J.M.

62. At all times relevant to this matter, Patient J.M. resided at 3004 30th Street SW, Lehigh Acres, Florida 22976. GX 32. Patient J.M.'s residence is approximately 140 miles (one-way) from Respondent's registered address. GX 60.

63. All of the prescriptions filled by Patient J.M. at Respondent were paid for in cash. GX 31, 33.

64. Dr. Sullivan examined the dispensing data and the patient profile for Patient J.M. and identified multiple ''red flags.'' Specifically, Dr. Sullivan concluded that the distance travelled by Patient J.M. was a ''red flag,'' as was the fact that Patient J.M. was prescribed a cocktail of benzodiazepine and opioid with the opioid prescribed at the highest strength. Tr. 289–90.

65. Between June 22, 2017, and September 7, 2018, Respondent filled 23 prescriptions for controlled substances for Patient J.M., including eight prescriptions for oxycodone 30 mg; six prescriptions for hydromorphone 8 mg; and nine prescriptions for alprazolam 2 mg. Information regarding the controlled substances dispensed to Patient J.M. is accurately set forth in Government Exhibit 33.

66. Respondent maintained a patient profile for Patient J.M. The patient profile for Patient J.M. contained no pharmacist notes or comments. GX 32.

67. Dr. Sullivan testified that the notes contained the Patient J.M.'s patient profile were insufficient to resolve (or to suggest an attempt to resolve) any of the red flags that he identified. Tr. 290. [Dr. Sullivan testified that the red flags raised by

Patient J.M.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 290–91.]

Patient M.M.

68. At all times relevant to this matter, Patient M.M. resided at 1145 W Walnut Street, Lakeland, Florida 22815. GX 35. The prescriptions that Patient M.M. filled at Respondent were issued by a practitioner located at 1670 San Carlos Blvd., Fort Myers Beach, Florida 22931. GX 36.

69. Patient M.M.'s residence is approximately 130 miles (one-way) from the prescriber's location. GX 61. All of the prescriptions filled by Patient M.M. at Respondent were paid for in cash. GX 34, 36.

70. Between June 6, 2017, and August 16, 2018, Respondent filled 14 prescriptions for controlled substances for Patient M.M., including 14 prescriptions for hydromorphone 8 mg. Information regarding the controlled substances dispensed to Patient M.M. is accurately set forth in Government Exhibit 36.

71. Between January 3, 2019, and April 16, 2019, Respondent filled at least 5 prescriptions for controlled substances for Patient M.M., including 5 prescriptions for hydromorphone 8 mg. Information regarding the controlled substances dispensed to Patient M.M. is accurately set forth in Government Exhibit 34.

72. Dr. Sullivan examined the dispensing data and the patient profile for Patient M.M. and identified multiple ''red flags.'' Specifically, Dr. Sullivan concluded that the distance travelled by Patient M.M. from her home to her physician was a ''red flag,'' as was the fact that Patient M.M. was prescribed the highest available strength of hydromorphone.[30] Tr. 292–95.

73. Respondent maintained a patient profile for Patient M.M. The patient profile for Patient M.M. contained no pharmacist notes or comments. GX 35.

74. Dr. Sullivan testified that the notes contained in Patient M.M.'s patient profile were insufficient to resolve (or to suggest an attempt to resolve) any of the red flags that he identified. Tr. 300. [Dr. Sullivan testified that the red flags raised by Patient M.M.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 299–300.]

Patient N.B.

75. At all times relevant to this matter, Patient N.B. resided at 2132 SE 5th Place, Cape Coral, Florida 33990. GX 38. Patient N.B.'s residence is approximately 135 miles (one-way) from Respondent's registered address. GX 62.

76. All of the prescriptions filled by Patient N.B. at Respondent were paid for in cash. GX 37, 39.

77. Between June 21, 2017, and August 14, 2018, Respondent filled 19 prescriptions for controlled substances for Patient N.B., including 12 prescriptions for hydromorphone 8 mg, four prescriptions for alprazolam 2 mg, and three prescriptions for alprazolam 1 mg. Information regarding the controlled substances dispensed to Patient N.B. is accurately set forth in Government Exhibit 39.

78. Between September 14, 2018, and April 10, 2019, Respondent filled at least nine prescriptions for controlled substances for Patient N.B., including five prescriptions for oxycodone 30 mg, three prescriptions for alprazolam 1 mg, and one prescription for hydromorphone 8 mg. Information regarding the controlled substances dispensed to Patient N.B. is accurately set forth in Government Exhibit 37.

79. Dr. Sullivan examined the dispensing data and the patient profile for Patient N.B. and identified multiple ''red flags.'' Specifically, Dr. Sullivan concluded that the distance travelled by Patient N.B. was a ''red flag,'' as was the fact that Patient N.B. was prescribed a cocktail of benzodiazepine and opioid at the highest strengths of both medications. Tr. 301–02, 305.

80. Respondent maintained a patient profile for Patient N.B. The only pharmacist note in the profile for Patient N.B. stated: ''Doctor OK Patient to Receive Medication in Compound Capsule Form.'' GX 38.

81. Dr. Sullivan testified that the notes contained in Patient N.B.'s patient profile were insufficient to resolve (or to suggest an attempt to resolve) any of the red flags that he identified. Tr. 306. [Dr. Sullivan testified that the red flags raised by Patient N.B.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 302–07.]

Patient R.B.

82. At all times relevant to this matter, Patient R.B. resided at 2512 Pauldo Street, Fort Myers, Florida 33916. GX 41. Patient R.B.'s residence is approximately 140 miles (one-way) from Respondent's registered address. GX 63.

83. All of the prescriptions filled by Patient R.B. at Respondent were paid for in cash. GX 40, 43.

84. Between June 28, 2017, and August 16, 2018, Respondent filled 24 prescriptions for controlled substances for Patient R.B., including 12 prescriptions for hydromorphone 8 mg, 11 prescriptions for alprazolam 2 mg, and one prescription for alprazolam 1 mg. Information regarding the controlled substances dispensed to Patient R.B. is accurately set forth in Government Exhibit 43.

85. Between September 12, 2018, and April 15, 2019, Respondent filled at least 10 prescriptions for controlled substances for Patient R.B., including five prescriptions for hydromorphone 8 mg and five prescriptions for alprazolam 1 mg. Information regarding the controlled substances dispensed to Patient R.B. is accurately set forth in Government Exhibit 40.

86. Respondent maintained a patient profile for Patient R.B. The patient profile for Patient R.B. contained no pharmacist notes or comments. GX 41.

87. Dr. Sullivan examined the dispensing data and the patient profile for Patient R.B. and identified multiple ''red flags.'' Specifically, Dr. Sullivan concluded that the distance travelled by Patient R.B. was a ''red flag,'' as was the fact that Patient R.B. was prescribed a cocktail of benzodiazepine and opioid with the opioid prescribed at the highest strength. Tr. 310–11.

88. Dr. Sullivan testified that the notes contained in Patient R.B.'s patient profile were insufficient to resolve (or to suggest an attempt to resolve) any of the red flags that he identified. Tr. 313. [Dr. Sullivan testified that the red flags raised by Patient R.B.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 311, 313, 321.]

Patient R.G.

89. At all times relevant to this matter, Patient R.G. resided at 1915 NE 5th Street, Cape Coral, Florida 33909. GX 47. Patient R.G.'s residence is approximately 130 miles (one-way) from Respondent's registered address. GX 64.

90. All of the prescriptions filled by Patient R.G. at Respondent were paid for in cash. GX 46, 49.

91. Between June 28, 2017, and September 7, 2018, Respondent filled 29 prescriptions for controlled substances for Patient R.G., including 17 prescriptions for oxycodone 30 mg, and 12 prescriptions for alprazolam 2 mg. Information regarding the controlled

[30] For reasons explained later in this Recommended Decision, I am not accepting Dr. Sullivan's opinion that the roundtrip distance from M.M.'s home to the prescriber's office, to the Respondent, and back home, is a red flag, as proposed by the Government. Gov't PHB, pp. 20–21, ¶ 101.

substances dispensed to Patient R.G. is accurately set forth in Government Exhibit 49.

92. Dr. Sullivan examined the dispensing data and the patient profile for Patient R.G. and identified multiple ''red flags.'' Specifically, Dr. Sullivan concluded that the distance travelled by Patient R.G. was a ''red flag,'' as was the fact that Patient R.G. was prescribed a cocktail of benzodiazepine and opioid at the highest strengths of both medications. Tr. 322–23.

93. Respondent maintained a patient profile for Patient R.G. The only pharmacist note in the profile for Patient R.G. stated: ''Watch Fill Dates!!!!!!!!!!!!'' GX 47.

94. Dr. Sullivan testified that the notes contained in Patient R.G.'s patient profile were insufficient to resolve (or to suggest an attempt to resolve) any of the red flags that he identified. Tr. 328. [Dr. Sullivan testified that the red flags raised by Patient R.G.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 322–23, 326, 328–29.]

Patient R.L.

95. At all times relevant to this matter, Patient R.L. resided at 135 SW 29th Terrace, Cape Coral, Florida 33914. GX 51. Patient R.L.'s residence is approximately 140 miles (one-way) from Respondent's registered address. GX 65.

96. All of the prescriptions filled by Patient R.L. at Respondent were paid for in cash. GX 50, 52.

97. Between June 21, 2017, and September 4, 2018, Respondent filled 16 prescriptions for controlled substances for Patient R.L., including 14 prescriptions for hydromorphone 8 mg, one prescription for oxycodone 30 mg, and one prescription for alprazolam 2 mg. Information regarding the controlled substances dispensed to Patient R.L. is accurately set forth in Government Exhibit 52.

98. Between December 27, 2018, and April 16, 2019, Respondent filled at least five prescriptions for controlled substances for Patient R.L., including five prescriptions for oxycodone 30 mg. Information regarding the controlled substances dispensed to Patient R.L. is accurately set forth in Government Exhibit 50.

99. Dr. Sullivan examined the dispensing data and the patient profile for Patient R.L. and identified multiple ''red flags.'' Specifically, Dr. Sullivan concluded that the distance travelled by Patient R.L. was a ''red flag,'' as was the fact that Patient R.L. was prescribed opioids at the highest strengths available. Tr. 330–31.

100. Respondent maintained a patient profile for Patient R.L. The only pharmacist note in the profile for Patient R.L. stated: ''Next Fill 6/10/18—10 Days Early March & April—Told Him This 5/11/18 GD[.]'' GX 51.]

101. Dr. Sullivan testified that the notes contained in Patient R.L.'s patient profile were insufficient to resolve (or to suggest an attempt to resolve) the red flags that he identified. Tr. 335. [Dr. Sullivan testified that the red flags raised by Patient R.L.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 332, 335–36.]

Compounding

102. Respondent repeatedly dispensed both commercially-available tablet and compounded capsule forms of controlled substances to the same patients, indicating that those patients did not have a legitimate therapeutic need for the compounded form. *See, e.g.,* Tr. 256, 290, 297, 321, 325, 326.

103. In May 2012, then-TFO Jeffrey Shearer conducted an interview with Respondent's owner regarding the compounding that he was doing at Respondent. Tr. 183.

104. Respondent's owner indicated that his formulary was designed to ensure that the compounded product was ''essentially similar'' to the commercially-produced product. Respondent's owner stressed that his compounded product had the same ''bioavailability'' as the commercially available product. Tr. 184–85.

105. TFO Shearer observed that Respondent's owner was compounding thousands of dosage units at one time. Respondent's owner explained that he did so because it was ''cost effective'' to produce large volumes at the same time. Tr. 185.

106. Respondent's owner told TFO Shearer that some of his customers did not want the compounded capsules, but that Respondent's owner assured the patients that the capsules and the tablets were ''the same, that they would have the same effect.'' Tr. 185–86.

**Analysis**

*Findings as to Allegations*

The Government alleges that the Respondent's COR should be revoked because the Respondent failed to ensure that it only filled prescriptions issued for legitimate medical purposes, and within the course of professional practice, in violation of its corresponding responsibility, and repeatedly filled prescriptions in the face of obvious [and unresolvable] red flags of diversion, and in violation of state law under the Florida Administrative Code, and state requirements for the minimum standard of care, and its registration would be inconsistent with the public interest, as provided in 21 U.S.C. 824(a)(4) and 21 U.S.C. 823(f). The Government also alleges that the Respondent engaged in a pattern of manufacturing controlled substances without proper registration.

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). Where the Government has sustained its burden and made its *prima facie* case, a respondent must both accept responsibility for his actions and demonstrate that he will not engage in future misconduct. *Patrick W. Stodola, M.D.,* 74 FR 20,727, 20,734 (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 38,363, 38,364 (2013). Where the Government has sustained its burden, the registrant must present sufficient mitigating evidence to assure the Administrator that he can be entrusted with the responsibility commensurate with such a registration. *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008).

The Agency's conclusion that ''past performance is the best predictor of future performance'' has been sustained on review in the courts, *Alra Labs., Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), as has the Agency's consistent policy of strongly weighing whether a registrant who has committed acts inconsistent with the public interest has accepted responsibility and demonstrated that he or she will not engage in future misconduct. *Hoxie,* 419 F.3d at 482–83; *see also Ronald Lynch, M.D.,* 75 FR 78,745, 78,754 (2010) (holding that the Respondent's attempts to minimize misconduct undermined acceptance of responsibility); *George C. Aycock, M.D.,* 74 FR 17,529, 17,543 (2009) (finding that much of the respondent's testimony undermined his initial acceptance that he was ''probably at fault'' for some misconduct); *Krishna-Iyer,* 74 FR 463 (noting, on remand, that despite the respondent having undertaken measures to reform her practice, revocation had been appropriate because the respondent had refused to acknowledge her responsibility under the law); *Med.*

*Shoppe-Jonesborough,* 73 FR 387 (noting that the respondent did not acknowledge recordkeeping problems, let alone more serious violations of federal law, and concluding that revocation was warranted).

The burden of proof at this administrative hearing is a preponderance-of-the-evidence standard. *Steadman* v. *SEC,* 450 U.S. 91, 100–01 (1981). The Administrator's factual findings will be sustained on review to the extent they are supported by ''substantial evidence.'' *Hoxie,* 419 F.3d at 481. The Supreme Court has defined ''substantial evidence'' as such relevant evidence as a reasonable mind might accept as adequate to support a conclusion. *Consol. Edison Co. of New York* v. *NLRB,* 305 U.S. 197, 229 (1938). While ''the possibility of drawing two inconsistent conclusions from the evidence'' does not limit the Administrator's ability to find facts on either side of the contested issues in the case, *Shatz* v. *U.S. Dep't of Justice,* 873 F.2d 1089, 1092 (8th Cir. 1989); *Trawick,* 861 F.2d at 77, all ''important aspect[s] of the problem,'' such as a respondent's defense or explanation that runs counter to the Government's evidence, must be considered. *Wedgewood Village Pharm.* v. *DEA,* 509 F.3d 541, 549 (D.C. Cir. 2007); *Humphreys* v. *DEA,* 96 F.3d 658, 663 (3rd Cir. 1996). The ultimate disposition of the case must be in accordance with the weight of the evidence, not simply supported by enough evidence to justify, if the trial were to a jury, a refusal to direct a verdict when the conclusion sought to be drawn from it is one of fact for the jury. *Steadman,* 450 U.S. at 99 (internal quotation marks omitted).

Regarding the exercise of discretionary authority, the courts have recognized that gross deviations from past agency precedent must be adequately supported, *Morall,* 412 F.3d at 183, but mere unevenness in application does not, standing alone, render a particular discretionary action unwarranted. *Chein* v. *DEA,* 533 F.3d 828, 835 (D.C. Cir. 2008) (citing *Butz* v. *Glover Livestock Comm'n Co.,* 411 U.S. 182, 188 (1973)). It is well-settled that since the Administrative Law Judge has had the opportunity to observe the demeanor and conduct of hearing witnesses, the factual findings set forth in this Recommended Decision are entitled to significant deference, *Universal Camera Corp.* v. *NLRB,* 340 U.S. 474, 496 (1951), and that this Recommended Decision constitutes an important part of the record that must be considered in the Administrator's decision. *Morall,* 412 F.3d at 179. However, any recommendations set forth herein regarding the exercise of discretion are by no means binding on the Administrator and do not limit the exercise of his discretion. 5 U.S.C. 557(b) (2006); *River Forest Pharmacy, Inc.* v. *DEA,* 501 F.2d 1202, 1206 (7th Cir. 1974); *Attorney General's Manual on the Administrative Procedure Act* 8 (1947).

Analysis of Dispensing Allegations

The Government alleges that the Respondent filled numerous prescriptions for eleven patients that raised red flags of drug abuse and/or diversion, to include drug cocktails; early fills; traveling long distances; prescriptions for the highest strengths of oxycodone, hydromorphone, and alprazolam; paying in cash; and dispensing compounded capsules without therapeutic justification. ALJ Ex. 1, pp. 4–7. The Government further alleges that [the red flags presented by these prescriptions were so strongly indicative of drug abuse and diversion that they could not have been resolved by a pharmacist acting in the usual course of professional practice.][*1] *Id.* The Government claims that by filling these eleven patients' controlled substance prescriptions, the Respondent violated its corresponding responsibility under 21 CFR 1306.04(a) and dispensed controlled substances outside the usual course of pharmacy practice in violation of 21 CFR 1306.06, in addition to Florida Administrative Code r. 64B16–27.831. *Id.* [Omitted for relevance.]

With respect to each patient, the Government presented documentary evidence and testimony from its pharmacy expert, Dr. Sullivan, that the Respondent filled numerous controlled substance prescriptions that raised red flags, including drug cocktails, early fills, long distance, highest strengths, and cash payments. The Government further presented evidence that [the red flags presented by these prescriptions could not have been resolved by a pharmacist acting in the usual course of professional practice.] Finally, the Government proved the Respondent compounded medication without therapeutic justification.

I will now turn to the evidence the Government presented for each patient. After examining the evidence for each patient, I will determine whether the Government has presented a *prima facie* case that the Respondent filled these prescriptions in violation of federal and state law.

Patient A.G.

From January 2018 to April 2019, the Respondent dispensed a drug cocktail of alprazolam and oxycodone to A.G. on six occasions. GX 14. During the same time period, the Respondent dispensed a drug cocktail of alprazolam and hydromorphone to A.G. on three occasions. *Id.*

Dr. Sullivan testified that the Respondent filled several prescriptions for A.G. before his prior month's supply of medication ran out. Tr. 257. For example, the Respondent filled oxycodone and alprazolam prescriptions for A.G. on January 17, 2019, the 28th day after dispensing a 30-day supply of each drug to him on December 20, 2018 (2 days early). ALJ Ex. 42,[31] p. 12; GX 14. The Respondent filled an alprazolam prescription for A.G. on February 14, 2019, the 28th day after dispensing a 30-day supply on January 17, 2019 (2 days early). *Id.* The Respondent filled another oxycodone prescription for A.G. on April 12, 2019, the 23rd day after dispensing a 28-day supply on March 20, 2019 (5 days early). *Id.* The Respondent also filled an alprazolam prescription for A.G. on April 12, 2019, the 23rd day after dispensing a 30-day supply on March 20, 2019 (7 days early). *Id.* These prescriptions should not have been filled early unless the Respondent documented a good reason for doing so. Tr. 257.

Patient A.G.'s home address was located about 130 miles from the Respondent. ALJ Ex. 42, p. 10; GX 55. Dr. Sullivan opined that this distance should have raised a red flag to a reasonable pharmacist.[32] Tr. 254.

[*1] I have modified this paragraph to clarify that the Government alleged that the red flags presented by the prescriptions in this case could not have been resolved by a pharmacist acting within the usual course of professional practice. Because the Government presented sufficient evidence to support this allegation, I do not need to consider the Government's alternative claim that Respondent failed to take adequate steps under Florida and federal law to resolve the red flags.

[31] Because the Government structured its direct examination of Dr. Sullivan by using the demonstrative exhibit for ease of reference, I will cite to that document as well as the Government Exhibit from which the information is derived. I will mark the demonstrative exhibit as ALJ Exhibit 42. I will treat the demonstrative exhibit similar to a summary of voluminous records under Federal Rule of Evidence 1006. The demonstrative exhibit, however, was never introduced into evidence, so it is being used as a guide or aid for review of the record. Thus, the admitted evidence trumps the demonstrative exhibit with respect to any inconsistency between the two.

[32] Although we do not know if A.G., in fact, travelled 131 miles from his home to the Respondent each time he filled a prescription there, the Respondent knew he lived that far away, and was therefore on notice of a well-established red flag of drug abuse and/or diversion. This is true of ten of the eleven patients. The fact that the patients lived over 100 miles away is a red flag even if the patients did not travel that distance each time they

From June 2017 to August 2018, the Respondent dispensed ten prescriptions each for oxycodone, hydromorphone, and alprazolam. ALJ Ex. 42, p. 11; GX 17. Each of these prescriptions, except for one alprazolam prescription, was written for the highest commercially available strength of the drug. *Id.;* Tr. 255. All of the oxycodone prescriptions dispensed during this time period were for 30 mg dosage units, the highest strength available of oxycodone. *Id.* All of the hydromorphone prescriptions dispensed during this time period were for 8 mg dosage units, the highest strength available of hydromorphone. *Id.* Nine of the ten alprazolam prescriptions dispensed during this time period were for 2 mg dosage units, the highest strength available of alprazolam. *Id.* Dispensing these controlled substances at their highest strengths, especially in combination with each other, raised red flags that required resolution. Tr. 256.

In addition to these red flags, patient A.G. paid for all of his prescriptions in cash. GX 14; GX 17. Dr. Sullivan testified that paying in cash is a red flag.[33] Tr. 214.

Although patient A.G. presented prescriptions to the Respondent that raised multiple red flags of drug abuse and/or diversion, the Respondent filled each prescription. Tr. 259, 267; GX 17; ALJ Ex. 42, p. 11. [Omitted for relevance. Dr. Sullivan testified that the red flags raised by Patient A.G.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 256–57, 267–68.]

Patient A.H.

From January 2018 to August 2018, the Respondent dispensed a drug cocktail of alprazolam and hydromorphone to A.H. on five occasions. ALJ Ex. 42, p. 15; GX 21.

The Respondent provided three early fills of hydromorphone prescriptions for A.H. from February to March 2019. Tr. 270–71; ALJ Ex. 42, p. 16; GX 19. The Respondent dispensed hydromorphone to A.H. on February 15, 2019, the 24th day after dispensing a 30-day supply on January 22, 2019 (6 days early). *Id.* The Respondent also dispensed hydromorphone to A.H. on February 27, 2019, the 12th day after dispensing a 30-day supply on February 15, 2019 (18 days early). *Id.* The Respondent then dispensed hydromorphone to A.H. on March 14, 2019, the 15th day after dispensing a 30 day-supply on February 27, 2019 (15 days early). *Id.* Filling three consecutive hydromorphone prescriptions early is a red flag. Tr. 271. A pharmacist acting within the usual course of professional practice would have either refused to fill these prescriptions until at least the day before the prior month's supply would have run out or refused to fill future prescriptions of the same drug for the patient. *Id.*

Patient A.H.'s home address was located about 130 miles from the Respondent. ALJ Ex. 42, p. 14; GX 56; Tr. 268. Dr. Sullivan opined that this distance is a red flag. Tr. 268.

From January 2018 to August 2018, the Respondent dispensed six prescriptions of hydromorphone and five prescriptions of alprazolam. ALJ Ex. 42, p. 15; GX 21. Each of these prescriptions was written for the highest strength of the drug. *Id.;* Tr. 269. All of the hydromorphone prescriptions dispensed during this time period were for 8 mg dosage units, the highest strength available of hydromorphone. *Id.* All of the alprazolam prescriptions dispensed during this time period were for 2 mg dosage units, the highest strength available of alprazolam. *Id.* Dispensing these controlled substances at their highest strengths, especially in combination with each other, raised red flags that required resolution. Tr. 269.

In addition to these red flags, patient A.H. paid for all of his prescriptions in cash. GX 19; GX 21. Dr. Sullivan testified that paying in cash is a red flag. Tr. 214.

Although patient A.H. presented prescriptions to the Respondent that raised multiple red flags of drug abuse and/or diversion, the Respondent filled each prescription. Tr. 272; GX 20; ALJ Ex. 42, p. 17. [Dr. Sullivan testified that the red flags raised by Patient A.H.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 269, 273.]

Patient B.S.

From August 2017 to August 2018, the Respondent dispensed a drug cocktail of alprazolam and hydromorphone to B.S. on five occasions. ALJ Ex. 42, p. 19; GX 24; Tr. 274. From December 2018 to March 2019, the Respondent dispensed a drug cocktail of alprazolam and oxycodone to B.S. on three occasions. ALJ Ex. 42, p. 20; GX 22; Tr. 276–77.

Dr. Sullivan also pointed out the duplicative therapy that the Respondent dispensed in January and February 2019. Tr. 276; ALJ Ex. 42, p. 20. After dispensing a 30-day supply of oxycodone to B.S. on January 31, 2019, only five days later the Respondent dispensed a 28-day supply of hydromorphone. *Id.* Then only two weeks later, the Respondent dispensed another 30-day supply of oxycodone to B.S. *Id.* Oxycodone and hydromorphone are potent immediate-release narcotic pain killers. Tr. 276. The fact that B.S. presented overlapping prescriptions for different immediate-release opioids with duplicative therapy was a red flag of abuse and/or diversion. *Id.*

Patient B.S.'s home address was located about 148 miles from the Respondent. ALJ Ex. 42, p. 18; GX 57; Tr. 273–74. Dr. Sullivan opined that this distance is a red flag. Tr. 273–74.

From August 2017 to August 2018, the Respondent dispensed 12 prescriptions of hydromorphone and 7 prescriptions of alprazolam. ALJ Ex. 42, p. 19; GX 24; Tr. 274. All but one of these prescriptions was written for the highest commercially available dosage strength of the drug. *Id.* All of the hydromorphone prescriptions dispensed during this time period were for 8 mg dosage units, the highest strength of hydromorphone. *Id.* All but one of the alprazolam prescriptions dispensed during this time period were for 2 mg dosage units, the highest strength of alprazolam. *Id.* From December 2018 to April 2019, the Respondent dispensed four

visited the pharmacy. The focus is on the information the Respondent knew, and the Respondent knew the patients lived over 100 miles away because it had their addresses on the prescriptions. According to Dr. Sullivan, this information should have aroused the Respondent's suspicion. The remaining patient (M.M.) lived approximately 134 miles from his prescriber's office, which represents its own red flag of long distance travel to obtain the prescription. Tr. 291–94.

[33] The Respondent argues that it did not view cash payments as suspicious because it did not accept insurance as a form of payment. Resp't PHB, at 19–20, 35. I am not convinced by this argument for two reasons. First, the Respondent did not provide any direct evidence that the only form of payment it accepted during the relevant time period was cash. Rather, it drove at this issue indirectly by asking hypothetical questions such as how would the Respondent get paid if it did not have contracts with insurance carriers or pharmacy benefit managers. Tr. 443–44. Second, even if the only form of payment that the Respondent accepted was cash, the fact that a patient was willing to pay in cash should still have aroused the Respondent's suspicion since it is a [part of the standard of professional practice of pharmacy as testified by Dr. Sullivan. Tr. 221–225.] The fact that the patients in this case were willing to pay in cash was even more concerning given the other red flags that they raised. Dr. Sullivan testified that paying in cash for controlled substances remains suspicious when it occurs with the other red flags involved here, even if the pharmacy did not take insurance. Tr. 475–76. [DEA has consistently relied on the testimony of pharmacy experts in finding that cash payments are a red flag of diversion or abuse. *See, e.g., Edge Pharm.,* 81 FR 72,092, 72,103, 72,111–12 (2016) (crediting Florida pharmacy expert's testimony that paying in cash or cash equivalent, such as by credit or debit card, creates a suspicion that a controlled substance may be abused or diverted).]

prescriptions of oxycodone and one prescription of hydromorphone. ALJ Ex. 42, p. 20; GX 22; Tr. 276. All four of the oxycodone prescriptions were written for 30 mg, the highest strength of oxycodone. *Id.* The hydromorphone prescription was written for 8 mg, the highest strength of hydromorphone. *Id.* Dispensing these controlled substances at their highest strengths, especially in combination with each other, raised red flags that required resolution. Tr. 274, 276–77.

[Text omitted.] * J [34] *Id.*

In addition to these red flags, patient B.S. paid for all of his prescriptions in cash. GX 22; GX 24. Dr. Sullivan testified that paying in cash is a red flag. Tr. 214.

Although patient B.S. presented prescriptions to the Respondent that raised multiple red flags of drug abuse and/or diversion, the Respondent filled each prescription. Tr. 277–78; GX 23; ALJ Ex. 42, p. 21. [Dr. Sullivan testified that the red flags raised by Patient B.S.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 274, 276–77.]

Patient C.R.

From July 2017 to August 2018, the Respondent dispensed a drug cocktail of alprazolam and oxycodone to C.R. on five occasions. ALJ Ex. 42, p. 23; GX 27; Tr. 280. On one of these occasions, the Respondent dispensed morphine tablets in addition to oxycodone and alprazolam. *Id.*

Patient C.R.'s home address was located about 134 miles from the Respondent. ALJ Ex. 42, p. 22; GX 58; Tr. 279. Dr. Sullivan opined that this distance is a red flag. Tr. 279.

From July 2017 to August 2018, the Respondent dispensed six prescriptions of oxycodone. ALJ Ex. 42, p. 23; GX 27; Tr. 279–80. Each of these six oxycodone prescriptions were for 30 mg dosage units, the highest strength available of oxycodone. *Id.*

In addition to these red flags, patient C.R. paid for all of her prescriptions in cash. GX 25; GX 27. Dr. Sullivan testified that paying in cash is a red flag. Tr. 214.

Although patient C.R. presented prescriptions to the Respondent that raised multiple red flags of drug abuse and/or diversion, the Respondent filled each prescription. Tr. 281–82; GX 24; ALJ Ex. 42, p. 23. [Omitted for relevance. Dr. Sullivan testified that the red flags raised by Patient C.R.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 279–83.]

Patient J.D.

On one occasion the Respondent dispensed a drug cocktail of hydromorphone and methadone to J.D. Tr. 283–84; ALJ Ex. 42, p. 26; GX 30. Dr. Sullivan testified that taking these two immediate-release narcotic pain killers at the same time put J.D. ''at extreme risk of overdose.'' Tr. 284.

The Respondent provided three early fills of hydromorphone prescriptions for J.D. from May to June 2018. Tr. 284–87; ALJ Ex. 42, p. 27; GX 30. The Respondent dispensed hydromorphone to J.D. on May 30, 2018, the 20th day after dispensing a 30-day supply on May 10, 2018 (10 days early). *Id.* The Respondent also dispensed hydromorphone to J.D. on June 15, 2018, the 16th day after dispensing a 30-day supply on May 30, 2018 (14 days early). *Id.* The Respondent then dispensed hydromorphone to J.D. on June 30, 2018, the 15th day after dispensing a 30 day-supply on June 15, 2018 (15 days early). *Id.* Dr. Sullivan testified that filling three consecutive hydromorphone prescriptions early is a red flag. Tr. 285. He testified that a pharmacist acting within the usual course of professional practice would have either refused to fill these prescriptions until at least the day before the prior month's supply would have run out or refused to fill future prescriptions of the same drug for the patient. Tr. 271.

Patient J.D.'s home address was located about 130 miles from the Respondent. ALJ Ex. 42, p. 25; GX 59; Tr. 283. Dr. Sullivan opined that this distance is a red flag. Tr. 283.

From January 2018 to September 2018, the Respondent dispensed nine prescriptions of hydromorphone. ALJ Ex. 42, p. 26; GX 30; Tr. 283–84. Each of these nine hydromorphone prescriptions were for 8 mg dosage units, the highest strength available of hydromorphone. *Id.*

In addition to these red flags, patient J.D. paid for all of her prescriptions in cash. GX 28; GX 30. Dr. Sullivan testified that paying in cash is a red flag. Tr. 214.

Although patient J.D. presented prescriptions to the Respondent that raised multiple red flags of drug abuse and/or diversion, the Respondent filled each prescription. Tr. 287–88; GX 29; ALJ Ex. 42, p. 28. [Omitted for relevance. Dr. Sullivan testified that the red flags raised by Patient J.D.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 284, 288–89.]

Patient J.M.

From June 2017 to September 2018, the Respondent dispensed a drug cocktail of alprazolam and oxycodone to J.M. on five occasions. ALJ Ex. 42, p. 30; GX 33; Tr. 289–90. During the same time period, the Respondent dispensed a drug cocktail of alprazolam and hydromorphone to J.M. on three occasions. *Id.*

Patient J.M.'s home address was located about 144 miles from the Respondent. ALJ Ex. 42, p. 29; GX 60; Tr. 289. Dr. Sullivan opined that this distance is a red flag. Tr. 289.

From June 2017 to September 2018, the Respondent dispensed nine prescriptions of alprazolam, eight prescriptions of oxycodone, and six prescriptions of hydromorphone. ALJ Ex. 42, p. 30; GX 33; Tr. 289–90. All of these prescriptions were for the highest strength available of the drug. All of the nine alprazolam prescriptions were for 2 mg dosage units, the highest strength of alprazolam. *Id.* All of the eight oxycodone prescriptions were for 30 mg dosage units, the highest strength of oxycodone. *Id.* All of the six hydromorphone prescriptions were for 8 mg dosage units, the highest strength of hydromorphone. *Id.*

In addition to these red flags, patient J.M. paid for all of her prescriptions in cash. GX 31; GX 33. Dr. Sullivan testified that paying in cash is a red flag. Tr. 214.

Although patient J.M. presented prescriptions to the Respondent that raised multiple red flags of drug abuse and/or diversion, the Respondent filled each prescription. Tr. 290; GX 32; ALJ Ex. 42, p. 31. [Dr. Sullivan testified that the red flags raised by Patient J.M.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 290–91.]

Patient M.M.

The Respondent provided three early fills of hydromorphone prescriptions for M.M. from January to March 2019. Tr. 299–300; ALJ Ex. 42, p. 34; GX 34. The Respondent dispensed hydromorphone to M.M. on January 24, 2019, the 21st day after dispensing a 28-day supply on January 3, 2019 (7 days early). *Id.* The Respondent also dispensed hydromorphone to J.D. on February 19, 2019, the 26th day after dispensing a 30-

*J As referenced herein, the ALJ did not find that Dr. Sullivan's testimony regarding the ibuprofen prescriptions was factually supported. I find it unnecessary given the strength of the other evidence in this case to reach this issue, and therefore, I am omitting the references to this testimony as irrelevant.

[34] [Texted omitted where footnote was included.]

day supply on January 24, 2019 (4 days early). *Id.* The Respondent then dispensed hydromorphone to J.D. on March 15, 2019, the 24th day after dispensing a 30-day supply on February 19, 2019 (6 days early). *Id.* Dr. Sullivan testified that filling three consecutive hydromorphone prescriptions early is a red flag. Tr. 285, 300. He testified that a pharmacist acting within the usual course of professional practice would have either refused to fill these prescriptions until at least the day before the prior month's supply would have run out or refused to fill future prescriptions of the same drug for the patient. Tr. 271, 300.

Patient M.M.'s home address was located about 38 miles from the Respondent. GX 60, pp. 5–6; Tr. 292–93. The concern about the distance M.M. would have had to travel, however, was the distance from his home to the prescribing doctor's office. Tr. 293–94. Patient M.M.'s home was located about 134 miles from the office of the doctor who issued him controlled substance prescriptions. GX 61, pp. 1–3. Dr. Sullivan opined that the distance from M.M.'s home to the doctor's office is a red flag.[35] Tr. 292–94.

From June 2017 to August 2018, and from January to April 2019, the Respondent dispensed 14 and 5, respectively, hydromorphone prescriptions to patient M.M. ALJ Ex. 42, p. 33–34; GX 34; GX 36; Tr. 295. All of these 19 prescriptions were for 8 mg dosage units, the highest strength of hydromorphone. *Id.*

Dr. Sullivan also pointed out the red flag raised by M.M.'s prescriptions for folic acid 0.4 mg. Tr. 295–96; ALJ Ex. 42, p. 33; GX 36. From June 2017 to August 2018, the Respondent dispensed folic acid 0.4 mg to M.M. on eight occasions. *Id.* Folic acid is a vitamin and 0.4 mg of folic acid is a dose that could be obtained over-the-counter without a prescription. Tr. 295. Dr. Sullivan opined that it is common for doctors who unlawfully prescribe controlled substances to add low doses of non-controlled medication to make their controlled substance prescribing appear legitimate. *Id.* For the same reasons I gave earlier with respect to B.S., however, I do not accept Dr. Sullivan's testimony in this regard.

[35] I am not accepting Dr. Sullivan's testimony that the roundtrip distance from M.M.'s home to the doctor's office, and then to the Respondent, and then back home, is a red flag. Tr. 293. There was no evidence M.M. ever made that round trip. The 38 miles from M.M.'s home to the Respondent is not overly suspicious on its face. I believe the Government withdrew its allegation as to that distance. I will, however, accept Dr. Sullivan's testimony that the 134 miles from M.M.'s home to the doctor's office is a red flag. Tr. 294.

Dr. Sullivan also observed a concerning lapse in M.M.'s opioid prescriptions from July 2018 to January 2019. Tr. 297–98; ALJ Ex. 42, p. 34; GX 34. After M.M. filled a hydromorphone prescription in July 2018, M.M. did not present another prescription until January 2019, when she presented a prescription for 8 mg dosage units of hydromorphone, the highest strength of that drug. *Id.* The seven-month lapse in hydromorphone prescriptions followed by a prescription for the highest strength of hydromorphone should have raised a red flag because returning abruptly to such a high dose after not taking it for seven months would have put M.M. at ''heightened risk for overdose.'' *Id.*

In addition to these red flags, patient M.M. paid for all of her prescriptions in cash. GX 34; GX 36. Dr. Sullivan testified that paying in cash is a red flag. Tr. 214.

Although patient M.M. presented prescriptions to the Respondent that raised multiple red flags of drug abuse and/or diversion, the Respondent filled each prescription. Tr. 300–01; GX 35; ALJ Ex. 42, p. 35. [Dr. Sullivan testified that the red flags raised by Patient M.M.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 299–300.]

Patient N.B.

From June 2017 to August 2018, the Respondent dispensed a drug cocktail of alprazolam and hydromorphone to N.B. on six occasions. ALJ Ex. 42, p. 37; GX 39; Tr. 302. From September 2018 to January 2019, the Respondent dispensed a drug cocktail of alprazolam and oxycodone to N.B. on two occasions, and a cocktail of alprazolam and hydromorphone on one occasion. ALJ Ex. 42, p. 38; GX 37; Tr. 305.

The Respondent provided two early fills of prescriptions for N.B. from January to March 2019. Tr. 303–04; ALJ Ex. 42, p. 38; GX 37. First, the Respondent dispensed oxycodone and alprazolam to N.B. on January 16, 2019, the 27th day after dispensing a 30-day supply of each drug on December 20, 2018 (3 days early). *Id.* Then, the Respondent dispensed oxycodone to N.B. on March 13, 2019, the 19th day after dispensing a 28-day supply on February 22, 2019 (9 days early). *Id.* A pharmacist acting within the usual course of professional practice would have either refused to fill these prescriptions until at least the day before the prior month's supply would have run out or refused to fill future prescriptions of the same drug for the patient. Tr. 271, 300, 304.

Patient N.B.'s home address was located about 137 miles from the Respondent. ALJ Ex. 42, p. 36; GX 62; Tr. 301. Dr. Sullivan opined that this distance is a red flag. Tr. 301.

From June 2017 to August 2018, the Respondent dispensed 12 prescriptions of hydromorphone to N.B. ALJ Ex. 42, p. 37; GX 39; Tr. 302. All of these 12 hydromorphone prescriptions were for 8 mg dosage units, the highest strength of hydromorphone. *Id.* In addition, the Respondent also dispended four prescriptions of alprazolam in 2 mg dosage units, the highest strength of alprazolam. *Id.* Dr. Sullivan also pointed out that on one occasion the Respondent dispensed alprazolam to N.B. in 2 mg and 1 mg dosage units. *Id.* He testified that aking the same controlled substance in two different strengths is a red flag. *Id.*

[Text omitted, *see supra* n.*J.]

Dr. Sullivan also observed a concerning two-month gap in N.B.'s opioid prescriptions in October and November 2018. Tr. 304–05; ALJ Ex. 42, p. 38; GX 37. N.B. presented a prescription for hydromorphone in September 2018 and then presented an oxycodone 30 mg prescription in December 2018, but did not present any opioid prescriptions to the Respondent in October and November. *Id.* Dr. Sullivan testified that not taking opioids for two months and then starting up again on the highest strength of oxycodone is concerning and puts the patient at heightened risk of overdose. Tr. 297–98, 304–05. This lapse in filling opioid prescriptions raises a red flag. *Id.*

In addition to these red flags, patient N.B. paid for all of her prescriptions in cash. GX 37; GX 39. Dr. Sullivan testified that paying in cash is a red flag. Tr. 214.

Although patient N.B. presented prescriptions to the Respondent that raised multiple red flags of drug abuse and/or diversion, the Respondent filled each prescription. Tr. 306–07; GX 38; ALJ Ex. 42, p. 39. [Omitted for relevance. Dr. Sullivan testified that the red flags raised by Patient N.B.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 302–07.]

Patient R.B.

From June 2017 to August 2018, the Respondent dispensed a drug cocktail of alprazolam and hydromorphone to R.B. on twelve occasions. ALJ Ex. 42, p. 41; GX 43; Tr. 311.

The Respondent provided one early fill of hydromorphone to R.B. On February 18, 2019, the Respondent dispensed hydromorphone to R.B. on

February 18, 2019, the 27th day after dispensing a 31-day supply of hydromorphone on January 22, 2019 (4 days early). ALJ Ex. 42, p. 42; GX 40; Tr. 312.

Patient R.B.'s home address was located about 138 miles from the Respondent. ALJ Ex. 42, p. 40; GX 63; Tr. 307. Dr. Sullivan opined that this distance is a red flag. Tr. 307.

From June 2017 to August 2018, the Respondent dispensed 12 prescriptions of hydromorphone and 12 prescriptions of alprazolam to R.B. ALJ Ex. 42, p. 41; GX 43; Tr. 311. All of the 12 hydromorphone prescriptions were for 8 mg dosage units, the highest commercially available strength of hydromorphone. *Id.* Eleven of the 12 alprazolam prescriptions were for 2 mg dosage units, the highest strength of alprazolam. *Id.*

As with patients M.M. and N.B., Dr. Sullivan also observed a concerning three-month gap in R.B.'s opioid prescriptions in October, November, and December 2018. Tr. 312; ALJ Ex. 42, p. 42; GX 40. R.B. presented a prescription for hydromorphone in September 2018 and did not present another hydromorphone prescription to the Respondent until January 2019.[36] *Id.* A three-month lapse in opioid treatment renders the patient opioid naïve and puts the patient at heightened risk of overdose upon resumption of opioid treatment. Tr. 297–98, 304–05, 312. This lapse in filling opioid prescriptions raises a red flag. *Id.*

Dr. Sullivan also observed that R.B.'s PDMP report revealed evidence of pharmacy shopping, which Dr. Sullivan considered significant. Tr. 316–17. The PDMP report showed that R.B. filled controlled substance prescriptions at five different pharmacies, to include the Respondent. Tr. 316–17; GX 44, p. 5.

In addition to these red flags, patient R.B. paid for all of her prescriptions that were filled by the Respondent in cash. GX 40; GX 43. Dr. Sullivan testified that paying in cash is a red flag. Tr. 214. Although R.B. always paid in cash at the Respondent, she used insurance to purchase controlled substance prescriptions at other pharmacies on three occasions. GX 44, pp. 4–5; Tr. 317–19. Dr. Sullivan noted that a patient does not break the law by alternating between paying in cash and using insurance. Tr. 319. It is, however, another red flag that a pharmacist should resolve. Tr. 318–19. When a pharmacist evaluates the red flag raised by a patient paying in cash for controlled substances, it would be relevant to consider the fact that the patient was using insurance to fill prescriptions at another location. Tr. 318.

Although patient R.B. presented prescriptions to the Respondent that raised multiple red flags of drug abuse and/or diversion, the Respondent filled each prescription. Tr. 313; GX 41; ALJ Ex. 42, p. 43. [Dr. Sullivan testified that the red flags raised by Patient R.B.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 311, 313, 321.]

Patient R.G.

From June 2017 to September 2018, the Respondent dispensed a drug cocktail of alprazolam and oxycodone to R.G. on twelve occasions. ALJ Ex. 42, p. 45; GX 49; Tr. 322–24.

The Respondent provided multiple early fills of prescriptions for R.G. from February to May 2018. Tr. 326–28; ALJ Ex. 42, p. 46; GX 49. The Respondent dispensed alprazolam and oxycodone to R.G. on February 21, 2018, the 23rd day after dispensing a 30-day supply of each drug on January 29, 2018 (7 days early). *Id.* The Respondent again dispensed alprazolam and oxycodone to R.G. on March 19, 2018, the 26th day after dispensing a 30-day supply of each drug on February 21, 2018 (4 days early). *Id.* The Respondent then dispensed alprazolam to R.G. on April 17, 2018, even though the doctor instructed that the prescription should not be filled until April 20, 2018 (3 days early). *Id.* The Respondent dispensed oxycodone to R.G. on May 8, 2018, the 21st day after dispensing a 30-day supply of oxycodone on April 17, 2018 (9 days early). *Id.* A pharmacist acting within the usual course of professional practice would have either refused to fill these prescriptions until at least the day before the prior month's supply would have run out or refused to fill future prescriptions of the same drug for the patient. Tr. 271, 300, 304, 328.

Patient R.G.'s home address was located about 131 miles from the Respondent. ALJ Ex. 42, p. 44; GX 64; Tr. 322. Dr. Sullivan opined that this distance is a red flag. Tr. 322.

From June 2017 to September 2018, the Respondent dispensed 17 prescriptions of oxycodone and 12 prescriptions of alprazolam to R.G. Tr. 322–24; ALJ Ex. 42, p. 45; GX 49. All of these 29 prescriptions were for the highest strength of the drug. *Id.* All of the 17 oxycodone prescriptions were for 30 mg dosage units, the highest strength of oxycodone. *Id.* All of the 12 alprazolam prescriptions were for 2 mg dosage units, the highest strength of alprazolam. *Id.*

In addition to these red flags, patient R.G. paid for all of his prescriptions in cash. GX 46; GX 49. Dr. Sullivan testified that paying in cash is a red flag. Tr. 214.

Although patient R.G. presented prescriptions to the Respondent that raised multiple red flags of drug abuse and/or diversion, the Respondent filled each prescription. Tr. 328–29; GX 47; ALJ Ex. 42, p. 47. [Omitted for relevance. Dr. Sullivan testified that the red flags raised by Patient R.G.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 322–23, 326, 328–29.]

Patient R.L.

From June 2017 to September 2018, the Respondent dispensed a drug cocktail of alprazolam and hydromorphone to R.L. on one occasion. ALJ Ex. 42, p. 49; GX 52; Tr. 331.

The Respondent provided four early fills of hydromorphone to R.L. from February to May 2018. Tr. 333–34; ALJ Ex. 42, p. 51; GX 52. First, the Respondent dispensed hydromorphone to R.L. on February 26, 2018, the 25th day after dispensing a 30-day supply of hydromorphone on February 1, 2018 (5 days early). *Id.* The Respondent dispensed hydromorphone to R.L. again on March 22, 2018, the 24th day after dispensing a 30-day supply of hydromorphone on February 26, 2018 (six days early). *Id.* Then the Respondent dispensed hydromorphone to R.L. on April 17, 2018, the 26th day after dispensing a 30-day supply of hydromorphone on March 22, 2018 (4 days early). *Id.* The Respondent also dispensed hydromorphone to R.L. on May 11, 2018, the 24th day after

[36] Patient R.B.'s PDMP report indicates that the hydromorphone prescription he received from the Respondent in September 2018 was for a 120-day supply. GX 40; ALJ Ex. 42, p. 42. If that were true, the gap in opioid prescriptions from September 2018 to January 2019 would not raise any concern because the September 2018 prescription would have lasted four months. That number, however, must have been incorrectly reported to the PDMP. In fact, the September 2018 prescription was written for a 30-day supply, not 120-days as reported in the PDMP. This becomes evident by comparing the PDMP report to the actual prescription, which is one of the few hard-copy prescriptions in evidence. The PDMP report indicates that the Rx number for the September 2018 hydromorphone prescription (10th from the top) is 5011489 and was issued by Dr. L. GX 40. The corresponding prescription bearing the same Rx number on the fill sticker is located at Government Exhibit 44, pages 6–7 (prescription at top right corner). That prescription was written by Dr. L. for 120 tablets of hydromorphone 8 mg, to be taken one tablet every 6 hours (or 4 tablets per day). GX 44, p. 6. A 120-tablet prescription with these instructions would last one month, not four months. Thus, R.B.'s three month lapse in filling opioid prescriptions at the Respondent remains a concern that the Respondent should have addressed.

dispensing a 30-day supply of hydromorphone on April 17, 2018 (6 days early). *Id.* Filling four consecutive hydromorphone prescriptions early is a red flag. Tr. 271, 285, 300, 334. A pharmacist acting within the usual course of professional practice would have either refused to fill these prescriptions until at least the day before the prior month's supply would have run out or refused to fill future prescriptions of the same drug for the patient. Tr. 334.

Patient R.L.'s home address was located about 138 miles from the Respondent. ALJ Ex. 42, p. 48; GX 65; Tr. 330. Dr. Sullivan opined that this distance is a red flag. Tr. 330.

From June 2017 to September 2018, the Respondent dispensed 14 prescriptions of hydromorphone, one prescription of oxycodone, and one prescription of alprazolam to R.L. Tr. 331–32; ALJ Ex. 42, p. 49; GX 52. All of these 16 prescriptions were for the highest strength of the drug. *Id.* All of the 14 hydromorphone prescriptions were for 8 mg dosage units, the highest strength of hydromorphone. *Id.* The oxycodone prescription was for 30 mg dosage units, the highest strength of oxycodone. *Id.* The alprazolam prescription was for 2 mg dosage units, the highest strength of alprazolam. *Id.* From December 2018 to April 2019, the Respondent dispensed five prescriptions of oxycodone to R.L. in 30 mg dosage units, the highest strength of oxycodone. Tr. 331–32; ALJ Ex. 42, p. 50; GX 50.

In addition to these red flags, patient R.L. paid for all of his prescriptions in cash. GX 50; GX 52. Dr. Sullivan testified that paying in cash is a red flag. Tr. 214.

Although patient R.L. presented prescriptions to the Respondent that raised multiple red flags of drug abuse and/or diversion, the Respondent filled each prescription. Tr. 334–36; GX 51; ALJ Ex. 42, p. 52. [Omitted for relevance. Dr. Sullivan testified that the red flags raised by Patient R.L.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 332, 335–36.]

*Analysis of Dispensing Evidence for All Eleven Patients*

[Analysis omitted for brevity and relevance.] *K [37] [38] [39] [40] [41] [42] [43]

[As discussed in more detail *infra,* the Government's evidence showed that Respondent repeatedly filled controlled substances prescriptions for eleven patients that raised numerous red flags of drug abuse and diversion. These red flags included early fills, long distances traveled, cash payments, dangerous drug cocktails, and high-strength narcotics. Dr. Sullivan offered credible and unrebutted expert testimony that, for each of these customers, these red flags could not have been resolved by a reasonable pharmacist acting within the usual course of his professional practice. Thus, by filling these prescriptions, Respondent violated its corresponding responsibility and filled prescriptions outside the usual course of professional practice, in violation of 21 CFR 1306.04 and 1306.06. Respondent also violated Florida law, which requires pharmacists to ''exercise[ ] sound professional judgment,'' to conduct a prospective drug use review before dispensing a controlled substance, and to take appropriate steps to avoid or resolve problems with the prescriptions. Fla. Admin. Code rs. 64B16–27.831, 64B16–27.810.]

*Analysis of Unlawful Manufacturing Allegation*

Finally, the Government alleges that the Respondent engaged in ''manufacturing'' controlled substances, as that term is defined in the CSA, without a separate DEA registration authorizing the manufacture of controlled substances, in violation of 21 U.S.C. 841(a)(1) and 21 CFR 1301.13(e). ALJ Ex. 1, ¶ 20–28. Specifically, the Government alleges that the Respondent compounded oxycodone and hydromorphone capsules in such large quantities that this activity constituted manufacturing rather than permissible compounding for individual patients. *Id.*

DEA regulations require registrants to obtain a separate registration for each regulated business activity in which they engage. 21 CFR 1301.13(e). Section 1301.13(e) provides ten separate business activities, to include manufacturing and dispensing.[44] *Id.* at (e)(1)(i), (iv). Each business activity is ''deemed to be independent of each other.'' 21 U.S.C. 1301.13(e). In other words, a registration for one activity does not authorize the registrant to engage in another activity. *Id.* To engage in both dispensing and manufacturing, a registrant would need to apply for and obtain separate registrations for each activity. No person or entity may engage in a regulated business activity ''until the application for registration is granted and a Certificate of Registration is issued by the Administrator to such person [or entity].'' 21 CFR 1301.13(a).

Requiring separate registrations for manufacturing and dispensing is more than mere formality. In fact, the CSA imposes stricter requirements on manufacturers than dispensers, not to mention a different standard for issuing a sanction. *Wedgewood Village Pharm.,* 71 FR 16,593, 16,594 (2006); *compare* 21 U.S.C. 823(a) (setting forth six public interest factors for manufacturers of Schedule I and II controlled substances), *with* 21 U.S.C. 823(f) (establishing five similar, yet different, public interest factors for practitioners, which includes pharmacies engaged in dispensing). Additionally, the CSA imposes higher

*K I disagree with the ALJ's decision not to credit Dr. Sullivan's testimony that the red flags in this case could not have been resolved by a pharmacist operating in the usual course of professional practice. Because the ALJ did not credit this testimony, his analysis centered on whether Respondent had adequately resolved the red flags with each prescription and whether Respondent had adequately documented the resolution of red flags. RD, at 90–100. The ALJ concluded that he was unable to determine that Respondent had violated its corresponding responsibility for the majority of the prescriptions, because Dr. Sullivan testified that red flags may be resolved in the patient profile or on the face of the prescription, and the Government did not admit copies of the majority of the prescriptions into evidence. *Id.* Instead, the ALJ found that Respondent had violated Florida law—which the ALJ interpreted as requiring pharmacists to resolve red flags in the patient profile—and therefore, that Respondent had dispensed controlled substances outside the usual course of professional practice, in violation of 21 CFR 1306.06. In its Exceptions, Respondent argued that the ALJ's interpretation of Florida law was incorrect, because it does not require pharmacists to document the resolution of red flags. Resp Exceptions, at 8–17.

As discussed in more detail above, it is not necessary for me to resolve this conflict. Because Dr. Sullivan offered credible and unrebutted expert testimony that the prescriptions in this case presented unresolvable red flags of drug abuse and diversion, and that these prescriptions would not have been filled by a pharmacist acting within the usual course of professional practice, I have concluded that Respondent violated Florida and federal law. Thus, I need not determine whether Respondent made adequate attempts under Florida law to resolve red flags and document their resolution. Therefore, I have omitted the RD's discussion of Florida and federal law requirements for documenting the resolution of red flags. I have also omitted the RD's discussion of whether Respondent adequately documented the resolution of red flags in this case.

This section also included a discussion of Florida requirements for conducting a drug utilization review of each controlled substance prescription. This discussion has been incorporated into the section below summarizing the evidence under Factors Two and Four of the public interest analysis.

[37] [Text omitted where footnote was included.]

[38] [Text omitted where footnote was included.]

[39] [Text omitted where footnote was included.]

[40] [Text omitted where footnote was included.]

[41] [Text omitted where footnote was included.]

[42] [Text omitted where footnote was included.]

[43] [Text omitted where footnote was included.]

[44] Although not relevant to this case, the other business activities include distributing, reverse distributing, research (Schedule I), research (Schedules II–V), narcotic treatment programs, importing, exporting, and chemical analysis. 21 U.S.C. 1301.13(e)(1).

standards for recordkeeping, reporting, and security on manufacturing than it does on dispensing. 71 FR 16,594. Manufacturers are also required to obtain a registration annually, whereas dispensers are only required to obtain a registration every three years. *Id.* (citing 21 U.S.C. 822(a)(1)–(2)).

The Respondent is registered with the DEA as a ''retail pharmacy.'' GX 1. Pursuant to this registration, the Respondent may dispense controlled substances in Schedules II–V. *Id.;* 21 CFR 1301.13(e)(1)(iv). The Respondent's registration as a retail pharmacy authorizing it to engage in the regulated activity of dispensing does not permit the Respondent to manufacture controlled substances; thus, any manufacturing it performed would be unlawful. To prevail on its claim that the Respondent manufactured controlled substances, the Government must show by a preponderance of the evidence that the Respondent engaged in an activity that met the CSA's definition of ''manufacturing.''

Although the CSA does not define what the term ''to compound'' means, it does define ''manufacture.'' *[L] *Wedgewood Village Pharm.* v. *DEA,* 509 F.3d 541, 543 (D.C. Cir. 2007) (noting the CSA does not define ''compounding''). ''The term 'manufacture' means the production, preparation, propagation, *compounding,* or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substance or labeling or relabeling of its container.'' 21 U.S.C. 802(15) (emphasis added). Importantly, the CSA includes compounding in its definition of manufacturing. *Id.* Not all compounding, however, is considered to be manufacturing. The definition of manufacturing ''does not include the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice.'' *Id.* [Omitted.] [45] [46]

*[M] The thrust of the Respondent's argument is that because the CSA does not define compounding, the appropriate question is whether the Respondent complied with Florida law and other federal laws. Resp't PHB, at 37–38. The Respondent argues that it engaged in anticipatory compounding (*i.e.,* compounding before receiving a prescription), which is permissible under Florida law and the Food, Drug, and Cosmetic Act (hereinafter, FDCA).*[N] *Id.* at 37–41. Florida law provides that lawful compounding includes ''[t]he preparation of drugs or devices in anticipation of prescriptions based on routine, regularly observed prescribing patterns.'' Fla. Admin. Code r. 64B16–27.700(1)(a).*[O] [However, as explained herein, the facts on the record do not support a finding that Respondent was compounding in this manner, nor do they support a finding that Respondent was compounding within the usual course of the professional practice of pharmacy in order to meet the CSA's manufacturing exemption.] [Text omitted.] [47]

*[P] The clearest evidence that the Respondent manufactured, rather than compounded for individual patients, comes from the closing inventory conducted by DI Albert and Mr. Clement, Sr., in September 2018. Tr. 52, 54, 56, 165–66; GX 7. The closing inventory documented the number of controlled substances the Respondent had on hand at the time. *Id.* DI Albert observed Mr. Clement, Sr., conduct the inventory and Mr. Clement, Sr., signed off on it. Tr. 56, 166.

The closing inventory shows that on September 10, 2018, the Respondent had 3,546 compounded capsules of hydromorphone 8 mg on hand and 574 compounded capsules of oxycodone 30 mg on hand. GX 7, p. 1. These capsules were sitting in a safe when they were counted. Tr. 56. Several thousand capsules sitting in a safe is not consistent with compounding for an individual patient's therapeutic needs as an incident to dispensing [nor is it consistent with anticipated prescriptions based on routine prescribing patterns as described in Florida law]. It is consistent with manufacturing capsules in bulk and storing them until a prescription is presented.

The Respondent argues that no evidence of record proves that it ''produced significantly large quantities of any drug.'' Resp't PHB, at 41. Whether the 4,120 capsules stored in the Respondent's safe on September 10, 2018, constitutes a ''significantly large'' quantity is beside the point. Whether the Respondent produced a large or small amount of compounded capsules, however, is relative, and my finding on this allegation has nothing to do with the amount of capsules produced. [Omitted.] [48]

This is especially true when the Respondent typically filled only two to four prescriptions per day. Tr. 508. The rough math shows that four thousand compounded capsules could be enough for two weeks of dispensing. Considering that a month's supply of oxycodone would be roughly 112 tablets (GX 18, p. 6) and a month's supply of hydromorphone would be roughly 120 tablets (GX 44, p. 6), the Respondent had enough oxycodone capsules on hand to fill approximately 5 prescriptions and enough hydromorphone capsules on hand to fill about 29 prescriptions. Together, this would approximate the number of prescriptions the Respondent typically saw over the course of two weeks. This lends further support to my conclusion that the amount of compounded capsules the Respondent had on hand on September 10, 2018, is [more

*[L] Respondent argues in its Exceptions that it was permitted to compound under the definition of ''dispense'' in the CSA. Resp Exceptions, at 17–22. However, as the ALJ stated,

[u]nder the CSA, ''dispense'' means ''to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the *lawful order* of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or *compounding* necessary to prepare the substance for such delivery.'' 21 U.S.C. 802(10) (emphases added).

RD, at 105. Respondent has not demonstrated that there was a lawful order of a practitioner to prepare the substance for such delivery to fall under the definition of ''dispense.''

[45] [Text omitted where footnote was included.]

[46] [Text omitted where footnote was included.]

*[M] RD's discussion was relocated.

*[N] The RD contained an analysis of the FDCA requirements in rebuttal of Respondent's assertion, but declined to make a finding as to whether Respondent was in compliance. RD, at 107–09. As the RD noted, the FDCA does not have a direct impact on DEA's interpretation of the CSA manufacturing provision. *Id.*

*[O] Even if Florida law were controlling in this case, there is no evidence that Respondent's compounding was permissible under Florida law. Although Florida Law permits what the Respondent describes as ''anticipatory compounding,'' there are plain language restrictions in the regulation that require the preparation to be in anticipation of prescriptions. As described herein, the facts of this case contradict the Respondent's claim that its compounding was in compliance with this law. Respondent also cited to Fla. Admin. Code r. 64B16–27.700(1)(c) that permits ''the preparation of commercially available products from bulk when the prescribing practitioner has prescribed the compounded product on a per prescription basis,'' but the evidence shows that Respondent typically contacted the physicians for permission to substitute compounded capsules when the prescriptions were written for tablets. The Respondent has presented no evidence or argument to support that physicians were specifically prescribing the compounded product, which appears to be what is required by this section of Florida code. Furthermore, there is no evidence that this section, or the other section of the Florida code, permits the Respondent to compound without an individualized patient need in accordance with the usual course of professional practice.

[47] [Text omitted where footnote was included.]

*[P] RD's discussion was relocated.

[48] [Text omitted where footnote was included.]

consistent with manufacturing than dispensing compounding within the scope of the CSA.]

In addition to the closing inventory, the Government also points to statements made by Mr. Clement, Sr., in 2012. Gov't PHB, at 46. In May 2012, during execution of an administrative inspection warrant (AIW) at the Respondent pharmacy, TFO Shearer interviewed Mr. Clement, Sr., the Respondent's owner. Tr. 183. Mr. Clement, Sr., was not in custody at the time and was free to leave. *Id.* In the interview, Mr. Clement, Sr., told TFO Shearer about his process for manufacturing oxycodone and hydromorphone in capsules. Tr. 183–84. Mr. Clement, Sr., told TFO Shearer that he could buy a 100 gram bottle of oxycodone powder for $1,100, enough to manufacture about 6,000 dosage units. Tr. 185. Tablets of oxycodone purchased from commercial distributors cost roughly $2–$10 per pill. *Id.* In other words, $1,100 worth of powder could produce at least $12,000 worth of dosage units. Mr. Clement, Sr., told TFO Shearer that he manufactured thousands of capsules per batch because it was cost effective. Tr. 184–85. The batch records that TFO Shearer reviewed in 2012 documented that Mr. Clement, Sr., produced thousands of pills in each batch. *Id.* Mr. Clement, Sr., also told TFO Shearer that he persuaded patients to take capsules even if they did not want them because capsules have the same effect as tablets.[49] Tr. 185–86.

Although these statements were made in 2012, they demonstrate that the Respondent had a system in place to compound thousands of capsules at a time. Tr. 184–85. These statements also demonstrate that the Respondent's motive for mass-compounding thousands of capsules per batch was cost effectiveness, rather than patients' unique therapeutic needs. Tr. 184–86. These statements provide additional support to the conclusion that the Respondent's compounding was cost-driven rather than patient-driven, and that the Respondent was, therefore, manufacturing and not compounding as the CSA understands those terms.

The Government also points to the batch records obtained pursuant to the 2017 subpoena. Gov't PHB, at 46; Tr. 27. A batch record documents the production of a controlled substance and lists the ingredients in the controlled substance. Tr. 33. The batch record is created by the person who makes the substance. *Id.* The batch records indicate how many capsules were used in the production of each batch. Tr. 38, 40–41. The batch records in Government Exhibit 5 document the production of hydromorphone 8 mg. The batch records in Government Exhibit 6 document the production of oxycodone 30 mg. The hydromorphone batch records show that the Respondent ''compounded'' from 600 to 2,400 capsules per batch, with 1,200 capsules being the most frequently occurring quantity. *See generally* GX 5. The oxycodone batch records show that the Respondent ''compounded'' from 600 to 1,800 capsules per batch, with 1,200 capsules being the most frequently occurring quantity. *See generally* GX 6. These numbers are consistent with the number of compounded capsules found during the 2018 closing inventory and with Mr. Clement, Sr.'s, statements to TFO Shearer in 2012. [When viewed with the other facts,] these numbers are also consistent with manufacturing rather than [dispensing] compounding.

Furthermore, the Respondent's dispensing records also demonstrate that the patients for whom the Respondent compounded oxycodone and hydromorphone did not have valid therapeutic needs for compounded medication. Dr. Sullivan explained that the definition of compounding in the practice of pharmacy is to ''make[ ] a drug . . . from scratch, make it in a finished form from an unfinished form, to meet the individual, unique therapeutic needs of a patient.'' Tr. 230. Compounding would be necessary, he continued, if the patient had an allergy to the commercially available version or if the patient needed a unique dose or strength that was not available in the mass-produced product. Tr. 230–31. [Omitted. Dr. Sullivan also testified that the dosage units dispensed in GE–11, at 7, demonstrated that 90,179 dosage units of the compounded 8 milligram hydromorphone capsules. Tr. 248. He testified that ''[t]here cannot be that many patients that need to have compounded hydromorphone 8 milligram tablets to meet the unique therapeutic needs of the patient. In [his] opinion, that's manufacturing.'' Tr. 249; *see also* Tr. 250 (same for oxycodone).]

Dispensing records, however, show that the Respondent dispensed both commercially manufactured tablets and compounded capsules to the same patient. The fact that the Respondent dispensed both commercially available tablets and compounded capsules of the same controlled substances to the same patients indicates that the patients lacked ''unique therapeutic needs'' for the compounded version. Tr. 231, 256. For example, the Respondent dispensed seven prescriptions of oxycodone 30 mg tablets to patient A.G. from June 2017 to August 2018. ALJ Ex. 42, p. 11. During that same time period, the Respondent also dispensed to A.G. three prescriptions of oxycodone 30 mg compounded capsules. *Id.* A note dated March 13, 2017, in A.G.'s profile states that a doctor approved dispensing medication to A.G. in compounded capsules. GX 15, p. 1; ALJ Ex. 42, p. 13. After March 2017, however, the Respondent continued dispensing both tablets and compounded capsules to A.G. ALJ Ex. 42, p. 11. Thus, even if a doctor approved of A.G. taking compounded capsules, it was not for a therapeutic or medical reason because he continued to alternate between capsules and tablets. [Dr. Sullivan testified that nothing in the record demonstrated that there was a therapeutic need for the compounded medication. Tr. 258–59].

In another example, the Respondent dispensed both tablets and compounded capsules to patient R.G. to fill the same oxycodone prescription. GX 49; Tr. 325–26. Dr. Sullivan opined that R.G. clearly had no valid therapeutic need for compounded capsules since he also took the tablet form of the same drug. Tr. 326. Patient R.G. also received oxycodone in capsules on 15 occasions from June 2017 to September 2018, and in tablets on 2 occasions during the same time period. ALJ Ex. 42, p. 45. As Dr. Sullivan observed, the fact that the Respondent dispensed oxycodone to R.G. in both capsule and tablet forms, and dispensed capsules and tablets together on one occasion, demonstrates that the Respondent was not compounding for R.G. in response to a unique therapeutic need for compounded capsules. Tr. 325–26. Furthermore, no profile for any of the patients documents an allergy or other reason that would have necessitated compounded capsules. Tr. 339; GX 15, 20, 23, 26, 29, 32, 35, 38, 41, 47, 51.

Dr. Sullivan pointed out numerous other instances where the Respondent's dispensing history demonstrated that patients lacked legitimate therapeutic justification for compounded capsules. From January 2018 to December 2018, the Respondent dispensed compounded capsules of hydromorphone 8 mg to A.H. on eight occasions: January 4;

[49] While reliable hearsay statements may be admissible in these administrative proceedings, Mr. Clement, Sr.'s, statements to TFO Shearer in 2012 are not hearsay. They enjoy enhanced credibility as they would qualify as statements by a party opponent and would, therefore, be excluded from the definition of hearsay. Fed. R. Evid. 801(d)(2). [Respondent argues that this conversation was six or seven years ago and to rely on it would be arbitrary and capricious. Resp't Exceptions, at 3. This conversation lends further support for a finding that has other support in the record. Also, I note that Respondent did not refute this evidence through the testimony of Mr. Clement, Sr.]

February 15; March 5; April 3; May 2; August 16; September 11; and December 5. ALJ Ex. 42, pp. 15–16; GX 19; GX 21. The Respondent then dispensed tablets of hydromorphone 8 mg to A.H. on the following five occasions in 2019: January 22; February 15; February 27; March 14; and April 18. *Id.* The fact that the Respondent dispensed capsules of hydromorphone to A.H. on eight occasions in 2018 and then tablets of hydromorphone on five occasions in 2019 demonstrates that A.H. had no unique therapeutic justification that required the Respondent to compound hydromorphone capsules for him. Tr. 255–56, 258–59, 269.

Dr. Sullivan noted a lack of therapeutic justification to compound hydromorphone for B.S. since he received hydromorphone in both tablets and capsules. Tr. 274. From August 2017 to August 2018, the Respondent filled 12 hydromorphone prescriptions with compounded capsules for B.S.: August 22, 2017; September 27, 2017; October 18, 2017; November 15, 2017; December 12, 2017; January 4, 2018; January 29, 2018; February 28, 2018; March 26, 2018; April 23, 2018; May 22, 2018; and August 24, 2018. ALJ Ex. 42, p. 19; GX 24. On February 5, 2019, the Respondent filled a hydromorphone prescription for B.S. with tablets. ALJ Ex. 42, p. 20; GX 22. The fact that the Respondent dispensed hydromorphone tablets to B.S. in 2019 shows that B.S. had no unique therapeutic justification that required the Respondent to compound hydromorphone capsules for him on 12 occasions in 2017 and 2018. Tr. 255–56, 258–59, 269, 274.

The Respondent dispensed oxycodone capsules and tablets to C.R., indicating that there was no valid therapeutic reason for the Respondent to compound oxycodone capsules for her. Tr. 255–56, 258–59, 269, 274, 279–80. On July 19, 2017, and October 26, 2017, the Respondent filled oxycodone prescriptions for C.R. with compounded capsules. ALJ Ex. 42, p. 23; GX 27. The Respondent then filled four oxycodone prescriptions for C.R. with tablets: March 6, 2018; April 19, 2018; July 12, 2018; and August 28, 2018. *Id.*

Dr. Sullivan observed that J.M. alternated between tablets and capsules of oxycodone, demonstrating that there was no valid therapeutic need for the Respondent to compound oxycodone capsules for her. Tr. 290. First, the Respondent dispensed oxycodone tablets to J.M. on January 25, 2018, and then filled J.M.'s next oxycodone prescription with compounded capsules on March 1, 2018. ALJ Ex. 42, p. 30; GX 33; Tr. 290. The next month the Respondent switched back to oxycodone tablets on April 4, 2018, followed by oxycodone capsules on April 19, 2018, and then switched back again to tablets on May 16, 2018. *Id.* The fact that the Respondent alternated between dispensing oxycodone tablets and capsules to J.M. demonstrates that there was no valid therapeutic reason for the Respondent to compound oxycodone capsules for her. Tr. 255–56, 258–59, 269, 274, 279–80, 290.

Dr. Sullivan observed that the Respondent dispensed oxycodone tablets and compounded capsules to M.M. Tr. 295, 297. From June 2017 to August 2018, the Respondent filled 14 oxycodone prescriptions for M.M. with compounded capsules. Tr. 295, 297; ALJ Ex. 42, pp. 33–34; GX 34; GX 36. From January 2019 to April 2019, the Respondent filled five oxycodone prescriptions for M.M. with tablets. *Id.* The fact that the Respondent dispensed compounded oxycodone capsules to M.M. for over a year and then switched to dispensing oxycodone tablets to her for several months demonstrates that there was no valid medical reason for the Respondent to have compounded oxycodone for her. Tr. 255–56, 258–59, 269, 274, 279–80, 290, 295, 297.

Dr. Sullivan observed that the Respondent compounded hydromorphone capsules for N.B. without any apparent therapeutic justification. Tr. 302. From June 2017 to August 2018, the Respondent filled twelve hydromorphone prescriptions for N.B. with compounded capsules. ALJ Ex. 42, p. 37; GX 39.

Dr. Sullivan pointed out that the Respondent compounded hydromorphone capsules for R.B. without any apparent medical justification. Tr. 311, 319–20. From June 2017 to January 2019, the Respondent filled 14 hydromorphone prescriptions for R.B. with compounded capsules. GX 40; GX 43; ALJ Ex. 42, pp. 41–42. At least three of those prescriptions were originally written for tablets and were substituted for capsules by the Respondent. Tr. 319–20; GX 44, pp. 6–7. The Respondent then dispensed hydromorphone tablets to R.B. on three occasions from February to April 2019. ALJ Ex. 42, p. 42; GX 40. The fact that the Respondent dispensed tablets and capsules of hydromorphone to R.B., switching prescribed tablets to capsules, demonstrates that there was no valid therapeutic reason for the Respondent to compound hydromorphone for R.B. Tr. 311, 319–21.

Lastly, Dr. Sullivan noted that the Respondent compounded capsules of hydromorphone for R.L. without any apparent medical justification. Tr. 331; ALJ Ex. 42, p. 49; GX 52. From June 2017 to September 2018, the Respondent filled 14 hydromorphone prescriptions for R.L. with compounded capsules. *Id.*

[Contrary to the Respondent's contention, due to the credible and unrebutted testimony of the Government's expert witness, Respondent's compounding cannot fall into the CSA's exception to the definition of manufacturing ''in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice.'' *Q 21 U.S.C. 802(15). Dr. Sullivan's testimony was clear that the compounding here was outside the course of professional practice, because there was no individualized therapeutic need for the compounded capsules, as evidenced by the quantities dispensed and the alternating of compounded capsules and commercially available product and the lack of documentation or other support demonstrating any individualized need. Further, as described above, Respondent's reliance on Florida law is unavailing for many

*Q In finding that Respondent engaged in manufacturing, the ALJ relied primarily on a statutory interpretation of ''incident to'' and determined that the compounding in this case would not be considered ''incident to'' the dispensing. RD, at 103–06. I find that it is unnecessary to rely on a statutory interpretation of ''incident to'' in this case, because the evidence on the record clearly establishes that this compounding was not in the course of professional practice, which the statute states plainly is required for the exception to the manufacturing definition to apply. In analyzing this issue, the ALJ discussed the Agency's decision in *Wedgewood,* which clarifies that to use a dispensing registration for compounding the important consideration is that the compounding is ''for a specific patient on a patient by patient basis.'' *Id.* (citing *Wedgewood Village Pharm.,* 71 FR 16,593, 16,595 (2006)). It is noted that *Wedgewood* was appealed and remanded, based primarily on the Agency's interpretation of distribution—not manufacturing, *Wedgewood Village Pharmacy* v. *DEA,* 509 F.3d 541, 550–52 (D.C. Cir. 2007) and therefore, that the Agency's interpretation in *Wedgewood* regarding what constitutes manufacturing remains intact; however, I also find it unnecessary to rely on prior Agency interpretation in this case, because, again, the statute is clear regarding the requirement that such compounding must be in the course of professional practice. My conclusions rely on Dr. Sullivan's testimony that patients must have a specific need for compounded capsules and other support in the record that the usual course of professional practice requires such a need. As discussed in more detail herein, the record does not demonstrate that Respondent's customers had individualized needs. The RD also provided examples where courts, including the Supreme Court, have defined the term ''compounding'' to require individualized patient need. RD, at 105, n.45, and 116. Although not in the context of the CSA, these interpretations further support Dr. Sullivan's credible and unrebutted testimony regarding the course of the professional practice and the lack of individualized need for compounded capsules in this case.

reasons. Although Florida law permits compounding based on routine, regularly observed prescribing patterns, there is nothing in Florida law to suggest that this anticipation would negate the professional practice of pharmacy requirement for there to be individualized therapeutic need, which the record has repeatedly demonstrated was lacking with regard to these compounded capsules.*[R] *See* Fla. Admin. Code r. 64B16–27.700(1)(a).]

In sum, the evidence paints a picture of a pharmacy mass-compounding bulk quantities of oxycodone and hydromorphone in thousands of capsules per batch. The evidence further reveals the Respondent's motive for doing so: Profit rather than patient need. The evidence shows that the Respondent's ''compounding'' was not incidental to the act of dispensing and was not in the course of its professional practice. [Omitted]. Thus, the Respondent engaged in manufacturing thousands of controlled substance dosages over a period of several years without the proper registration. For these reasons, the Government's allegation that the Respondent illegally manufactured controlled substances is SUSTAINED. ALJ Ex. 1, pp. 8–10, ¶ 20–28. [Although I find that this constitutes a separate violation of federal law, which I consider under Factor Four below, I also find that there is more than enough evidence of other violations in this case to support a sanction of revocation, even if I had not sustained this allegation.]

*Government's Burden of Proof and Establishment of a Prima Facie Case*

[In order to make a *prima facie* case that a ground for revocation of Respondent's registration exists, the Government must demonstrate that Respondent's continued registration is inconsistent with the public interest]. [Text omitted for clarity.].

Public Interest Determination: The Standard

Pursuant to 21 U.S.C. 823(a)(4) (2006 & Supp. III 2010), the Administrator[50] may revoke a DEA Certificate of Registration if the Registrant has committed such acts as would render its registration inconsistent with the public interest. Evaluation of the following factors have been mandated by Congress in determining whether maintaining such registration would be inconsistent with ''the public interest'':

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The [registrant's] experience in dispensing, or conducting research with respect to controlled substances.

(3) The [registrant's] conviction record under Federal or State laws relating to the manufacture, 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). Any one or a combination of factors may be relied upon, and when exercising authority as an impartial adjudicator, the Agency may properly give each factor whatever weight it deems appropriate in determining whether a registrant's registration should be revoked. *Id.* (citation omitted); *David H. Gillis, M.D.,* 58 FR 37,507, 37,508 (1993); *see also Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005); *Henry J. Schwarz, Jr., M.D.,* 54 FR 16,422, 16,424 (1989). Moreover, the Agency is ''not required to make findings as to all of the factors,'' *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *see also Morall,* 412 F.3d at 173, and is not required to discuss consideration of each factor in equal detail, or even every factor in any given level of detail. *Trawick* v. *DEA,* 861 F.2d 72, 76 (4th Cir. 1988) (holding that the Administrator's obligation to explain the decision rationale may be satisfied even if only minimal consideration is given to the relevant factors, and that remand is required only when it is unclear whether the relevant factors were considered at all). The balancing of the public interest factors ''is not a contest in which score is kept; 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.'' *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009).

*Factors Two and Four: Experience in Dispensing, and Compliance With Applicable State, Federal, or Local Laws Relating to Controlled Substances*

The Government seeks the revocation of the Respondent's COR based primarily on conduct most appropriately considered under Public Interest Factors Two and Four.[51] The Government has also raised one allegation under Factor Five.

[Factors Two and Four are often analyzed together. *See, e.g., Fred Samimi, M.D.,* 79 FR 18,698, 18,709 (2014); *John V. Scalera, M.D.,* 78 FR 12,092, 12,098 (2013). Under Factor Two, the DEA analyzes a registrant's ''experience in dispensing . . . controlled substances.'' 21 U.S.C. 823(f)(2). Factor Two analysis focuses on an applicant's acts that are inconsistent with the public interest, rather than on an applicant's neutral or positive acts and experience. *Randall L. Wolff, M.D.,* 77 FR 5106, 5121 n.25 (2012) (explaining that ''every registrant can undoubtedly point to an extensive body of legitimate prescribing over the course of [the registrant's] professional career'') (quoting *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 463 (2009)). Similarly, under Factor Four, the DEA analyzes an applicant's compliance with federal and state controlled substance laws. 21 U.S.C. 823(f)(4). Factor Four analysis focuses on violations of state and federal laws and regulations. *Volkman* v. *DEA,* 567 F.3d 215, 223–24 (6th Cir. 2009) (citing *Gonzales* v. *Oregon,* 546 U.S. 243, 272, 274 (2006)); *see Joseph Gaudio, M.D.,* 74 FR 10,083, 10,090–91 (2009).] *[S] [52]

*Standard of Care as to Charged Violations* *[T]

[According to the CSA's implementing regulations, ''[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice.'' 21 CFR 1306.06.

*[R] Although stated in a different context, there is further support for this finding in *Department of Health, Petitioner* v. *Discovery Experimental and Development, Inc., Respondent Discovery Experimental and Development, Inc., Petitioner,* 2003 WL 1921003 (April 18, 2003), where a Florida Administrative Law Judge stated that Fla. Admin. Code r. 64B16–27.700 ''requires patient specific compounding of medicinal drugs, on a per prescription basis where there is an established patient-physician relationship, and the patient has been made aware that a pharmacist will prepare the compounded drug.'' *Id.* at n.14). Although the portion of the Florida regulation cited to by Respondent would permit advance preparation of compounded drugs under state law, there is no evidence that Florida intended it to permit a pharmacy to compound drugs without a specific therapeutic need. In fact, the Government's expert opined that such compounding is not within the course of professional practice of pharmacy, and in his opinion, constitutes manufacturing.

[50] This authority has been delegated pursuant to 28 CFR 0.100(b) and 0.104 (2008).

[51] 21 U.S.C. 823(f)(2), (4). There is nothing in the record to suggest that a state licensing board made any recommendation regarding the disposition of the Respondent's DEA COR (Factor One). Likewise, the record contains no evidence that the Respondent has been convicted of (or charged with) a crime related to controlled substances (Factor Three).

*[S] For brevity and keeping with recent cases, I have removed the RD's legal analysis of Factors Two and Four and replaced it with this text.

[52] [Text omitted where footnote was included.]

*[T] This section was modified to clarify the analysis of a pharmacist's corresponding responsibility under 21 CFR 1306.04(a).

Further, a controlled substance prescription must be ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). While the ''responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner . . . a corresponding responsibility rests with the pharmacist who fills the prescription.'' *Id.* The regulations establish the parameters of the pharmacy's corresponding responsibility.

> An order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of . . . 21 U.S.C. 829 . . . and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

*Id.* ''The language in 21 CFR 1306.04 and caselaw could not be more explicit. A pharmacist has his own responsibility to ensure that controlled substances are not dispensed for non-medical reasons.'' *Ralph J. Bertolino, d/b/a Ralph J. Bertolino Pharmacy,* 55 FR 4729, 4730 (1990) (citing *United States* v. *Hayes,* 595 F.2d 258 (5th Cir. 1979), *cert. denied,* 444 U.S. 866 (1979); *United States* v. *Henry,* 727 F.2d 1373 (5th Cir. 1984) (reversed on other grounds)). As the Supreme Court explained in the context of the CSA's requirement that schedule II controlled substances may be dispensed only by written prescription, ''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).

To prove a pharmacist violated his or her corresponding responsibility, the Government must show that the pharmacist acted with the requisite degree of scienter. *See* 21 CFR 1306.04(a) (''[T]he person *knowingly* filling [a prescription issued not in the usual course of professional treatment] . . . shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.'') (emphasis added). DEA has also consistently interpreted the corresponding responsibility regulation such that ''[w]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid [actual] knowledge of the real purpose of the prescription.'' *Bertolino,* 55 FR 4730 (citations omitted); *see also JM Pharmacy Group, Inc. d/b/a Pharmacia Nueva and Best Pharmacy Corp.,* 80 FR 28,667, 28,670–72 (2015) (applying the standard of willful blindness in assessing whether a pharmacist acted with the requisite scienter). Pursuant to their corresponding responsibility, pharmacists must exercise ''common sense and professional judgment'' when filling a prescription issued by a physician. *Bertolino,* 55 FR 4730. When a pharmacist's suspicions are aroused by a red flag, the pharmacist must question the prescription and, if unable to resolve the red flag, refuse to fill the prescription. *Id.; Medicine Shoppe-Jonesborough,* 300 F. App'x 409, 412 (6th Cir. 2008) (''When pharmacists' suspicions are aroused as reasonable professionals, they must at least verify the prescription's propriety, and if not satisfied by the answer they must refuse to dispense.'').

Finally, ''[t]he corresponding responsibility to ensure the dispensing of valid prescriptions extends to the pharmacy itself.'' *Holiday CVS,* 77 FR 62,341 (citing *Med. Shoppe—Jonesborough,* 73 FR 384; *United Prescription Servs., Inc.,* 72 FR 50,397, 50,407–08 (2007); *EZRX, L.L.C.,* 69 FR 63,178, 63,181 (2004); *Role of Authorized Agents in Communicating Controlled Substance Prescriptions to Pharmacies,* 75 FR 61,613, 61,617 (2010); *Issuance of Multiple Prescriptions for Schedule II Controlled Substances,* 72 FR 64,921, 64,924 (2007) (other citations omitted)). The DEA has consistently held that the registration of a pharmacy may be revoked as the result of the unlawful activity of the pharmacy's owners, majority shareholders, officers, managing pharmacist, or other key employee. *EZRX, L.L.C.,* 69 FR 63,181; *Plaza Pharmacy,* 53 FR 36,910, 36,911 (1988). Similarly, ''[k]nowledge obtained by the pharmacists and other employees acting within the scope of their employment may be imputed to the pharmacy itself.'' *Holiday CVS,* 77 FR 62,341.

In this matter, the Government did not allege that Respondent dispensed the prescriptions at issue having actual knowledge that the prescriptions lacked a legitimate medical purpose. Instead, the Government alleged that Respondent violated its corresponding responsibility by filling prescriptions that raised red flags that were so strongly indicative of drug abuse and diversion that they could not have been resolved by a pharmacist acting in the usual course of professional practice. ALJ Ex. 1, pp. 4–7. Agency decisions have consistently found that prescriptions with similar red flags were so suspicious as to support a finding that the pharmacists who filled them violated their corresponding responsibility because they had actual knowledge of, or were willfully blind to, the prescriptions' illegitimacy.*[U] Additionally, DEA has consistently held, based on the credible testimony of pharmacy experts, that prescriptions may raise red flags that are so strongly indicative of diversion that they cannot be resolved by a pharmacist acting within the usual course of professional practice, and should not be filled.*[V] DEA has also held that a pharmacist who fills prescriptions that present unresolvable red flags engages in knowing diversion of controlled substances.*[W]]

[Text omitted for brevity.]*[X]

The Government has introduced a preponderance of evidence to prove that the Respondent dispensed numerous controlled substance prescriptions for at least eleven patients that raised red flags of drug abuse and/or diversion. These

*[U] *See, e.g., Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy,* 83 FR 10,876, 10,898, *pet. for rev. denied,* 789 F. App'x 724 (11th Cir. 2019) (long distances; pattern prescribing; customers with the same street address presenting the same prescriptions on the same day; drug cocktails; cash payments; early refills); *Hills Pharmacy,* 81 FR 49,816, 49,836–39 (2016) (multiple customers presenting prescriptions written by the same prescriber for the same drugs in the same quantities; customers with the same last name and street address presenting similar prescriptions on the same day; long distances; drug cocktails); *The Medicine Shoppe,* 79 FR 59,504, 59,507, 59,512–13 (2014) (unusually large quantity of a controlled substance; pattern prescribing; irregular dosing instructions; drug cocktails); *Holiday CVS,* 77 FR 62,316, 62,317–22 (2012) (long distances; multiple customers presenting prescriptions written by the same prescriber for the same drugs in the same quantities; customers with the same last name and street address presenting virtually the same prescriptions within a short time span; payment by cash); *East Main Street Pharmacy,* 75 FR 66,149, 66,163–65 (2010) (long distances; lack of individualized therapy or dosing; drug cocktails; early fills/refills; other pharmacies' refusals to fill the prescriptions).

*[V] *See, e.g., Pharmacy Doctors Enterprises,* 83 FR 10,286, 10,888 (2018) (crediting expert testimony that certain red flags were ''not resolvable''); *The Medicine Shoppe,* 79 FR 59,504, 59,507–08 (2014) (same); *Holiday CVS, LLC,* 77 FR 62,316, 62,319 (2012) (same); *cf. Edge Pharmacy,* 81 FR 72,092, 72,112 n.54 (2016) (noting that ''many of the prescriptions presented unresolvable red flags'').

*[W] *The Medicine Shoppe,* 79 FR at n.10.

*[X] I have omitted, for brevity, text regarding the legal standard requiring a nexus between the state laws that have been violated and the CSA's purpose of preventing drug abuse and diversion. I find that the Florida laws in this case are sufficiently related to controlled substances to be considered in my public interest analysis, and that my consideration of these state law violations bears a rational relationship to the core purpose of the CSA. *See Salman Akbar, M.D.,* 86 FR 52,181, 52,194–95 (2021) (citing 21 U.S.C. 823(a)(4); *Judulang* v. *Holder,* 556 U.S. 42, 63 (2011)).

red flags included early fills, long distances traveled, cash payments, dangerous drug cocktails, and high-strength narcotics, among others. [Dr. Sullivan offered credible and unrebutted testimony that these red flags could not have been resolved by a reasonable pharmacist acting within the usual course of his professional practice. Therefore, I find that the Respondent filled prescriptions for controlled substances that the pharmacists knew were not prescribed for legitimate medical purposes, or were willfully blind to such, in violation of their corresponding responsibility under 21 CFR 1306.04(a) and outside the usual course of professional practice in violation of 21 CFR 1306.06.*[Y]

Further, the Government introduced evidence that Respondent violated Florida law by repeatedly filling prescriptions that raised unresolvable red flags. Florida law and the Florida standard of care require a pharmacist to conduct a prospective drug use review before dispensing a controlled substance. Tr. 211, 227–28; Fla. Admin. Code r. 64B16–27.810. This includes ''review[ing] the patient record and each new and refill prescription presented for dispensing'' to identify, among other things, ''[o]ver-utilization or under-utilization,'' ''[t]herapeutic duplication,'' ''drug-drug interactions,'' and ''[c]linical abuse/misuse.'' Fla. Admin. Code r. 64B16–27.810. After conducting this review, the pharmacist must ''take appropriate steps to avoid or resolve the potential problems.'' *Id.* The purpose of the prospective drug use review is to identify red flags that require resolution before dispensing a controlled substance. Tr. 207–08, 211. Additionally, Florida law requires pharmacists to ''exercise[ ] sound professional judgment,'' review each prescription ''with each patient's unique situation in mind,'' and ''attempt to work with the patient and the prescriber to assist in determining the validity of the prescription.'' Fla. Admin. Code r. 64B16–27.831.

Respondent violated Fla. Admin. Code rs. 64B16–27.810 and 64B16–27.831 by repeatedly filling prescriptions that presented unresolvable red flags. Based on Dr. Sullivan's credible expert testimony, as supported by Florida law and prior Agency Decisions, a pharmacist acting in accordance with Florida law would have declined to fill these prescriptions after conducting a prospective drug use review.]

The Respondent failed to rebut or discredit the Government's case. The Respondent did not introduce any documentary evidence and it only offered the testimony of a single witness, who failed to convincingly rebut the Government's evidence. In light of the record as to this factor, I find that the Government has overwhelmingly proven that the Respondent failed to comply with federal and state law with respect to its corresponding responsibility for the prescriptions in evidence.

Furthermore, I find that the Government has sponsored a preponderance of evidence to show that the Respondent engaged in unlawful manufacturing of controlled substances without the proper DEA registration, in violation of 21 U.S.C. 841(a)(1) and 21 CFR 1301.13(e). Thus, the Government has introduced evidence against the Respondent with respect to two aspects of the controlled drug supply chain, dispensing and manufacturing. The totality of this evidence demonstrates a concerning lack of compliance with applicable federal and state law that poses a significant risk of diversion and threatens public health and safety. This evidence further demonstrates a lack of commitment on the Respondent's part with respect to its federal and state controlled substance obligations. Therefore, I find that this factor significantly favors revoking the Respondent's registration.*[Z]

[Section omitted for brevity and relevance.] *[AA] [53] [54]

*[Y] I have omitted the RD's discussion of Respondent's efforts (or lack thereof) to document a resolution of the red flags in this case.

*[Z] As found herein, there is substantial record evidence that Respondent dispensed controlled substances prescriptions outside the usual course of the professional practice in Florida and in violation of its corresponding responsibility and in violation of state law. There is also substantial record evidence that Respondent manufactured controlled substances outside the usual course of professional practice and without the proper registration. I, therefore, have concluded that Respondent engaged in misconduct that supports a determination that its registration is inconsistent with the public interest. *See Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy,* 83 FR 10,876, 10,903 (2018).

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). At the time the Government issued the OSC, the Government had clear evidence that Respondent repeatedly filled prescriptions that presented a combination of red flags that could not have been resolved by a pharmacist acting in the usual course of professional practice, which 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.*

*[AA] The Government argued that I should consider under Factor Five that ''Respondent's business consisted almost entirely of dispensing controlled substances to customers who exhibited one or more significant red flags.'' Gov't Posthearing, at 39–40. The ALJ declined to consider this conduct under Factor Five. RD, at 130–31. I find that the Government has provided substantial evidence related to Factors Two and Four to support my finding that Respondent's continued registration is inconsistent with the public interest and that the appropriate remedy in this case is revocation. Therefore, I decline to consider the Government's evidence under Factor Five.

[53] [Text omitted where footnote was included.]

[54] [Text omitted where footnote was included.]

*[BB] This sentence was relocated for clarity, and text was omitted for brevity.

*Acceptance of Responsibility*

With the Government's *prima facie* burden having been met, the Respondent must present sufficient mitigating evidence to assure the Administrator that it can be entrusted with the responsibility incumbent with such registration. *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008); *Samuel S. Jackson,* 72 FR 23,848, 23,853 (2007).*[BB] As past performance is the best predictor of future performance, DEA has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for its actions and demonstrate that it will not engage in future misconduct. *ALRA Labs, Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995); *Medicine Shoppe,* 73 FR 387; *see also Hoxie* v. *DEA,* 419 F.3d 477, 483 (6th Cir. 2005) (reasoning that ''admitting fault'' is ''properly consider[ed]'' by DEA to be an ''important factor[]'' in the public interest determination). Likewise, in making the public interest determination, ''this Agency places great weight on a registrant's candor, both during an investigation and in [a] subsequent proceeding.'' *Robert F. Hunt,* 75 FR 49,995, 50,004 (2010); *Hoxie,* 419 F.3d at 483.

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 62,316, 62,346 (2012); *Daniel A. Glick, D.D.S.,* 80 FR 74,800, 74,801 (2015).

The Respondent has not unequivocally accepted responsibility for the proven violations. In fact, the Respondent has not tendered any acceptance of responsibility at all, whether equivocal or unequivocal. The Respondent's owner and pharmacist-in-charge never testified at the hearing in order to accept responsibility. Instead, the Respondent's sole witness, a pharmacy tech, never admitted that the Respondent committed any wrongdoing. The Respondent's post-hearing brief is silent on this issue. Resp't PHB, p. 29, ¶ (i); p. 32, ¶ (ii); p. 36, ¶ (iii). [In its

opening statement, Respondent previewed its failure to accept responsibility]. Respondent argued that the Government had failed to satisfy its burden; accused the DEA of never intending to clearly or objectively evaluate the evidence; attacked the credentials of the Government's expert; claimed that the Respondent exercised appropriate judgment when dispensing the relevant controlled substance prescriptions in compliance with Florida law; and complained about the so-called ''ivory tower aspirational'' standard the DEA is imposing on its conduct. Tr. 503–05. In other words, the message from the Respondent's post-hearing brief and its opening statement is that it has done nothing wrong. These sentiments are inconsistent with a registrant that is remorseful for misconduct and determined to regain the Agency's trust. By failing to accept responsibility, the Respondent has failed to overcome the Government's *prima facie* case. In addition to failing to accept responsibility, the Respondent has also failed to offer any evidence of remediation.

*Egregiousness and Deterrence*

*[CC] The egregiousness and extent of an applicant's misconduct are significant factors in determining the appropriate sanction. *See Jacobo Dreszer,* 76 FR 19,386, 19,387–88 (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. Volkman,* 73 FR 30,630, 30,644 (2008); *see also Gregory D. Owens,* 74 FR 36,751, 36,757 n.22 (2009). [Likewise, DEA considers its interest in deterring future misconduct by both the registrant as well as other registrants. *David A. Ruben, M.D.,* 78 FR 38363, 38364 (2013).]

I find that the proven misconduct is egregious and that deterrence considerations weigh in favor of revocation. The proven misconduct involves repeated instances of dispensing high-strength schedule II controlled substances despite the presence of well-known signs of drug abuse and diversion. The proven misconduct also involves repeat instances of failing to follow state law and state standards of practice [by filling prescriptions that presented unresolvable red flags].*[DD] Respondent repeatedly dispensed high-strength schedule II opioids, sometimes dangerously combined with high-strength benzodiazepines, to patients who raised multiple red flags of diversion. [These red flags included paying in cash, filling prescriptions early, filling dangerous combinations of high-strength narcotics and benzodiazepines, and traveling between two and five hundred miles round trip to Respondent. The Government's expert credibly testified that the rationales that the patients offered for traveling such extraordinary distances should have concerned the pharmacists. Patient A.G. wrote on his questionnaire that he traveled two hundred and eighty miles roundtrip for ''quick and good service,'' GX 18; and Patient R.B. wrote that she traveled the same distance because ''[i]t's cheaper and [she has] found that they are good people.'' GX 44, at 1. Dr. Sullivan testified that the red flags raised by these prescriptions were so strongly indicative of drug abuse and diversion that a pharmacist acting in the usual course of professional practice would not have filled them. Respondent's decision to repeatedly turn a blind eye to these red flags] constitutes egregious misconduct because it allowed for the potential of unchecked diversion of controlled substances into illegitimate channels.

[Omitted for brevity.] *[EE]

In addition to the severity of the Respondent's dispensing misconduct, the Respondent also unlawfully manufactured thousands of capsules of schedule II controlled substances without being registered with the DEA as a manufacturer. As noted earlier, registered manufacturers of controlled substances are held to higher standards than practitioners with respect to recordkeeping, reporting, security, and frequency of renewing registration. Thus, manufacturing controlled substances without the DEA's blessing enabled the Respondent to produce thousands of dosage units of controlled substances over several years in the absence of regulatory monitoring. As with unlawful dispensing, unlawful manufacturing is an egregious violation and warrants the revocation of registration.

I further find that deterrence considerations weigh in favor of revocation. Allowing the Respondent to retain its COR despite the proven misconduct would send the wrong message to the regulated community. Imposing a sanction less than revocation would create the impression that registrants can maintain DEA registration despite repeatedly [ignoring glaring red flags of drug abuse and diversion], and despite engaging in a regulated activity without obtaining approval from the DEA to engage in that activity. Revoking the Respondent's COR communicates to registrants that the DEA takes all failings under the CSA seriously and that severe violations will result in severe sanctions.

*Advice of Counsel*

When the DEA executed an AIW at the Respondent in September 2018, the Respondent's owner and pharmacist-in-charge, Mr. Clement, Sr., refused to speak to DI Albert upon advice of counsel to not answer any questions. Tr. 168, 173, 177. The Respondent has an absolute right to seek advice of counsel, and no adverse inference from obtaining advice of counsel may be drawn. It does not provide, however, any defense to actions taken, including failing to eventually respond to DEA inquiries following consultation with counsel, or lack of cooperation with the DEA's investigation.

*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 Administrator that he can be entrusted with the responsibility commensurate with such a registration. *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008).

There is no evidence that suggests the Respondent has learned any lessons from its misconduct. As just discussed, the Respondent does not appear to believe it has done anything wrong. [Text omitted for clarity.] The Respondent's failure to accept responsibly and present remediation evidence has convinced this Tribunal that the DEA cannot trust Respondent with the obligations of a DEA registration. [Omitted for relevance.] *[FF]

*[CC] Omitted for brevity.

*[DD] Paragraph modified for consistency with my finding that the prescriptions in this case presented a combination of red flags that could not have been resolved by a pharmacist acting in the usual course of professional practice.

*[EE] I have omitted, for brevity, the RD's statements that revocation is the appropriate remedy notwithstanding the lack of evidence related to Factors One, Three, and Five. As discussed in more detail above, the Agency is ''not required to make findings as to all of the factors,'' *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *see also Morall,* 412 F.3d at 173, and is not required to discuss consideration of each factor in equal detail, or even every factor in any given level of detail. *Trawick* v. *DEA,* 861 F.2d 72, 76 (4th Cir. 1988).

*[FF] I have omitted the ALJ's discussion of Respondent's failure to cooperate with DEA investigators during inspections. Although cooperation with law enforcement can be relevant to sanction determinations, it is not necessary for me to consider this evidence in this case. I find that revocation is the appropriate remedy based on the

**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. Furthermore, I find that the Respondent has not accepted responsibility, or presented sufficient evidence demonstrating that the Agency can entrust it with a COR.

Therefore, I recommend that the Respondent's DEA COR No. FP2302076 should be *revoked,* and that any pending applications for modification or renewal of the existing registration, and any applications for additional registrations, be *denied.*

Signed: May 5, 2020.

**Mark M. Dowd,**

*U.S. Administrative Law Judge*

*The Respondent's Exceptions* *[GG]

On May 26, 2020, Respondent filed its exceptions to the Recommended Decision. DEA regulations require that Exceptions ''include a statement of supporting reasons for such exceptions, together with evidence of record (including specific and complete citations of the pages of the transcript and exhibits) and citations of the authorities relied upon.'' 21 CFR 1316.66. For the most part, Respondent's Exceptions not only fail to comply with this regulatory requirement, but they also lack evidentiary support in the Administrative Record. Additionally, some of Respondent's Exceptions repeat arguments that were already raised in Respondent's Posthearing Brief, and were adequately addressed by the ALJ in the adopted Recommended Decision.

Exceptions #1 and 2

In the first two Exceptions, Respondent argues that the ALJ erred in concluding that approximately thirty of the documents that the Government admitted into evidence were accurate and reliable. Resp Exceptions, at 5–8. These documents consist of: (1) Dispensing data, prescription records, and other patient records that DEA downloaded from Respondent's computers during the September 2018 AIW; and (2) dispensing data that DEA obtained from Florida's controlled substance dispensing database, E–FORSCE. *Id.* Because all of these records were generated by Respondent, and Respondent has not identified any specific concerns with the accuracy of these records, I find that these Exceptions are without merit.

The only record evidence that Respondent identifies as potentially undercutting the reliability of these records is Mr. Clement, Jr.'s testimony that Respondent's computers were inoperable when DEA returned them after the search warrant was executed in August of 2019, which precluded Respondent from confirming the accuracy of the records that DEA downloaded. Resp Exceptions, at 6–7 (citing Tr. 515, 517–18). Respondent also argues that DEA did not present ''sufficient evidence to prove the accuracy or reliability of the[se] records,'' because DI—who laid the foundation for each document—did not download the records from Respondent's computers himself, and therefore could not attest to whether any errors were made when the records were extracted.*[HH] *Id.* at 5–6 (citing Tr. 62–65, 134–36).

Respondent, however, has not identified any inconsistencies or errors in the documents that would cause me to question their reliability. For example, Respondent has not identified any particular prescriptions that it believes it did not dispense, or patients to whom it did not dispense.*[II] Moreover, Respondent has not identified any discrepancies between the E–FORSCE dispensing records, which DEA obtained directly from E–FORSCE, and the dispensing records that DEA downloaded from Respondent's computers. It is reasonable for DEA to rely on these records as evidence of Respondent's dispensing, because these are all records that Respondent is required to generate under Florida *[JJ] and federal law.*[KK]

Exception #3

Respondent next argues that the RD's conclusion that Florida law and the Florida standard of care require pharmacists to document the resolution of red flags ''was based upon a clear error of law, and thus arbitrary and capricious.'' Resp Exceptions, at 8–17. Respondent argues that the RD's conclusion that Respondent violated 21 CFR 1306.04(a) and 1306.06 was dependent on his erroneous conclusion that Florida law requires documentation, and therefore, Respondent argues that these conclusions should be overturned. *Id.*

I do not need to address this Exception because I have concluded above, based on Dr. Sullivan's credible and unrebutted expert testimony, that the prescriptions that Respondent dispensed raised red flags that could not have been resolved by a pharmacist acting within the usual course of professional practice. I have also concluded that, by filling these prescriptions, Respondent violated its corresponding responsibility because the pharmacists knew these controlled substances were not prescribed for

egregiousness of Respondent's conduct and its failure to accept responsibility.

*[GG] Jack Folson, Jr., who identifies himself as a clinical pharmacist in Westland, Michigan, filed a document on June 9, 2020, titled Amicus Brief Concerning the Standard of Practice in Pharmacy, Law and Decision of the Administrative Law Judge. Mr. Folson states that Respondent retained him to review the trial transcript and the RD, and he outlines his disagreements with the RD and Dr. Sullivan's testimony. The ALJ issued an Order Regarding Respondent's Amicus Brief on June 10, 2020. Order, at 1. The Order stated that Respondent had already filed the one set of exceptions it was entitled to file, and that the Amicus Brief was essentially a second set of exceptions that was filed after the May 26, 2020 deadline. *Id.* The ALJ also noted that the Amicus Brief repeatedly cites to materials outside of the record and includes unsworn expert testimony. *Id.* at 2. I agree with the RD's conclusion that the Amicus Brief is a set of untimely exceptions that is not permitted by the agency's adjudicative process. *Id.* at 2. Further the Brief presented evidence that was not on the record of the hearing, which I cannot consider, because doing so would, among other things, deprive the Government of an opportunity to address Respondent's representations and prevent a full credibility assessment. *See Lisa Hamilton,* 84 FR 71,465, 71,466 n.3 (2019). Therefore, I do not consider the Amicus Brief in my Decision.

*[HH] Respondent also argues that the Government did not adequately authenticate these records, but Respondent waived this objection by failing to raise it in writing prior to the hearing and failing to show good cause for not raising it prior to the hearing. *See* 21 CFR 1316.59; *see also* Tr. 64–68. Moreover, Respondent has not raised any noteworthy objections to the authenticity of these records.

*[II] The one error that Respondent identifies in the PDMP data does little to undercut the reliability of the PDMP data, and in fact, it elucidates the suspicious nature of Respondent's dispensing. Resp Exceptions, at 7 (citing RD, at 86 n.36). The PDMP indicates that Respondent prescribed a 120-day supply of hydromorphone to Patient R.B. in September 2018, when in fact the prescription was for a 30-day supply. RD, at 86 n.36. This PDMP error highlights an unexplained lapse in Patient R.B.'s opioid prescriptions, because this patient did not fill another hydromorphone prescription for four months after receiving the 30-day supply. *Id.*

In questioning the PDMP data, Respondent also states that ''the Government's own expert acknowledged that there are errors in the PDMP data.'' Resp Exceptions, at 7. Respondent cites to Dr. Sullivan's testimony—in response to the question of whether he has ''ever encountered . . . a data entry error'' in the PDMP—that he ''know[s] that there are data entry errors in the PDMP. Potential errors.'' *Id.* This testimony is not specific enough to undermine the reliability of the PDMP data, especially because Respondent is required by state law to accurately report each controlled substance that it dispenses to E–FORSCE. *See* Fla. Stat. § 893.055(3)(a) (2019) (requiring certain information to be reported to E–FORSCE each time a controlled substance is dispensed, including the date the prescription was filled; the patient's name and other identifying information; and the name, quantity, and strength of the controlled substance dispensed).

*[JJ] *See* Fla. Stat. § 893.055(3)(a).

*[KK] *See generally* 21 CFR 1304.04; *see also* Tr. 492 (DI's testimony that pharmacists must keep accurate dispensing logs).

legitimate medical purposes, or were willfully blind to such, in violation of their corresponding responsibility under 21 CFR 1306.04(a), and Respondent dispensed controlled substances outside the usual course of professional practice, in violation of 21 CFR 1306.04(a) and 1306.06. Because the red flags were unresolvable, I find that it is irrelevant whether Respondent took adequate steps under Florida law to document any attempts to resolve the red flags.

Exception #4

Respondent's final Exception restates, nearly verbatim, arguments that it made in its Posthearing brief. *Compare* Resp Exceptions, at 17–21 *with* Resp Posthearing, at 36–41. I find that the RD adequately addresses these arguments, and I agree with the RD's conclusion that Respondent engaged in illegal manufacturing. I therefore find that this Exception is without merit.

**Order**

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(f), I hereby revoke DEA Certificate of Registration No. FP2302076 issued to Pronto Pharmacy, LLC. Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(f), I further hereby deny any pending applications for renewal or modification of this registration, as well as any other pending application of Pronto Pharmacy, LLC for registration in Florida. Pursuant to the authority vested in me by 21 U.S.C. 824(f), as well as 28 CFR 0.100(b), I further order that all controlled substances seized pursuant to the Order of Immediate Suspension of Registration are forfeited to the United States. This Order is effective December 20, 2021.

**Anne Milgram,**

*Administrator.*

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Part V

## Department of Commerce

Bureau of Industry and Security

Publication of a Report on the Effect of Imports of Vanadium on the National Security: An Investigation Conducted Under Section 232 of the Trade Expansion Act of 1962, as Amended; Notice

**DEPARTMENT OF COMMERCE**

**Bureau of Industry and Security**

**RIN 0694–XC079**

## Publication of a Report on the Effect of Imports of Vanadium on the National Security: An Investigation Conducted Under Section 232 of the Trade Expansion Act of 1962, as Amended

**AGENCY:** Bureau of Industry and Security, Commerce.

**ACTION:** Publication of a report.

**SUMMARY:** The Bureau of Industry and Security (BIS) in this notice is publishing a report that summarizes the findings of an investigation conducted by the U.S. Department of Commerce (the ''Department'') pursuant to Section 232 of the Trade Expansion Act of 1962, as amended (''Section 232''), into the effect of imports of vanadium on the national security of the United States. This report was completed on February 22, 2021 and posted on the BIS website in July 2021. BIS has not published the appendices to the report in this notification of report findings, but they are available online at the BIS website, along with the rest of the report (*see* the **ADDRESSES** section).

**DATES:** The report was completed on February 22, 2021. The report was posted on the BIS website in July 2021.

**ADDRESSES:** The full report, including the appendices to the report, are available online at *https://www.bis.doc.gov/index.php/documents/section-232-investigations/2793-vanadium-section-232-report-public-with-appendices/file*.

**FOR FURTHER INFORMATION CONTACT:** Kevin Coyne, Industrial Studies Division, Bureau of Industry and Security, U.S. Department of Commerce, (202) 482–5481, *Vanadium232@bis.doc.gov*. Unless otherwise protected by law, any information received from the public during the course of this investigation may be made publicly available. For more information about the Section 232 program, including the regulations and the text of previous investigations, please see *www.bis.doc.gov/232.*

**The Effect of Imports of Vanadium on the National Security**

**An Investigation Conducted Under Section 232 of the Trade Expansion Act of 1962, as Amended**

**U.S. Department of Commerce**

**Bureau of Industry and Security**

**Office of Technology Evaluation**

**February 22, 2021**

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**Prepared by Bureau of Industry and Security**

*http://www.bis.doc.gov*

## I. Executive Summary

This report summarizes the findings of an investigation conducted by the U.S. Department of Commerce (the ''Department'') pursuant to Section 232 of the Trade Expansion Act of 1962, as amended (19 U.S.C. 1862 (''Section 232'')), into the effect of imports of vanadium [1] on the national security of the United States.

Vanadium is used primarily as a strengthening agent in steel products, particularly for products in the construction industry and in tool steel. A smaller but essential use is in titanium aerospace alloys; military and

[1] *See* Figure 1 in Section IV, ''Product Scope of the Investigation,'' for the vanadium products addressed by this report.

commercial aircraft are dependent on vanadium-containing titanium products. Vanadium also has significant chemical uses, including as a catalyst in the production of sulfuric acid—itself an important industrial material used in a wide range of production—and in large scale energy storage.

There are three general methods of vanadium production: Primary (mining), co-production (from mined ore in concert with steelmaking), and secondary production or recycling (from residues and waste materials). Production generally results in vanadium pentoxide, which can be used in titanium and non-metallurgical uses or further converted, generally to ferrovanadium for incorporation into steel.

There is currently one primary producer of vanadium in the United States (uranium miner Energy Fuels Resources). There are two active secondary producers (the companies that submitted the Section 232 application, AMG Vanadium and U.S. Vanadium), plus a third secondary producer currently modernizing an idle facility (Gladieux Metals Recycling). The primary producer only produced vanadium during one of the last five years and supplied less than 4% of U.S. demand.

Globally, primary and co-production of vanadium is concentrated in four countries: China, Russia, South Africa, and Brazil, with China accounting for over half of global production. Since 1995, the United States has found that imports of ferrovanadium from all major primary producers except Brazil have been sold at less than fair value, resulting in antidumping duties. These duties remain in effect for China and South Africa but have since been revoked for Russia.

Although the United States is reliant on imports of vanadium pentoxide, ferrovanadium, or vanadium-bearing waste products to meet domestic demand, this import reliance will be mitigated by a major expansion being carried out by AMG Vanadium doubling their ferrovanadium production capacity, and the soon-expected completion of Gladieux's renovation, which will reintroduce significant domestic vanadium pentoxide production. In addition, two mining projects are in the exploratory or permitting phase, potentially adding domestic production capacity as soon as 2023.

The biggest challenge the industry faces is low and volatile vanadium prices. Prices are currently below the levels required for cost effective primary production in the United States, and make it difficult for secondary producers to source feedstock and operate profitably. Adding to producers' woes are the major demand declines due to COVID–19, with demand for vanadium in titanium products hit especially hard as a result of decreased consumption by the aerospace industry.

Given vanadium's almost-exclusive use in concert with steel and titanium, and, as steel and titanium are both considered critical to national security—with their domestic production threatened by imports, as reported in recent Section 232 reports—the Department finds that unilaterally imposing import tariffs or quotas in order to raise the domestic price of vanadium would largely impact domestic steel and titanium industries and would therefore have significant negative effects on the economic and national security of the United States. Cost increases for only domestic steel and titanium producers would put these critical industries, already threatened by low-cost imports, at a further disadvantage relative to foreign producers.

In conducting this investigation, the Secretary of Commerce (the ''Secretary'') noted the Department's prior investigations under Section 232. This report incorporates the statutory analysis from the Department's 2018 reports on the imports of steel and aluminum [2] with respect to applying the terms ''national defense'' and ''national security'' in a manner that is consistent with the statute and legislative intent.[3]

As required by the statute, the Secretary considered all factors set forth in Section 232(d). In particular, the Secretary examined the effect of imports on national security requirements, specifically:

i. Domestic production needed for projected national defense requirements;

ii. the capacity of domestic industries to meet such requirements;

iii. existing and anticipated availabilities of the human resources, products, raw materials, and other supplies and services essential to the national defense;

iv. the requirements of growth of such industries and such supplies and services including the investment, exploration, and development necessary to assure such growth; and

v. the importation of goods in terms of their quantities, availabilities, character, and use as those affect such industries; and the capacity of the United States to meet national security requirements.

In preparing this report, the Secretary also recognized the close relation of the economic welfare of the United States to its national security. Factors that can compromise the nation's economic welfare include, but are not limited to, the impact of ''foreign competition on the economic welfare of individual domestic industries; and any substantial unemployment, decrease in revenues of government, loss of skills, or any other serious effects resulting from the displacement of any domestic products by excessive imports.'' See 19 U.S.C. 1862(d). In particular, this report assesses whether vanadium is being imported ''in such quantities'' and ''under such circumstances'' as to ''threaten to impair the national security.'' [4]

*A. Findings*

In conducting the investigation, the Secretary found:

1. Vanadium Is Essential to U.S. National Security

(a) Vanadium is a critical mineral. The Department of Interior included vanadium on the 2018 List of Critical Minerals required by Executive Order 13817, issued December 20, 2017.[5] Pursuant to the Executive Order, the list established vanadium as essential to the national security of the United States and found that the absence of a vanadium supply would have significant consequences for the U.S. economy and national security.

(b) Vanadium is required for national defense systems because of its use in steel and titanium alloys. Vanadium is irreplaceable in key titanium aerospace applications, and many military airframes contain significant amounts of vanadium.

(c) Vanadium is required for critical infrastructure. A key feature in the high-strength, low-alloy (HSLA) steel products used in the construction industry, as well as in tool steel and

[2] U.S. Department of Commerce. Bureau of Industry and Security. *The Effect of Imports of Steel on the National Security* (Washington, DC: 2018) (''Steel Report'') and U.S. Department of Commerce. Bureau of Industry and Security. *The Effect of Imports of Aluminum on the National Security* (Washington, DC: 2018) (''Aluminum Report''). *https://www.bis.doc.gov/index.php/documents/steel/2224-the-effect-of-imports-of-steel-on-the-national-security-with-redactions-20180111/file https://www.bis.doc.gov/index.php/documents/aluminum/2223-the-effect-of-imports-of-aluminum-on-the-national-security-with-redactions-20180117/file.*

[3] Steel Report at 13–14; Aluminum Report at 12–13.

[4] 19 U.S.C. 1862(b)(3)(A).

[5] *https://www.usgs.gov/news/interior-releases-2018-s-final-list-35-minerals-deemed-critical-us-national-security-and.*

high-speed steels, vanadium steel alloys are used throughout U.S. critical infrastructure. In addition, nearly all vanadium-bearing titanium products are used in the critical transportation or defense sectors.

(d) The vanadium industry has significant effects on other industries critical to U.S. national security. As stated above, vanadium has essential uses in steel and titanium products, and vanadium resources in the United States are often co-located with uranium resources. The Department has recently found that imports in all three of these industries threaten to impair U.S. national security.

2. Imports of Vanadium Have Mixed Effects on the Economic Welfare of the U.S. Vanadium Industry

(a) The United States is presently reliant on imports of vanadium. The only primary vanadium producer in the United States has only produced during one of the last five years, due to low vanadium prices. Domestic secondary producers of vanadium import significant quantities of their feedstock, [TEXT REDACTED].

(b) U.S. reliance on imports of vanadium is not increasing. Although the country is reliant on imports of vanadium to meet civilian demand, major U.S. producers of ferrovanadium and vanadium pentoxide are in the process of expanding or restarting operations. Given the successful completion of these initiatives, U.S. capacity for ferrovanadium production from vanadium-bearing waste is projected to more than double in 2021, and U.S. capacity for vanadium pentoxide production from vanadium-bearing waste is projected to increase significantly with the re-opening of a secondary production facility. In addition, several domestic mining companies have idle production capacity or are exploring the development of vanadium mines. If domestic vanadium prices rise, or in the event of a national emergency, these companies may increase production and capacity, including through new mines.

(c) Given continuing low domestic prices, the U.S. vanadium industry may face significant financial challenges. [TEXT REDACTED] However, it is difficult to accurately characterize the financial health of the industry due to recent facility turnover, significant ongoing investments, and recent lack of operational activities.

(d) Significant resources exist in the United States for primary production. At least three companies have mines that have produced vanadium in the past, and two additional projects are under development.

(e) Secondary production of vanadium is environmentally beneficial. The vanadium-bearing waste products used in secondary production are classified by the Environmental Protection Agency (EPA) as hazardous waste. However, secondary production reclaims critical minerals and can divert significant amounts of material from landfills, instead using them in products critical to national defense.

3. Displacement of Domestically-Produced Vanadium by Imports Affects Our Internal Economy, But Is Mitigated by Ongoing Actions

(a) U.S. production of vanadium is well below domestic demand. Primary and secondary producers produced an annual average of 3.4 million kilograms of vanadium content from 2016 to 2019, while domestic imports of key vanadium products approached 8 million kilograms.

(b) Domestic production is highly concentrated and limits the capacity available for a national emergency. Just three domestic companies carried out vanadium production in 2019. Additional capacity in the future is not guaranteed, based on low vanadium prices.

(c) Domestic vanadium production currently requires significant imports of vanadium feedstock, limiting vanadium production capacity available for a national emergency. Only one vanadium producer in recent years has used entirely U.S. origin material, producing the equivalent of 1.4% of total domestic demand since 2016. Secondary producers all use significant levels of foreign feedstock; the United States is unable to satisfy all domestic demand with U.S. sourced material.

(d) Recent trade actions have successfully mitigated artificially low-priced imports of ferrovanadium. Of the four countries with significant primary production of vanadium, three have been subject to the imposition of antidumping duties on ferrovanadium based on petitions from domestic ferrovanadium producers. In all cases, imports of ferrovanadium from the subject countries fell to close to zero following the imposition of the duties.

(e) Critical minerals agreements with other countries will help ensure reliable supplies of vanadium. The United States government (USG) released in June 2019 *A Federal Strategy to Ensure Secure and Reliable Supplies of Critical Minerals,* which includes a goal of enhanced international trade and cooperation related to critical minerals.[6] The United States has subsequently entered into official critical minerals collaborations with Canada and Australia, both of which have significant vanadium resources.

4. Increased Global Capacity and Production of Vanadium Will Further Impact the Long-Term Viability of U.S. Vanadium Production

(a) China, which accounts for an estimated 50 to 60% of global vanadium production and consumption, possesses an outsized role in determining the global price of vanadium. This concentration of supply and demand means that policy changes in China have significant effects on the global vanadium market, including major price changes in the near past.

(b) Expansion of low-cost production in countries other than China will place downward pressure on global vanadium prices. Mines in development or exploration in Kazakhstan, Canada, and Australia have the ability to nearly double current global mine production, should they all enter production.

(c) Downward price pressure may be mitigated by increased demand for steel, titanium, and energy storage. Although currently significantly affected by COVID–19, higher demand in the steel and titanium industries would put upward pressure on vanadium prices. Additionally, annual growth projections for the use of vanadium-based batteries range from 13 to 42% through 2027, which could produce significant additional demand.

(d) Significant price swings impair the ability of domestic producers to plan and carry out capital expenditures. With vanadium projects taking years to complete and major price swings a common occurrence, companies may be challenged to find financing throughout the course of the development of new vanadium capabilities, or may find their projects not viable once completed.

5. Unilaterally Increasing Domestic Prices of Vanadium Would Harm Critical U.S. Industries

(a) Domestic vanadium prices significantly exceeding world prices would disadvantage the U.S. steel industry. The Department's 2018 Section 232 investigation on steel imports found that the steel industry was threatened by imports and in need of assistance to remain viable. As the predominant user of vanadium, the domestic steel industry would face new

[6] *https://www.commerce.gov/data-and-reports/reports/2019/06/federal-strategy-ensure-secure-and-reliable-supplies-critical-minerals.*

threats from foreign steel producers if its input costs were significantly higher than those in other countries.

(b) Domestic vanadium prices significantly exceeding world prices would also harm the U.S. titanium industry, to the benefit of Russian and Chinese producers. The titanium industry is dependent on vanadium because vanadium accounts for between 12 and 14% of the cost of a standard titanium alloy. The U.S. titanium industry is facing significant financial challenges from declines in demand (related to COVID–19), and may not be able to bear additional costs that international competitors do not.

*B. Conclusion*

Based on these findings, the Secretary concludes that the present quantities and circumstances of vanadium imports do not threaten to impair the national security as defined in Section 232. Although vanadium is critical to national security and the United States is currently dependent on imported sources of vanadium, [TEXT REDACTED] several significant factors, including the health of the U.S. industry, availability of idle domestic resources, existing USG actions, and the importance of vanadium to competitive steel and titanium industries, indicate that imports of vanadium do not currently threaten to impair national security.

The United States is currently reliant on imports to satisfy demand for vanadium products and is not producing significant amounts of vanadium from U.S.-origin material, but these circumstances are not expected to deteriorate. Two domestic secondary producers are in the process of expanding and/or upgrading their facilities, which will add significantly to the U.S. ability to produce ferrovanadium and vanadium pentoxide from vanadium-bearing waste materials.

Furthermore, in addition to the one existing domestic primary producer, several other companies are in the process of exploring vanadium mining ventures and will be in a position to produce within several years if vanadium prices rise sufficiently. Even if primary production is not feasible at current vanadium prices, the availability of these resources allows for production potential in the event of national emergency. An increase in the production of domestic primary vanadium, expansion of secondary production, and the addition of domestic feedstock for secondary production should mitigate the current levels of reliance on imports.

However, the projected rise in capacity does not necessarily mean that the domestic vanadium industry is healthy. Vanadium prices have a long history of volatility, with prices going through cycles of surging and plunging. The main users of vanadium—the steel and titanium industries—experienced major declines in demand in 2020 related to COVID–19, with the titanium industry particularly challenged by a large decrease in aerospace demand. If vanadium prices fail to rise, some of the capacity under exploration may not turn into production, and one or more secondary producers may face financial difficulty or challenges in sourcing vanadium-bearing feedstock.

Further, the lack of a finding of a threat to national security does not indicate that a healthy domestic vanadium industry is not of vital importance to the United States. While the Secretary does not believe that imports of vanadium need to be adjusted at this time, there are several steps that can and should be taken to support the domestic vanadium industry and related sectors to ensure safe and reliable sources of vanadium in the event of a national emergency, thereby enhancing and protecting U.S. national security.

*C. Recommendations*

The Department has identified several actions that would help to ensure reliable domestic sources of vanadium and lessen the potential for imports to threaten national security. These actions are not intended to be exhaustive or exclusive; the Secretary recommends pursuing all proposed actions.

Recommendation 1—Expansion of the National Defense Stockpile To Include High Purity Vanadium Pentoxide

The USG should support domestic vanadium production and ensure a source of vanadium in the event of national emergency by re-adding vanadium pentoxide to the National Defense Stockpile. Vanadium pentoxide was part of the stockpile until 1997; the stockpile held 6,200 tons of contained vanadium [7] in 1965 and had a goal of 7,000 tons though it held just 651 tons prior to the decision to reduce the target level to zero in 1993, following the end of the cold war.[8] Using high purity vanadium pentoxide—suitable for use in titanium alloys or chemical uses as well as conversion into ferrovanadium for use in the steel industry—would ensure vanadium held in the stockpile could be used for any necessary product in the event of national security.

National Defense Stockpile goals were initially set to ensure sufficient product to support one year's demand for the entire country but were later narrowed to focus on defense-specific needs, primarily due to funding constraints. Given the importance of vanadium and other critical minerals to the economy, the economic and national security of the United States would be better served by pursuing stockpile goals that support national security beyond defense-specific requirements. The re-addition of vanadium to the stockpile would require authorization and funding from Congress.

The Department recommends that the size of the proposed vanadium addition to the stockpile should be based on three benchmarks: Defense system requirements, broader national security requirements, and total domestic demand. As discussed above, defense system requirements may conservatively amount to 273 metric tons of vanadium content per year; this inventory level would be worth approximately $10.5 million based on average vanadium pentoxide prices since 2016.[9] Critical infrastructure requirements add an estimated 4,527 tons per year, resulting in a minimum stockpile goal based on total national security requirements of 4,800 tons of contained vanadium, at a cost of $184.8 million. Finally, total domestic apparent consumption (including defense and critical infrastructure needs) averaged 8,590 tons of contained vanadium annually from 2016 to 2019. Establishing a stockpile goal at this level, sufficient to meet all domestic demand, would be valued at $330.6 million.

Beyond the minimum stockpile level, the Secretary further recommends that the stockpile of vanadium pentoxide be authorized to expand in size during periods of unusually low prices (with purchases made from domestic producers), while remaining unchanged or shrinking during periods of higher-than-average prices. This policy would help mitigate the large historic price swings that have caused significant financial distress and impeded capital investment in the domestic vanadium industry while helping to regulate domestic prices.

[7] Vanadium is generally reported in terms of ''contained vanadium'', or the weight of only the vanadium portion of a vanadium compound. Vanadium represents 56% of the weight of vanadium pentoxide.

[8] USGS Vanadium Mineral Commodity Summaries. *https://www.usgs.gov/centers/nmic/vanadium-statistics-and-information.*

[9] Average price per pound vanadium pentoxide from 2016–2019 of $9.80, based on data from USGS: *https://pubs.usgs.gov/periodicals/mcs2020/mcs2020-vanadium.pdf.*

Implementing this policy would require legislative changes to the Strategic and Critical Materials Stockpiling Act (50 U.S.C. 98, *et seq.*) (Stockpiling Act). While the mitigation of critical mineral price swings and the purchase of critical minerals from domestic producers at a premium when prices are unusually low serves the interest of national defense, the Stockpiling Act requires that the stockpile ''not be used for economic or budgetary purposes,'' which may present a challenge in allowing the stockpile to exceed minimum defense needs based on prices. Allowing the stockpile to be used for economic purposes if such actions support the health and competitiveness of affected industries would help enhance U.S. national security.

As an additional potential benefit, once the vanadium holdings in the National Defense Stockpile are established, they could—with the authorization of Congress and in cooperation with the Department of Energy—be used without cost to support another sector: Large scale energy storage. As noted above, a potential new use for vanadium is in vanadium redox flow batteries, which have the advantage of using vanadium in both parts of the electrolyte, eliminating the risk of cross-contamination and allowing for the vanadium to be re-claimed from the batteries at a low cost with minimal yield loss.[10]

With vanadium accounting for approximately 30% of the cost of a vanadium redox flow battery and initial battery cost reductions needed to enable larger scale use, the USG could reduce the costs of the stockpile and support the energy storage sector by leasing a portion of the stockpile to be managed by vanadium redox flow battery companies, on condition of the leased vanadium being immediately reclaimable in the event of a national emergency. Given restrictions on transfers to and from the stockpile, this use of material in the stockpile would require either a legislative change to the Stockpiling Act or the designation of the leased material as still being part of the stockpile despite being used for energy storage.

Recommendation 2—Recycling Promotion

*The Federal Strategy to Ensure Secure and Reliable Supplies of Critical Minerals* (Federal Strategy) identifies an available, on-demand supply of critical minerals as ''essential to the economic prosperity and national defense of the United States.''[11] The Federal Strategy recommends the support of recycling and reprocessing of critical minerals, including vanadium. Given that nearly all vanadium production in the United States is performed through recycling, the USG should support the vanadium industry through USG-wide actions to promote the recycling of materials containing critical minerals.

A 2002 EPA analysis, carried out in support of the May 8, 2002 final rule on the identification and listing of spent catalysts as hazardous waste, showed that in 1999, just 55% of spent catalyst was recycled, in large part because the cost of recycling was estimated to be three times that of landfill disposal.[12] Bringing the recycling of vanadium-bearing wastes generated in the United States to or near 100% has the potential to greatly expand the availability of vanadium products of domestic origin. Such recycling will occur naturally with higher vanadium prices, as refiners typically receive a metals credit from vanadium producers based on vanadium sale price, but can also be encouraged through the consideration of recycling tax deductions or credits as well as EPA review of their regulatory authority governing disposal of hazardous waste.

For example, additional information submitted by industry to the Department reported that the 2020 International Maritime Organization's (IMO) regulation requiring the reduction of allowable levels of sulfur in maritime fuels from 3.5% to 0.5% has increased refinery catalyst use, which is expected to result in increased availability of spent catalyst used to produce vanadium.[13] Similar regulations in the United States would support both the EPA mission to protect human health and the environment and domestic production of critical minerals.

Recommendation 3—Continue USG Actions To Support Critical Minerals

Many of the challenges domestic vanadium producers face are not unique to vanadium; with this investigation the Department has completed Section 232 investigations on four of the 35 critical minerals. While the specific challenges of each critical mineral are distinct, many industrial trends are similar and broad solutions may be more effective than individual targeting. There are several ongoing and proposed U.S. government actions that support the domestic supply of critical minerals. Continuing to pursue these actions will provide necessary support to the domestic vanadium industry as well as to the broader critical minerals sector.

Among the key actions that will enable strong domestic critical minerals industries are Executive Order 13817 and the resulting Federal Strategy, Executive Order 13953 (*Addressing the Threat to the Domestic Supply Chain From Reliance on Critical Minerals From Foreign Adversaries and Supporting the Domestic Mining and Processing Industries*), proposals from the USG Nuclear Fuel Working Group, work being carried out by the Titanium Sponge Working Group, and legislative action to support domestic production of critical minerals. Since the list of suitable substitutions for vanadium in steel and certain chemical processes includes other minerals on the critical minerals list (including manganese, niobium, titanium, tungsten, and platinum), actions to support production of critical minerals as a whole would also help to address domestic vanadium supply challenges.

The Federal Strategy, developed pursuant to Executive Order 13817, was announced in June 2019, with six calls to action containing 24 goals and 61 recommended actions that federal agencies should pursue to improve the availability of critical minerals and their downstream supply chains in the United States to help reduce the country's vulnerability to supply chain disruptions. Many of the identified goals of the Federal Strategy are consistent with the findings and recommendations of this investigation, including:

(a) Support for downstream materials production capacity;

(b) enhancing the National Defense Stockpile's ability to meet military as well as civilian requirements;

(c) securing access to critical minerals through trade and investment with allies;

(d) identifying methods to encourage secondary use of critical minerals; and

(e) streamlining permit processes for critical mineral projects.

The President issued Executive Order 13953, ''Addressing the Threat to the Domestic Supply Chain From Reliance on Critical Minerals From Foreign Adversaries and Supporting the Domestic Mining and Processing Industries,'' (E.O. 13953), in September 2020. The Order identifies the need to ensure a consistent supply of critical

[10] Vanitec estimates cost of conversion from leachate to vanadium pentoxide at $1 per pound vanadium pentoxide with a 95% yield. *http://www.vanitec.org/vanadium/ESC-Meetings.*

[11] *https://www.commerce.gov/sites/default/files/2020-01/Critical_Minerals_Strategy_Final.pdf.*

[12] 67 FR 30811 and *https://archive.epa.gov/epawaste/hazard/web/pdf/backdoc.pdf.*

[13] *https://ig9we1q348z124x3t10meupc-wpengine.netdna-ssl.com/wp-content/uploads/AMG-Annual-Report-Web-FINAL.pdf.*

minerals and declares a national emergency to reduce the threat posed by the country's undue reliance on critical minerals from foreign adversaries. Many of the actions taken pursuant to E.O. 13953 will support the domestic vanadium industry, particularly vanadium mining.

In addition to Executive actions, there have recently been several legislative proposals that would provide support for vanadium and other critical minerals. Examples include H.R. 8143 (also known as the Reclaiming American Rare Earths (RARE) Act) and S. 3694 (the Onshoring Rare Earths (ORE) Act of 2020). Both bills as written restrict the definition of critical minerals to a subset of those identified by the Department of Interior in response to E.O. 13817, and need to be expanded to include vanadium and other critical minerals, but otherwise have features of significant value to the domestic vanadium industry. In addition to allowing a tax deduction for investments in property used for mining, reclaiming, or recycling critical materials, these bills would support the function of critical minerals in the broader economy by providing grants or allowing tax deductions for critical minerals extracted in the United States. In addition to expanding the bills to include vanadium (as noted above), in order to provide the most value to the country, the Department recommends that any legislation should ensure that extraction incentives include recycling and reclamation.

Finally, the Department's Section 232 investigations into imports of Uranium and Titanium sponge resulted in the creation of USG working groups tasked with developing recommendations additional to those made in each report. Given the significant intersections between the vanadium industry and the uranium and titanium industries, the implementation of the working groups' recommendations will support the vanadium industry as well.

## II. Legal Framework

### *A. Section 232 Requirements*

Section 232 of the Trade Expansion Act of 1962, as amended, provides the Secretary with the authority to conduct investigations to determine the effect on the national security of the United States of imports of any article. It authorizes the Secretary to conduct an investigation if requested by the head of any department or agency, upon application of an interested party, or upon his own motion. *See* 19 U.S.C. 1862(b)(1)(A).

Section 232 directs the Secretary to submit to the President a report with recommendations for ''action or inaction under this section'' and requires the Secretary to advise the President if any article ''is being imported into the United States in such quantities or under such circumstances as to threaten to impair the national security.'' *See* 19 U.S.C. 1862(b)(3)(A).

Section 232(d) directs the Secretary and the President to, in light of the requirements of national security and without excluding other relevant factors, give consideration to the domestic production needed for projected national defense requirements and the capacity of the United States to meet national security requirements. *See* 19 U.S.C. 1862(d).

Section 232(d) also directs the Secretary and the President to ''recognize the close relation of the economic welfare of the Nation to our national security, and . . . take into consideration the impact of foreign competition on the economic welfare of individual domestic industries'' by examining whether any substantial unemployment, decrease in revenues of government, loss of skills or investment, or other serious effects resulting from the displacement of any domestic products by excessive imports, or other factors, results in a ''weakening of our internal economy'' that may impair the national security.[14] *See* 19 U.S.C. 1862(d).

Once an investigation has been initiated, Section 232 mandates that the Secretary provide notice to the Secretary of Defense that such an investigation has been initiated. Section 232 also requires the Secretary to do the following:

(1) ''Consult with the Secretary of Defense regarding the methodological and policy questions raised in [the] investigation;''

(2) ''Seek information and advice from, and consult with, appropriate officers of the United States;'' and

(3) ''If it is appropriate and after reasonable notice, hold public hearings or otherwise afford interested parties an opportunity to present information and advice relevant to such investigation.'' [15] *See* 19 U.S.C. 1862(b)(2)(A)(i)–(iii).

As detailed in the report, all of the requirements set forth above have been satisfied.

In conducting the investigation, Section 232 permits the Secretary to request that the Secretary of Defense provide an assessment of the defense requirements of the article that is the subject of the investigation. *See* 19 U.S.C. 1862(b)(2)(B).

Upon completion of a Section 232 investigation, the Secretary is required to submit a report to the President no later than 270 days after the date on which the investigation was initiated. *See* 19 U.S.C. 1862(b)(3)(A). The report must:

(1) Set forth ''the findings of such investigation with respect to the effect of the importation of such article in such quantities or under such circumstances upon the national security;''

(2) Set forth, ''based on such findings, the recommendations of the Secretary for action or inaction under this section;'' and

(3) ''If the Secretary finds that such article is being imported into the United States in such quantities or under such circumstances as to threaten to impair the national security . . . so advise the President.'' S*ee* 19 U.S.C. 1862(b)(3)(A).

All unclassified and non-proprietary portions of the report submitted by the Secretary to the President must be published.

Within 90 days after receiving a report in which the Secretary finds that an article is being imported into the United States in such quantities or under such circumstances as to threaten to impair the national security, the President shall:

(1) ''Determine whether the President concurs with the finding of the Secretary''; and

(2) ''If the President concurs, determine the nature and duration of the action that, in the judgment of the President, must be taken to adjust the imports of the article and its derivatives so that such imports will not threaten to impair the national security'' (*see* 19 U.S.C. 1862(c)(1)(A)).

### *B. Discussion*

While Section 232 does not specifically define ''national security,'' both Section 232, and the implementing regulations at 15 CFR part 705, contain non-exclusive lists of factors that the Secretary must consider in evaluating the effect of imports on the national security. Congress in Section 232 explicitly determined that ''national security'' includes, but is not limited to, ''national defense'' requirements. *See* 19 U.S.C. 1862(d)).

In a 2001 report, the Department determined that ''national defense'' includes both the defense of the United States directly, and the ''ability to

[14] An investigation under Section 232 looks at excessive imports for their threat to the national security, rather than looking at unfair trade practices as in an antidumping investigation.

[15] Department regulations (i) set forth additional authority and specific procedures for such input from interested parties, *see* 15 CFR 705.7 and 705.8, and (ii) provide that the Secretary may vary or dispense with those procedures ''in emergency situations, or when in the judgment of the Department, national security interests require it.'' *Id.,* 705.9.

project military capabilities globally.'' [16] The Department also concluded in 2001 that, ''in addition to the satisfaction of national defense requirements, the term ''national security'' can be interpreted more broadly to include the general security and welfare of certain industries, beyond those necessary to satisfy national defense requirements, which are critical to the minimum operations of the economy and government.'' The Department called these ''critical industries.'' [17] While this report uses these reasonable interpretations of ''national defense'' and ''national security,'' it uses the more recent 16 critical infrastructure sectors identified in Presidential Policy Directive 21 [18] instead of the 28 industry sectors identified in the 2001 Report.[19]

Section 232 directs the Secretary to determine whether imports of any article are being made ''in such quantities'' or ''under such circumstances'' that those imports ''threaten to impair the national security.'' *See* 19 U.S.C. 1862(b)(3)(A). The statutory construction makes clear that either the quantities or the circumstances, standing alone, may be sufficient to support an affirmative finding. The two may also be considered together, particularly when the circumstances act to prolong or magnify the impact of the quantities being imported.

The statute does not define a threshold for when ''such quantities'' of imports are sufficient to threaten to impair the national security, nor does it define the ''circumstances'' that might qualify.

Similarly, the statute does not require a finding that the quantities or circumstances are impairing the national security. Instead, the threshold question under Section 232 is whether the quantities or circumstances ''threaten to impair the national security.'' *See* 19 U.S.C. 1862(b)(3)(A). This makes evident that Congress expected an affirmative finding under Section 232 before an actual impairment of the national security.[20]

Section 232(d) contains a list of factors for the Secretary to consider in determining if imports ''threaten to impair the national security'' [21] of the United States, and this list is mirrored in the implementing regulations. *See* 19 U.S.C. 1862(d) and 15 CFR 705.4. Congress was careful to note twice in Section 232(d) that the list provided, while mandatory, is not exclusive.[22] Congress' illustrative list is focused on the ability of the United States to maintain the domestic capacity to provide the articles in question as needed to maintain the national security of the United States.[23] Congress broke the list of factors into two equal parts using two separate sentences. The first sentence focuses directly on ''national defense'' requirements, thus making clear that ''national defense'' is a subset of the broader term ''national security.'' The second sentence focuses on the broader economy and expressly directs that the Secretary and the President ''shall recognize the close relation of the economic welfare of the Nation to our national security.'' [24] *See* 19 U.S.C. 1862(d).

In addition to ''national defense'' requirements, two of the factors listed in the second sentence of Section 232(d) are particularly relevant in this investigation. Both are directed at how ''such quantities'' of imports threaten to impair national security *See* 19 U.S.C. 1862(b)(3)(A). In administering Section 232, the Secretary and the President are required to ''take into consideration the impact of foreign competition on the economic welfare of individual domestic industries'' and any ''serious effects resulting from the displacement of any domestic products by excessive imports'' in ''determining whether such weakening of our internal economy may impair the national security.'' *See* 19 U.S.C. 1862(d).

After careful examination of the facts in this investigation, the Secretary has determined that the present quantities and circumstance of vanadium imports do not threaten to impair the national security, as defined in Section 232. Although vanadium is critical to national security and the United States is currently dependent on imported sources of vanadium, several significant factors, including the health of the U.S. industry, availability of idle domestic resources, existing USG actions, and the importance of vanadium to competitive domestic steel and titanium industries, indicate that imports of vanadium do not threaten to impair national security.

## III. Investigative Process

### *A. Initiation of Investigation*

On November 19, 2019, AMG Vanadium LLC and U.S. Vanadium LLC (hereafter ''Applicants'') petitioned the Secretary to conduct an investigation under Section 232 of the Trade Expansion Act of 1962, as amended, to determine the effect of imports of vanadium on the national security.

Upon receipt of the petition, the Department carefully reviewed the material facts outlined in the petition and held initial discussions internally as well as with the Department of Defense. Legal counsel at the Department also carefully reviewed the petition to ensure it met the requirements of the Section 232 statute and the implementing regulations. Subsequently, on May 28, 2020, the Department accepted the petition and initiated the investigation. Pursuant to Section 232(b)(1)(b), the Department notified the U.S. Department of Defense of its intent to conduct an investigation in a May 21, 2020 letter from Secretary Ross to then Secretary of Defense, Mark Esper (*see* Appendix A).

### *B. Public Comments*

On June 3, 2020, the Department published a **Federal Register** Notice (*see*

[16] Department of Commerce, Bureau of Export Administration; *The Effects of Imports of Iron Ore and Semi-Finished Steel on the National Security;* Oct. 2001 (''2001 Iron and Steel Report'') at 5.

[17] *Id.*

[18] Presidential Policy Directive 21; *Critical Infrastructure Security and Resilience;* February 12, 2013 (''PPD–21'').

[19] *See Op. Cit.* at 16.

[20] The 2001 Iron and Steel Report used the phrase ''fundamentally threaten to impair'' when discussing how imports may threaten to impair national security. *See* 2001 Iron and Steel Report at 7 and 37. Because the term ''fundamentally'' is not included in the statutory text and could be perceived as establishing a higher threshold, the Secretary expressly does not use the qualifier in this report. The statutory threshold in Section 232(b)(3)(A) is unambiguously ''threaten to impair'' and the Secretary adopts that threshold without qualification. 19 U.S.C. 1862(b)(3)(A).

[21] 19 U.S.C. 1862(b)(3)(A).

[22] *See* 19 U.S.C. 1862(d) (''the Secretary and the President shall, in light of the requirements of national security and without excluding other relevant factors . . .'' and ''serious effects resulting from the displacement of any domestic products by excessive imports shall be considered, without excluding other factors . . .'').

[23] This reading is supported by Congressional findings in other statutes. *See, e.g.,* 15 U.S.C. 271(a)(1)(''The future well-being of the United States economy depends on a strong manufacturing base . . .'') and 50 U.S.C. 4502(a)(''Congress finds that—(1) the security of the United States is dependent on the ability of the domestic industrial base to supply materials and services . . . (2)(C) to provide for the protection and restoration of domestic critical infrastructure operations under emergency conditions . . . (3) . . . the national defense preparedness effort of the United States government requires—(C) the development of domestic productive capacity to meet—(ii) unique technological requirements . . . (7) much of the industrial capacity that is relied upon by the United States Government for military production and other national defense purposes is deeply and directly influenced by—(A) the overall competitiveness of the industrial economy of the United States; and (B) the ability of industries in the United States, in general, to produce internationally competitive products and operate profitably while maintaining adequate research and development to preserve competitiveness with respect to military and civilian production; and (8) the inability of industries in the United States, especially smaller subcontractors and suppliers, to provide vital parts and components and other materials would impair the ability to sustain the Armed Forces of the United States in combat for longer than a short period.'').

[24] *Accord* 50 U.S.C. 4502(a).

Appendix B—**Federal Register**, Vol. 85, No. 107, 34179) announcing the initiation of an investigation to determine the effect of imports of vanadium on the national security. The notice also announced the opening of the public comment period. In the notice, the Department invited interested parties to submit written comments, opinions, data, information, or advice relevant to the criteria listed in Section 705.4 of the National Security Industrial Base Regulations (15 CFR 705.4) as they affect the requirements of national security, including the following:

(a) Quantity of the articles subject to the investigation and other circumstances related to the importation of such articles;

(b) Domestic production capacity needed for these articles to meet projected national defense requirements;

(c) The capacity of domestic industries to meet projected national defense requirements;

(d) Existing and anticipated availability of human resources, products, raw materials, production equipment, facilities, and other supplies and services essential to the national defense;

(e) Growth requirements of domestic industries needed to meet national defense requirements and the supplies and services including the investment, exploration and development necessary to assure such growth;

(f) The impact of foreign competition on the economic welfare of any domestic industry essential to our national security;

(g) The displacement of any domestic products causing substantial unemployment, decrease in the revenues of government, loss of investment or specialized skills and productive capacity, or other serious effects;

(h) Relevant factors that are causing or will cause a weakening of our national economy; and

(i) Any other relevant factors

The initial public comment period ended on July 20, 2020, and was followed by a public comment rebuttal period, which ended on August 17, 2020. Following requests from the general public, the Department published a copy of the Applicants' petition on September 25, 2020 and opened an additional public comment period, which ended October 9, 2020.

The Department received 32 responsive submissions during the initial public comment period, which were posted on *Regulations.gov* for public review and rebuttal filing. The Department received 47 rebuttal filings from 11 commenters, which were posted on *Regulations.gov* for public review. During the additional comment period, the Department received and posted seven comments on *Regulations.gov*.

Parties who submitted comments included representatives of the domestic vanadium production industry, representatives of the domestic uranium industry, representatives of the foreign vanadium production industry, consumers of vanadium products from the steel, titanium, and energy storage industries, as well as representatives of foreign governments, and other concerned organizations. The Department carefully reviewed all of the public comments and factored them into the investigative process. The public comments of key stakeholders are summarized in Appendix C, which also includes a link to the docket number (BIS–2020–0002) under which all public comments can be viewed in full on *Regulations.gov*.

*C. Information Gathering and Data Collection Activities*

Due to the limited number of firms engaged in the U.S. vanadium industry, it was determined that a public hearing was not necessary to conduct a comprehensive investigation. In lieu of holding a public hearing on this investigation, the Department issued a separate mandatory survey (*see* Appendix E) to participants in the vanadium production and distribution industry, collecting both qualitative and quantitative information. The survey was sent to 34 companies with the ability to develop, produce, or distribute vanadium products for use in the United States. Eight of these companies did not have locations in the United States, and were invited to participate in the survey on a voluntary basis.

The surveys provided a method for respondents to disclose confidential and non-public information. These surveys, to which response was mandatory for domestic respondents, were conducted using statutory authority pursuant to Section 705 of the Defense Production Act of 1950, as amended (50 U.S.C. 4555) (DPA), and collected detailed information concerning factors such as imports/exports, production, capacity utilization, employment, operating status, global competition, and financial information. The resulting data provided the Department with detailed industry information that was otherwise not publicly available and was needed to effectively conduct analysis for this investigation.

The Department deems the information furnished in the survey responses confidential and will not publish or disclose it except in accordance with Section 705 of the DPA, which prohibits the publication or disclosure of this information unless the President determines that the withholding of such information is contrary to the interest of the national defense. Therefore, the information submitted to the Department in response to the survey will not be shared with any non-government entity other than in aggregate form.

*D. Interagency Consultation*

The Department consulted with the Department of Defense's Office of Industrial Policy and the Defense Logistics Agency, regarding methodological and policy questions that arose during the investigation. The Department also consulted with other U.S. Government agencies with expertise and information regarding the vanadium industry including the Department of Energy, the Department of State, the Office of the United States Trade Representative, the Department of Homeland Security, the Environmental Protection Agency, and the Department of Interior's U.S. Geological Survey.

## IV. Product Scope of Investigation

The scope of this investigation defined vanadium products at the Harmonized Tariff Schedule of the United States (HTS) 10-digit level. The nine product categories and related HTS codes covered by this report are shown below in Figure 1.

FIGURE 1—VANADIUM PRODUCT SCOPE OF THE INVESTIGATION

| Heading/subheading/product | 10 Digit HTS code |
|---|---|
| Vanadium Oxides | 2825.30.0010<br>2825.30.0050 |
| Ferrovanadium | 7202.92.0000 |
| Vanadium Carbides | 2849.90.5000 |
| Vanadates | 2841.90.1000 |
| Vanadium Ore and Concentrates | 2615.90.6090 |
| Ash and Residues Containing Vanadium | 2620.40.0030<br>2620.99.1000 |
| Vanadium Sulfate | 2833.29.3000 |
| Vanadium Hydrides, Nitrides, Azides, Silicides, and Borides | 2850.00.2000 |
| Vanadium, Unwrought and Wrought | 8112.92.7000<br>8112.99.2000 |

Source: United States International Trade Commission and U.S. Department of Commerce, Bureau of Industry and Security.

In order to ensure that the full vanadium production process was covered, these HTS codes include vanadium products as well as vanadium-containing precursors. Vanadium is most commonly traded as vanadium oxides (typically vanadium pentoxide ($V_2O_5$)) and ferrovanadium (FeV), with usage in steelmaking accounting for the vast majority of consumption.

Detailed information was collected in the Department's survey responses from U.S. vanadium producers regarding vanadium-containing products. Data throughout this report is presented, to the extent possible, in kilograms or metric tons of contained vanadium. For example, vanadium pentoxide is 56% vanadium by weight, while vanadium content in ferrovanadium varies from 35% to 80% (though is typically consistent for a given producer). Prices of vanadium pentoxide, in keeping with industry conventions, are quoted in U.S. Dollars per pound of vanadium pentoxide (not vanadium content).

This report also considers the state of industries that depend on vanadium, in particular the U.S. titanium and steel industries, both of which manufacture materials that the U.S. government has recognized as critical to national security. As the Department is aware that the principal customers of vanadium are steel producers, understanding potential ramifications on the U.S. steel industry was necessary to ensure a complete analysis of the effect of vanadium imports on the national security. Vanadium is also a key element in the production of titanium alloy products that are critical to national security, with titanium sponge the subject of a recent Section 232 investigation and the focus of an ongoing working group. The Secretary's recommendations consider the interdependence of the U.S. vanadium industry and these crucial U.S. industries.

## V. Background on U.S. Vanadium Industry

### *A. Vanadium Production*

Vanadium is produced through three general methods: primary production (mining), co-production (from mined ore in concert with steelmaking), and secondary production (from residues and waste materials). Nearly all vanadium in the United States is generated through secondary production, with some vanadium mining occurring together with uranium mining in sandstone-hosted deposits.

Currently there is one primary producer of vanadium in the United States: Energy Fuels Resources (USA), Inc. (Energy Fuels). Although Energy Fuels' vanadium production activities are dependent on vanadium market prices, the company also may produce vanadium as a by-product of uranium mining, depending on uranium market prices. The United States had no primary production of vanadium from 2014 to 2018; Energy Fuels restarted production in 2019 following a surge in vanadium prices.[25] The company produced approximately 1.8 million pounds of vanadium pentoxide in 2019—equivalent to approximately 460,000 kilograms of contained vanadium—prior to ceasing production ''due to weak vanadium market conditions.'' [26] Energy Fuels' production accounted for under 1% of estimated worldwide primary- and co-production in 2019, with the remainder produced in four countries: China, Russia, South Africa, and Brazil (see Figure 2).

[25] United States Geological Survey Mineral Commodity Summaries—Vanadium, *https://www.usgs.gov/centers/nmic/vanadium-statistics-and-information.*

[26] Energy Fuels, Inc. 2019 SEC Form 10–K, *https://www.energyfuels.com/financials.*

FIGURE 2—ESTIMATED WORLDWIDE MINE PRODUCTION OF VANADIUM

[metric tons]

| Country | 2015 | 2016 | 2017 | 2018 | 2019 |
|---|---|---|---|---|---|
| China | 42,000 | 45,000 | 40,000 | 40,000 | 40,000 |
| Russia | 16,000 | 16,000 | 18,000 | 18,000 | 18,000 |
| South Africa | 12,000 | 10,000 | 7,960 | 7,700 | 8,000 |
| Brazil | 6,000 | 8,000 | 5,210 | 5,500 | 7,000 |
| United States | 0 | 0 | 0 | 0 | 460 |
| Total | 76,000 | 79,000 | 71,200 | 71,200 | 73,000 |

Source: United States Geological Survey Mineral Commodity Summaries—Vanadium, *https://www.usgs.gov/centers/nmic/vanadium-statistics-and-information*, and Energy Fuels 2019 SEC 10–K filing.

Energy Fuels sold approximately 50,000 of the 460,000 kilograms of contained vanadium it produced in 2019, with the remainder kept in inventory.[27] The company reports that its U.S. mines contain 6.6 million kilograms of measured vanadium content, with another 3.6 million kilograms indicated or inferred.[28] Energy Fuels also operates the only U.S. facility that can process both vanadium ore and conventional uranium, the White Mesa Mill.

Two Canada-based companies are in the process of exploring the development of mines located in the United States. In May 2020, First Vanadium Corporation announced the results of its Preliminary Economic Assessment (PEA) for an open pit mine near Carlin, Nevada, and forecast 16 years of vanadium production capabilities totaling 180 million pounds of vanadium pentoxide, equivalent to 46 million kilograms of vanadium content.[29] The second company, Silver Elephant Mining, owns Nevada Vanadium LLC, which is in the process of developing the Gibellini vanadium project near Eureka, Nevada. The Gibellini project is in the permitting process, with the Bureau of Land Management expected to reach a decision by August 2021.[30] The company plans to begin production in late 2023, producing 130 million pounds of vanadium pentoxide (33 million kilograms of vanadium content) over 14 years.[31] Other domestic vanadium resources exist, including Western Uranium & Vanadium's Sunday Mine Complex in Colorado and Anfield Resources' Velvet-Wood Mine in Utah, both of which have previously produced vanadium and have the potential to provide primary sources of vanadium, should market conditions support such production. In 2017, the United States Geological Survey (USGS) listed a total of 18 vanadium deposits in the United States, though data was not available on the extent of the deposits for most.[32] The identification of most of these deposits is drawn from assessments carried out in 1968 and 1975 by the American Institute of Mining, Metallurgical, and Petroleum Engineers and the U.S. Geological Survey.[33]

Worldwide, most vanadium is produced via co-production with steelmaking, with vanadium-bearing iron ore used in steel furnaces that produce a vanadium slag that is further converted into vanadium pentoxide and ferrovanadium. Co-production accounted for 71% of global vanadium production in 2019.[34] The concentrations of vanadium-bearing iron ore in China, Russia, and South Africa have made co-production more economically feasible in these countries than in others.

The main method of vanadium production in the United States is secondary production, using fossil fuel spent catalysts, residues, and ashes as feedstock. Fossil fuels can produce vanadium-bearing waste both through the use of vanadium catalysts used in the refining process and in the vanadium-rich residues generated from the burning of fuels high in vanadium content. After recovery, the spent catalysts and residues can be processed into vanadium pentoxide and ferrovanadium (see Figure 3). Secondary production of vanadium accounted for an estimated 11% of worldwide vanadium production in 2019, with the United States accounting for roughly one-third of the worldwide total (4% of total global production).[35]

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[27] Energy Fuels, Inc. 2019 Annual Presentation, *https://www.energyfuels.com/presentation.*

[28] Ibid.

[29] ''First Vanadium Announces Positive Preliminary Economic Assessment for the Carlin Vanadium Project in Nevada'', *https://www.firstvanadium.com/index.php/news/2020/548-irstanadiumnnouncesositiver eliminaryconomicsse20200511.*

[30] Bureau of Land Management Accepting Comments for Gibellini Mine, August 17, 2020. Available at *https://www.blm.gov/press-release/bureau-land-management-accepting-comments-gibellini-mine.*

[31] Silver Elephant Mining Corporate Presentation: Gibellini Vanadium, *https://www.silverelephantmining.com/projects/gibellini-vanadium/.*

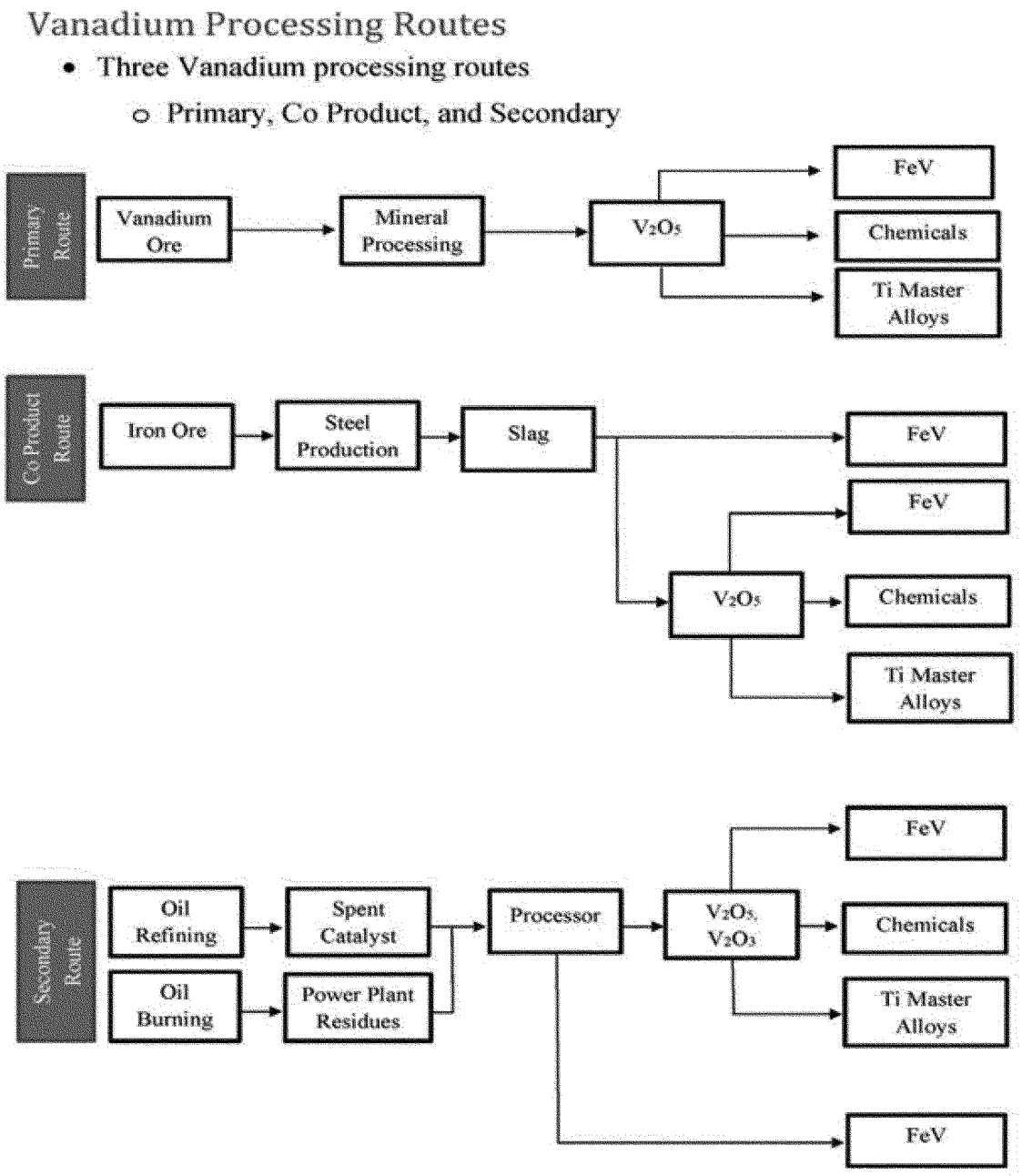
[32] Vanadium: Chapter U of Critical Mineral Resources of the United States—Economic and Environmental Geology Prospects for Future Supply (2017). *https://pubs.usgs.gov/pp/1802/u/pp1802u.pdf.*

[33] Fischer, R.P., 1968, The uranium and vanadium deposits of the Colorado Plateau region, in Ridge, J.D., ed., Ore deposits of the United States, 1933–1967: New York, N.Y., American Institute of Mining, Metallurgical, and Petroleum Engineers; Fischer, R.P., 1975, Geology and resources of base-metal vanadate deposits: U.S. Geological Survey Professional Paper 926–A, *http://pubs.er.usgs.gov/publication/pp926A* and Fischer, R.P., 1975, Vanadium resources in titaniferous magnetite deposits: U.S. Geological Survey Professional Paper 926–B, *http://pubs.er.usgs.gov/publication/pp926B.*

[34] Bushveld Minerals, About Vanadium, *https://www.bushveldminerals.com/about-vanadium/.*

[35] Ibid.

**Figure 3: Vanadium Processing Routes**




Source: Petition for Relief Under Section 232, available at https://www.regulations.gov, docket BIS-2020-0002, Document, BIS-2020-0002-0083

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Both Applicants are secondary producers of vanadium, using vanadium-bearing waste feedstock to produce vanadium products: AMG Vanadium operates a facility in Cambridge, Ohio that produces ferrovanadium, and U.S. Vanadium operates a facility in Hot Springs, Arkansas that produces vanadium pentoxide. In addition to the Applicants there is one other domestic secondary vanadium producer: Gladieux Metals Recycling in Freeport, Texas and one converter: Evergreen Metallurgical (doing business as Bear Metallurgical Company) in Butler, Pennsylvania.

AMG Vanadium's Ohio facility, which was originally built by the Vanadium Corporation of America, dates to 1952. Updates to the facility in 1970, following a merger with the Foote Mineral Corporation, led to the use of vanadium bearing slag as the facility's raw material input. A further overhaul after the acquisition of the facility by Advanced Metallurgical Group NV in 2007 resulted in AMG Vanadium's current use of spent catalyst as feedstock.[36]

AMG Vanadium is the country's largest producer of ferrovanadium, with average annual production from 2016 to 2019 of [TEXT REDACTED].[37] As stated above, the company uses vanadium-bearing spent catalyst as feedstock; [TEXT REDACTED].[38]

The completion of a new facility in Zanesville, Ohio (approximately 25 miles from its existing Cambridge facility) will allow AMG Vanadium to more than double its ferrovanadium production capacity to 5.5 million kilograms per year.[39] The new facility is expected to be completed in 2021, at a cost of just over $200 million, and will support approximately 100 new jobs.[40] The company has indicated that its expansion makes sense despite low vanadium prices, based on the fees it receives from refiners to process spent catalyst, which they expect to exceed their operating costs in 2021.[41] [TEXT REDACTED][42]

In October 2019, U.S. Vanadium LLC (U.S. Vanadium) purchased the vanadium production facility located in Hot Springs, Arkansas, from EVRAZ Stratcor (Stratcor), which had owned the facility since 2006. Vanadium production in Hot Springs dates from mining and milling operations established in 1966 by Union Carbide Corporation, which sold the mill to Stratcor in 1986 and closed the mine in 1989.[43]

U.S. Vanadium was the only company to produce vanadium pentoxide in the United States in 2020, following Energy Fuels' cessation of production and the ongoing idling of Gladieux Metals Recycling. [TEXT REDACTED][44]

Gladieux Metals Recycling (Gladieux) is the owner of an idle vanadium production facility in Freeport, Texas, which it purchased out of bankruptcy from Gulf Chemical and Metallurgical Corporation (Gulf) in 2017.[45] Gulf, which was majority-owned by the French company Eramet, had entered into bankruptcy and idled the vanadium processing facility as a result of low vanadium and molybdenum prices as well as the costs arising from environmental challenges. These costs included 11 felony pollution charges and a resulting $2.75 million fine in 2010, a $7.5 million fine in 2013, and over $50 million in capital expenditures related to environmental matters.[46] While the facility has been idle since 2017, Gladieux has been overhauling operations and has invested more than [TEXT REDACTED] to increase the plant's efficiency and make it more environmentally sound.[47]

Gladieux expects to restart operations [TEXT REDACTED].[48] [TEXT REDACTED]. Gladieux will use spent catalyst as its feedstock; [TEXT REDACTED].[49]

Bear Metallurgical (Bear) owns a facility in Butler, Pennsylvania, which [TEXT REDACTED], but converts vanadium pentoxide to ferrovanadium, primarily on a fee basis for customers.[50] Bear reported that [TEXT REDACTED][51] Bear produced [TEXT REDACTED].[52]

Prior to declaring bankruptcy in 2016, Bear was a wholly-owned subsidiary of Gulf Chemical and Metallurgical (Gulf). The company reported entering into bankruptcy because low vanadium and molybdenum prices limited their toll conversion volumes, with their reliance on Gulf being a significant factor; as noted above Gulf itself also declared bankruptcy in 2016, and subsequently idled vanadium pentoxide production.[53] Bear was purchased in 2016 by Yilmaden Holding, a subsidiary of the Turkey-based Yildirim Group.[54]

[TEXT REDACTED].

[TEXT REDACTED][55]

[36] AMG Vanadium: Our History, at *https://amg-v.com/timeline_amg_v/*.

[37] U.S. Department of Commerce, Bureau of Industry and Security, Section 232 Investigation into Imports of Vanadium Survey.

[38] Ibid.

[39] AMG Vanadium to Duplicate Ohio Recycling Facility. *https://www.spglobal.com/marketintelligence/en/news-insights/trending/2zqx3jqhyx72gfgkcowuzq2.*

[40] AMG Vanadium Constructing a Second Ohio Plant, Investing More Than $200 Million. *https://www.jobsohio.com/news/posts/amg-vanadium-constructing-a-second-ohio-plant-investing-more-than-200-million/*.

[41] AMG Annual General Meeting Minutes (May 1, 2019), as provided in public comments by Bushveld Minerals Limited, available at *https://www.regulations.gov/document?D=BIS-2020-0002-0013*.

[42] U.S. Department of Commerce, Bureau of Industry and Security, Section 232 Investigation into Imports of Vanadium Survey.

[43] Vanadium Mining, Encyclopedia of Arkansas. *https://encyclopediaofarkansas.net/entries/vanadium-mining-5915/*.

[44] U.S. Department of Commerce, Bureau of Industry and Security, Section 232 Investigation into Imports of Vanadium Survey.

[45] Callahan, Erinn. ''Recycling company buys Gulf Chemical.'' *The Facts,* May 16, 2017. *https://thefacts.com/news/article_fe738e6b-8b64-54fb-afd0-c66cbe35f63e.html.*

[46] Gulf Chemical & Metallurgical Corporation Chapter 11 Bankruptcy Filing, as provided in public comments by Bushveld Minerals Limited, available at *https://www.regulations.gov/document?D=BIS-2020-0002-0013*.

[47] Gladieux Metals Recycling. Comment in response to Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Vanadium, July 20, 2020. *https://www.regulations.gov/document?D=BIS-2020-0002-0033.*

[48] U.S. Department of Commerce, Bureau of Industry and Security, Section 232 Investigation into Imports of Vanadium Survey.

[49] Ibid.

[50] Often referred to as a tolling arrangement, with Bear as the ''toller'' and their customers, who provide material to be converted, as ''tollees.''

[51] U.S. Department of Commerce, Bureau of Industry and Security, Section 232 Investigation into Imports of Vanadium Survey.

[52] Ibid.

[53] Gulf Chemical & Metallurgical Corporation Chapter 11 Bankruptcy Filing, as provided in public comments by Bushveld Minerals Limited, available at *https://www.regulations.gov/document?D=BIS-2020-0002-0013*.

[54] Mughal, Sarah. ''Report: Yildirim Unit Wins Tender for Bear Metallurgical Assets.'' September 11, 2016. *S&P Global Market Intelligence. https://www.spglobal.com/marketintelligence/en/news-insights/trending/tetcr1ex6irl2ixbbkkqtw2.*

[55] USGS Vanadium Mineral Commodity Summary, 2020. *https://pubs.usgs.gov/periodicals/mcs2020/mcs2020-vanadium.pdf.*

| [TEXT REDACTED] | | | | | | |
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*B. Vanadium Uses*

The vast majority of vanadium is used in steelmaking. Estimates for both U.S. and worldwide usage put the steel industry at 90 to 93% of total vanadium usage.[56] The inclusion of small amounts of vanadium—typically well under 1% of the total volume—into steel adds ''strength, toughness, and wear resistance,'' as well as oxidation prevention.[57] The resulting high-strength, low-alloy (HSLA) steel products are common in the construction industry, particularly in earthquake-resistant rebar, as well as in buildings, bridges, and cranes. HSLA steel products are also used in the automotive sector, in shipbuilding, and in various defense-related uses such as armor plating.[58] Additionally, use of vanadium is common in tool steel, with chromium-vanadium steel commonly used in hand tools with vanadium concentrations of 0.15 to 0.2%.[59] Vanadium is also used at significantly higher concentrations in high speed steel used in cutting and drilling tools, as well as aerospace applications such as gas engine turbines, at concentrations that can exceed 5% vanadium.

Substitution for vanadium is possible in most steel products. Molybdenum produces similar mechanical properties in tool steels and is substituted on the basis of price and the existence of pre-established supply chains.[60] In HSLA steels, niobium is a standard substitute for vanadium, though ''significant technical adjustments to the steel production process'' are required.[61] Many Chinese steel mills, for instance, carried out this substitution in 2018 in response to a surge in vanadium prices.[62] Nonetheless, vanadium is generally preferred in applications such as rebar, though Roskill—a major metal and chemical industry research and consultancy group—notes that ''once mills are accustomed to niobium and have made the technical changes, they are unlikely to fully switch back.''[63]

Compared to its use in steel alloys, the aggregate use of vanadium in titanium alloys accounts for a much smaller percentage—approximately 3 to 5% of total vanadium demand—but it is ''irreplaceable in aerospace applications.''[64] Most titanium products contain vanadium; the vanadium is typically incorporated into the titanium melt process as a master alloy that is 65% vanadium and 35% aluminum, producing a variety of titanium mill products. The most common is Ti-6Al-4V, a product that is 4% vanadium by weight and between 12 and 14% by cost.[65] Other titanium alloys contain up to 15% vanadium by weight.

Most titanium products are used in the aerospace and military sectors, which account for approximately two-thirds of titanium mill product demand.[66] Titanium accounts for approximately 14% of the Boeing 787 airframe, for instance, and up to 39% of the weight of F–22 fighter jet.[67] Other national security titanium applications include ship components, military ground vehicles, and armor. Industrial use of titanium accounts for approximately 25% of demand; vanadium is used in the chemical industry, power plants, and desalination plants, but these sectors are more likely to use unalloyed ''commercially pure'' titanium.

The primary remaining vanadium uses, accounting for 2 to 4% of total vanadium demand, are categorized as chemical or non-metallurgical use. One key non-metallurgical use is in catalysts, with vanadium-based products being the most common catalysts used for selective catalytic reduction to reduce the production of nitrogen oxides in industrial power plants.[68] Vanadium is used as a catalyst in the production of sulfuric acid, itself an important industrial material used in the production of fertilizer, pulp and paper, titanium dioxide, cellulosic fibers and plastics, explosives, electronic chips, batteries, and pharmaceuticals.[69] Consumption of sulfuric acid is ''regarded as one of the best indexes of a nation's industrial development.''[70] A significant national security use of vanadium within the chemical industry is in longwave-infrared (LWIR) imaging, used for night vision and targeting systems. Vanadium oxide is the most frequently used material in the bolometers supporting LWIR imaging.[71]

[56] Vanadium: Chapter U of Critical Mineral Resources of the United States—Economic and Environmental Geology Prospects for Future Supply (2017). *https://pubs.usgs.gov/pp/1802/u/pp1802u.pdf.*

[57] Ibid.

[58] Ibid.

[59] Which is better for hand tools? Chromium-Molybdenum or Chromium-Vanadium Steel. *https://www.tekton.com/crmo-or-crv-steel.*

[60] Ibid.

[61] Vanadium: Chapter U of Critical Mineral Resources of the United States—Economic and Environmental Geology Prospects for Future Supply (2017). *https://pubs.usgs.gov/pp/1802/u/pp1802u.pdf.*

[62] Press Release: Roskill: Niobium industry looking for a future beyond steel. *https://www.globenewswire.com/news-release/2020/02/10/1982500/0/en/Roskill-Niobium-industry-looking-for-a-future-beyond-steel.html.*

[63] Vanadium Outlook to 2029, 18th Edition, Publicly available summary, *https://roskill.com/market-report/vanadium/.*

[64] Vanadium: Chapter U of Critical Mineral Resources of the United States—Economic and Environmental Geology Prospects for Future Supply (2017). *https://pubs.usgs.gov/pp/1802/u/pp1802u.pdf.*

[65] Titanium Metals Corporation Public Comment on Section 232 National Security Investigation of Imports of Vanadium. Available at *https://www.regulations.gov/document?D=BIS-2020-0002-0019.*

[66] Olin, Chris. Titanium Market Update: Highlighting Global Trends in 2017. Longbow Research.

[67] Boeing 787: From the Ground Up. *https://www.boeing.com/commercial/aeromagazine/articles/qtr_4_06/article_04_2.html* and U.S. Department of Commerce. Bureau of Industry and Security. *The Effect of Imports of Titanium Sponge on the National Security.*

[68] Types of Catalysts for SCR Operations, *https://sviindustrial.com/2020/04/08/types-of-catalysts-for-scr-operations/.*

[69] PubChem Sulfuric acid compound summary, NIH National Library of Medicine, National Center for Biotechnology Information. *https://pubchem.ncbi.nlm.nih.gov/compound/Sulfuric-acid#section=Uses.*

[70] National Mineral Information Center, Sulfur Statistics and information. *https://www.usgs.gov/centers/nmic/sulfur-statistics-and-information.*

[71] Andrew Voshell, Nibir Dhar, Mukti M. Rana, ''Materials for microbolometers: vanadium oxide or silicon derivatives,'' Proc. SPIE 10209, Image Sensing Technologies: Materials, Devices, Systems, and Applications IV, 102090M (28 April 2017); doi: 10.1117/12.2263999.

An additional chemical use of vanadium is in large scale batteries. This accounts for a very small percentage of current usage—estimated well under 1% of total demand—but is an area in which some researchers have seen potential for significant expansion. Vanadium redox flow batteries (VRBs) were first patented in 1986, and VRB technology was advanced by Pacific Northwest National Laboratory in 2011, significantly shrinking the size of the batteries and increasing temperature tolerance.[72] These batteries have attributes that make them valuable for use in energy grids such as longer life cycles, lack electrolyte cross-contamination, and the ability to remain idle without losing capacity.[73] The vanadium accounts for approximately 30% of the cost of a vanadium redox flow battery, requiring between 3 and 6 kilograms of vanadium per kilowatt-hour of energy storage.[74] Estimates of the potential market growth of the vanadium redox flow battery vary wildly, from minimal amounts to estimates exceeding 40% compound annual growth.[75] To date, use of vanadium redox flow batteries has not shown sharp growth, in part due to cost. As the Department of Energy noted as part of its 2020 Energy Storage Grand Challenge Draft Roadmap, ''future capital cost reductions will require replacing vanadium with lower cost raw materials to approach the $100/kWh targets required for wider-scale deployment of energy storage.'' [76]

## VI. Global Vanadium Industry Conditions

### *A. Overview*

Primary and co-production of vanadium is largely undertaken in four countries: China, Russia, South Africa, and Brazil (see Figure 5). In addition to these countries, the United States Geological Survey (USGS) lists known reserves in the United States and Australia. Worldwide resources significantly exceed known reserves, which are considered ''a working inventory of mining companies' supplies of an economically extractable mineral commodity;'' global reserves are estimated at 22 million metric tons, with world vanadium resources estimated to exceed 63 million metric tons.[77]

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[72] Yang, Z Gary. It's Big and Long-Lived, and It Won't Catch Fire: The Vanadium Redox-Flow Battery. IEEE Spectrum, October 26, 2017. *https://spectrum.ieee.org/green-tech/fuel-cells/its-big-and-longlived-and-it-wont-catch-fire-the-vanadium-redoxflow-battery.*

[73] Vanadium Redox Flow Batteries: Improving the performance and reducing the cost of vanadium redox flow batteries for large-scale energy storage. October 2013. U.S. Department of Energy Electricity Delivery & Energy Reliability, Energy Storage Program. Available at *https://www.energy.gov/sites/prod/files/VRB.pdf.*

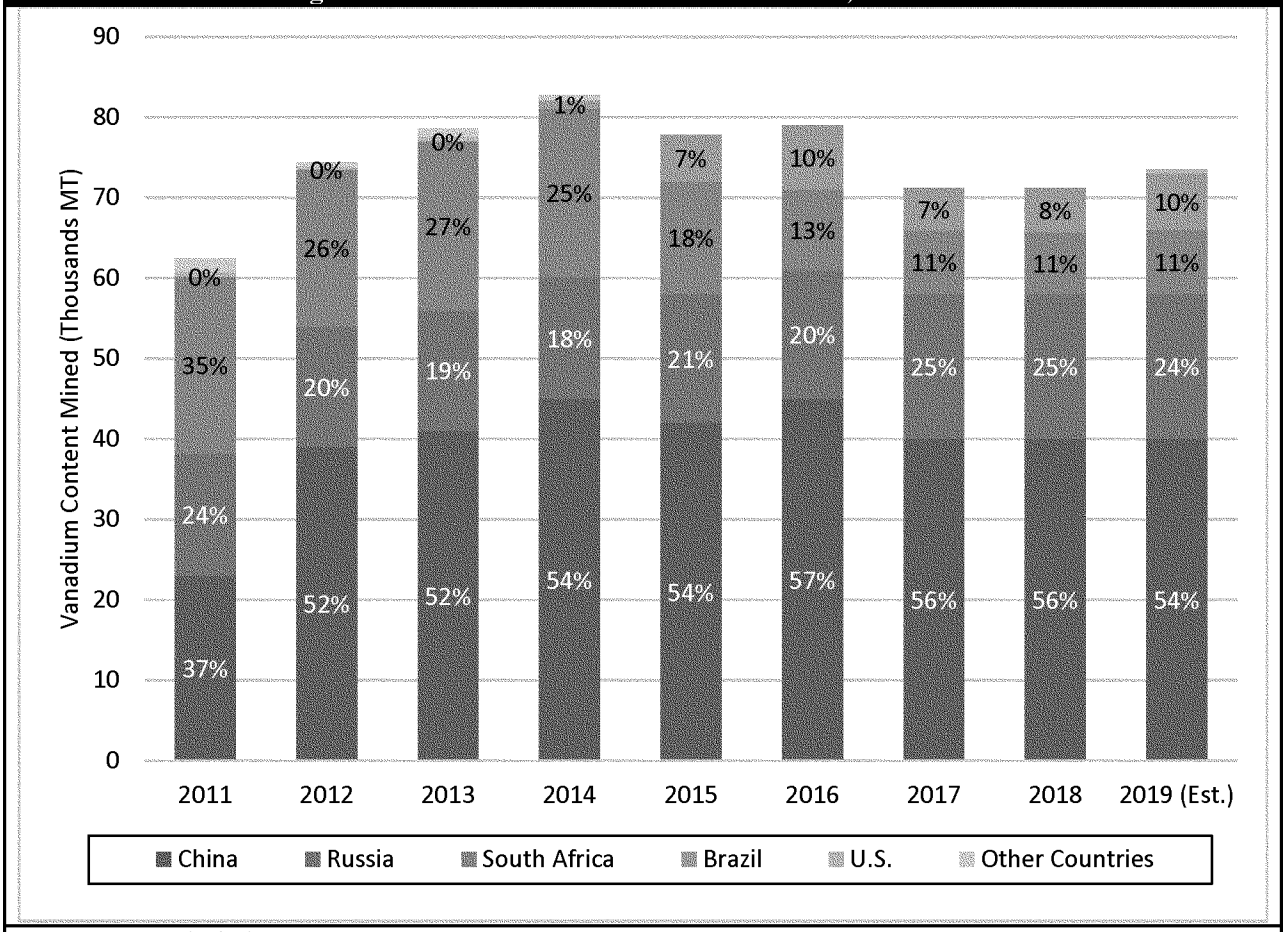
[74] Energy Storage & Vanadium Redox Flow Batteries 101, November 13, 2018. *http://www.bushveldminerals.com/wp-content/uploads/2018/11/Energy-Storage-Vanadium-Redox-Flow-Batteries-101.pdf.*

[75] Ibid.

[76] Department of Energy, ''Energy Storage Grand Challenge Draft Roadmap'', available at *https://www.energy.gov/energy-storage-grand-challenge/energy-storage-grand-challenge.*

[77] United States Geological Survey Mineral Commodity Summaries—Vanadium, *https://www.usgs.gov/centers/nmic/vanadium-statistics-and-information.*

**Figure 5: World Vanadium Mine Production, 2011 - 2019**




Source: U.S. Geological Survey

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Countries other than the United States that are in the process of developing significant reserves include Canada and Kazakhstan. Australia already maintains notable vanadium reserves, which it is seeking to expand, but does not have any recorded mine production. The Government of Australia reports nine vanadium production projects underway, with five of these at advanced stages of exploration, and some vanadium production possible in 2021.[78] One mine—the Windimurra mine—completed a feasibility study in April 2020 and expects to produce 4,250 tons of vanadium content annually.[79] The Windimurra mine has successfully produced vanadium in the past, operating from 1999 to 2003 with an annual production capacity of 3,000 tons contained vanadium.[80] Four other Australian projects are in the process of permitting, design, or pilot studies with a total potential annual production of 22,000 tons of contained vanadium.[81]

[78] Submission from the Australian Government to the United States Department of Commerce, Section 232 National Security Investigation into Imports of Vanadium, submitted to *https://www.regulations.gov*, docket BIS–2020–0002 July 20, 2020.

[79] Ibid.

[80] United States Geological Survey, Vanadium Minerals Yearbook reports. Available at *https://www.usgs.gov/centers/nmic/vanadium-statistics-and-information*.

[81] Submission from the Australian Government to the United States Department of Commerce, Section 232 National Security Investigation into Imports of Vanadium, submitted to *https://www.regulations.gov*, docket BIS–2020–0002 July 20, 2020.

Several mining projects for vanadium-bearing iron ore in Canada are in exploratory phases. Two are in the Lac Doré area of Québec, with partial funding provided by the government of Québec. One of the two, operated by BlackRock Metals, plans to begin operations in 2021, with cast iron and ferrovanadium as the main products.[82] This project is expected to yield 5,200 tons of ferrovanadium annually with 80% vanadium content, to be processed at a nearby facility.[83] The second company, VanadiumCorp Resources, is in the exploration phase, with drill testing programs completed in 2019 and a mineral resource estimate completed in October 2020.[84] The estimate showed 8 million metric tons of measured magnetite concentrate at 1.2% vanadium pentoxide content, equal to 56,000 tons of contained vanadium, with an additional 324,000 tons indicated and 155,000 tons inferred.[85] A third Canadian company, Vanadium One Iron Corporation, released the results of its PEA in February 2020 for its Mont Sorcier property in Québec, anticipating the ability to produce five million tons of ore per year with a 0.6% vanadium pentoxide content.[86]

FIGURE 6—ESTIMATED NEW MINE PRODUCTION POTENTIAL OF SELECT VANADIUM PROJECTS IN CANADA AND AUSTRALIA

[In metric tons contained vanadium]

| Country | Project | Status | Estimated reserves | Estimated annual production |
|---|---|---|---|---|
| Australia | Atlantic Vanadium: Windimurra Mine | In Development | 131,936 | 4,256 |
| Australia | Multicom: Saint Elmo Mine | Finalizing Environmental Approvals | 112,000 | 5,600 |
| Australia | Australian Vanadium Ltd: Australian Vanadium Project. | Feasibility Study | 97,152 | 5,715 |
| Australia | TNG Limited: Mount Peake Mine | Engineering Design | 124,320 | 3,360 |
| Australia | Technology Metals Australia: Gabanintha Mine. | Feasibility Study Completed 2019 | 114,688 | 7,168 |
| Australia | Total | | 580,096 | 26,099 |
| Canada | BlackRock Metals: Chibougamou Mine | Authorized | 176,439 | 4,152 |
| Canada | VanadiumCorp Resources: Lac Doré Project. | Mineral Resource Estimate Complete | 379,273 | 10,306 |
| Canada | VanadiumOne: Mont Sorcier Project | Preliminary Economic Analysis Complete | 117,600 | 16,800 |
| Canada | Total | | 673,312 | 31,258 |

Sources:

Submission from the Australian Government to the United States Department of Commerce, Section 232 National Security Investigation into Imports of Vanadium, submitted to *https://www.regulations.gov*, docket BIS–2020–0002 July 20, 2020.

BlackRock Mining Project Summary. Available at *https://comexqc.ca/en/fiches-de-projet/projet-dexploitation-dun-gisement-fer-vanadium-metaux-blackrock-inc/.*

VanadiumCorp Reports Lac Doré Mineral Resource Estimate. October 29, 2020. Available at *https://www.vanadiumcorp.com/releases/vanadiumcorp-reports-the-lac-dore-mineral-resource-estimate-mre-2/.*

VanadiumOne Iron Corp. Preliminary Economic Analysis Results, February 2020. Available at *https://www.vanadiumone.com/pea-results/.*

In Kazakhstan, the Ferro-Alloy Resources Group, based in Guernsey and listed on the London and Astana International Stock Exchanges, owns Firma Balusa, LLP, which holds the rights to the Balasausqandiq vanadium deposit in the southern part of the country. The site currently has minimal vanadium production, but has rapid expansion plans, forecasting in 2019 reaching production levels of 4,000 tons contained vanadium in 2020 and 13,000 tons in 2023.[87] The projected 2023 production would make Kazakhstan the world's third leading producer of mined vanadium based on current totals. The company's production levels appear significantly behind its initial plans, attributed primarily to the COVID–19 pandemic; through August of 2020 the company indicated it had produced 168 tons of vanadium pentoxide (94 tons contained vanadium) from secondary concentrate, and indicated the development of the Balasausqandiq deposit was ongoing.[88] The company says it ''plans to become the world's lowest cost primary producer.'' [89]

Beyond the estimated 73,000 tons of mine-produced vanadium reported worldwide in 2019, secondary production added as much as 30,000 tons to worldwide totals, with most of the additional production in the U.S., Germany, Austria, Japan, and Taiwan.[90] Significant producers outside of the U.S. include Treibacher in Austria, AMG Technologies in Germany, Shinko Chemical, Taiyo Koko, and Metal Technology in Japan, and Hong Jing Environment, Plum Movax, and Full Yield Industry of Taiwan. Interest in secondary production has risen in recent years as tightened environmental controls on fuels has increased interest in processing spent catalyst and fossil fuel residues. In addition to their U.S. expansion, AMG is exploring the

[82] ''Métaux BlackRock a un client pour son titane'', Radio-Canada, May 8, 2019, *https://ici.radio-canada.ca/nouvelle/1168744/ferrovanadium-usine-saguenay-client-mine-chibougamau.*

[83] ''BlackRock Project: Iron Ore Exploitation at lac Doré'', *https://iaac-aeic.gc.ca/050/documents/p62105/90319E.pdf.*

[84] VanadiumCorp Lac Doré Vanadium Project, *http://www.vanadiumcorp.com/projects/lac-dore-vanadium-project/.*

[85] VanadiumCorp Reports Lac Dore Mineral Resource Estimate (MRE). October 29, 2020. *https://www.vanadiumcorp.com/releases/vanadiumcorp-reports-the-lac-dore-mineral-resource-estimate-mre-2/.*

[86] Vanadium One Iron Corporation PEA Results, February 2020, *https://www.vanadiumone.com/pea-results/.*

[87] Ferro-Alloy Resources Ltd Corporate Presentation, March 2019. *http://ferro-alloy.com/en/news/FAR%20-%20Corporate%20Presentation%20-%20%20update%20March%202019.pdf.*

[88] Ferro-Alloy Resources Unaudited interim financial results for the six months to 30 June 2020. *http://www.ferro-alloy.com/en/investors/financials/.*

[89] Ferro-Alloy Resources Corporate Profile. *http://www.ferro-alloy.com/en/company/corporate-profile/.*

[90] Based on USGS estimates and Perles, Terry. Vanadium Market Fundamentals: China's 2019 4th International Vanadium Forum Chengdu, Sichuan, China. April 13, 2019. Submitted as public comment by Treibacher Industrie, July 20, 2020. Available at *https://www.regulations.gov/document?D=BIS-2020-0002-0026.*

construction of facilities in Saudi Arabia and China to process catalysts from those regions.[91]

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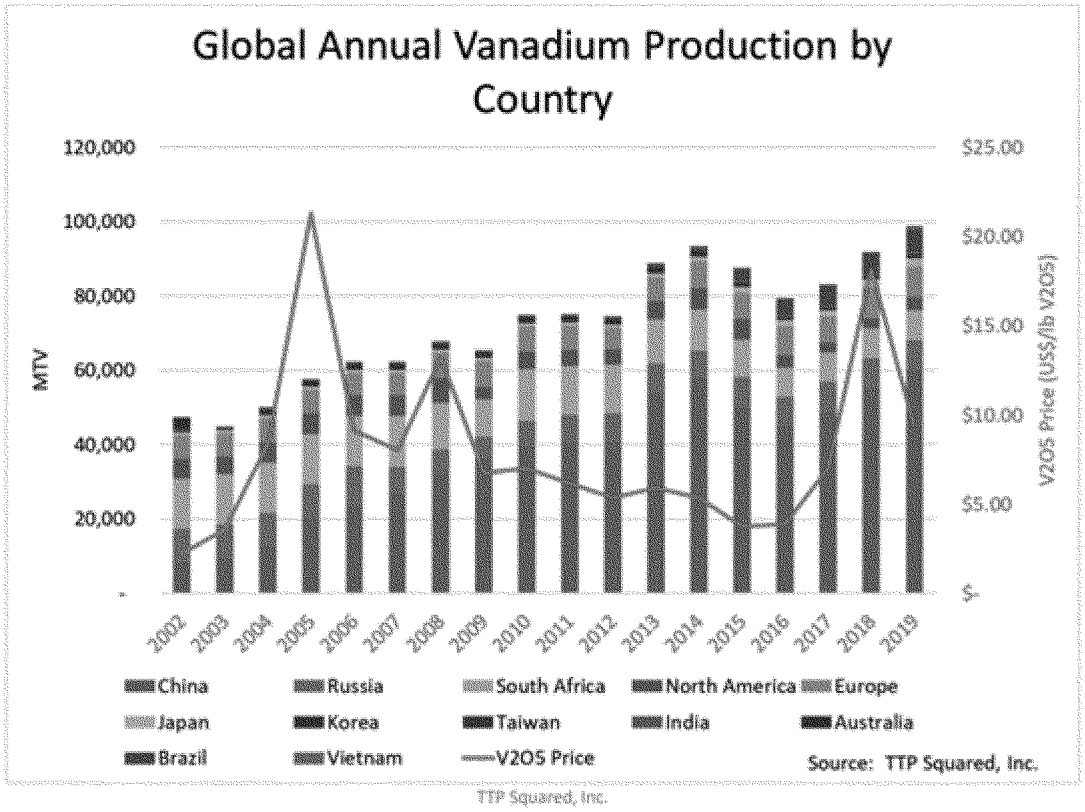
**Figure 7: Vanadium Pentoxide Production**




Source: Vanadium Market Analysis, Terry Perles, TTP Squared, April 3, 2020.
http://www.ferro-alloy.com/en/vanadium/TTP%20Squared%20market%20summary%203%20April%202020.pdf

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While China accounts for an estimated 50 to 60% of global vanadium production, exports of vanadium from China constitute only approximately 15% of worldwide vanadium exports, because most Chinese production is consumed domestically in the steel industry. Primary producers South Africa and Brazil, as well as European Union countries, which represent a much larger share of global vanadium exports than production. The European Union alone accounts for over one-quarter of global exports of contained vanadium (see Figure 8).

FIGURE 8—ESTIMATED 2019 SHARE OF PRODUCTION AND EXPORTS OF VANADIUM CONTENT IN VANADIUM PENTOXIDE AND FERROVANADIUM

| Country | Estimated 2019 share of world production (%) | Estimated 2019 share of world exports (%) |
|---|---|---|
| China | 55 | 15 |
| Russia | 18 | 15 |
| European Union Countries * | 9 | 27 |
| South Africa | 8 | 13 |
| Brazil | 7 | 13 |
| United States | 4 | 4 |
| Japan | 2 | 1 |
| India | 1 | 1 |
| South Korea | <1 | 7 |

[91] AMG 2019 Annual Report. Available at *https://ig9we1q348z124x3t10meupc-wpengine.netdna-ssl.com/wp-content/uploads/AMG-Annual-Report-Web-FINAL.pdf* and Shell & AMG Recycling B.V. Sign Agreement with Shandong Yulong Petrochemical Co., Ltd to Assess Building a Spent Residue Upgrading Catalyst Recycling Facility. Available at *https://www.globenewswire.com/news-release/2020/10/26/2114333/0/en/Shell-AMG-Recycling-B-V-Sign-Agreement-with-Shandong-Yulong-Petrochemical-Co-Ltd-to-Assess-Building-a-Spent-Residue-Upgrading-Catalyst-Recycling-Facility.html.*

FIGURE 8—ESTIMATED 2019 SHARE OF PRODUCTION AND EXPORTS OF VANADIUM CONTENT IN VANADIUM PENTOXIDE AND FERROVANADIUM—Continued

| Country | Estimated 2019 share of world production (%) | Estimated 2019 share of world exports (%) |
|---|---|---|
| Taiwan | <1 | 2 |
| Thailand | <1 | 1 |
| Canada | <1 | 2 |

Sources: U.S. Geological Survey, TTP Squared, Bureau of Industry and Security, IHS Markit Global Trade Atlas.
* Includes exports within the European Union.

Vanadium production generally results first in vanadium pentoxide, which may be exported or further processed into ferrovanadium for use in steel. A large portion of the difference between world production and export share for E.U. countries results from their import of vanadium oxides—principally from Russia—for conversion into ferrovanadium, which was then exported (see Figure 9). In fact, nearly all Russian exports of vanadium oxide went to the Czech Republic, home to EVRAZ Nikom, one of the E.U.'s main producers of ferrovanadium.

FIGURE 9—TOP WORLD TRADE PAIRINGS 2016–2019: VANADIUM OXIDES (HTS 2825.30)

[In tons vanadium oxide]

| Exporter | Importer | 2016 | 2017 | 2018 | 2019 | Share of country's exports (%) | Share of world exports (%) |
|---|---|---|---|---|---|---|---|
| Russia | Czech Republic | 6,656 | 8,656 | 8,676 | 9,683 | 99 | 23 |
| South Africa | Netherlands | 3,415 | 3,225 | 3,871 | 3,711 | 56 | 10 |
| China | South Korea | 3,140 | 4,620 | 3,186 | 2,750 | 47 | 9 |
| Brazil | Netherlands | 1,740 | 4,343 | 4,039 | 3,380 | 37 | 9 |
| Brazil | South Korea | 3,640 | 1,460 | 660 | 2,320 | 22 | 5 |
| South Korea | Japan | 1,181 | 2,357 | 1,840 | 2,051 | 73 | 5 |
| South Africa | United States | 1,676 | 1,744 | 1,603 | 1,521 | 26 | 4 |
| Brazil | United States | 660 | 1,377 | 2,442 | 1,993 | 18 | 4 |
| China | Netherlands | 2,376 | 1,860 | 1,199 | 615 | 21 | 4 |
| Netherlands | Austria | 2 | 46 | 3,100 | 1,773 | 75 | 3 |
| Brazil | Canada | 980 | 940 | 1,320 | 1,340 | 13 | 3 |
| China | Japan | 926 | 720 | 917 | 722 | 11 | 2 |
| China | United States | 930 | 565 | 639 | 69 | 8 | 1 |
| Brazil | Japan | 680 | 440 | 440 | 440 | 6 | 1 |
| China | Canada | 120 | 420 | 599 | 510 | 6 | 1 |
| South Africa | Japan | 267 | 244 | 391 | 560 | 6 | 1 |
| Taiwan | United States | 533 | 510 | 57 | 126 | 38 | 1 |
| Thailand | India | 60 | 320 | 520 | 240 | 55 | 1 |
| Brazil | India | 260 | 660 | 200 | 0 | 3 | 1 |
| South Africa | India | 0 | 0 | 486 | 480 | 4 | 1 |
| All Countries | All Countries | 33,293 | 37,220 | 39,074 | 38,719 | | |

Source: IHS Markit Global Trade Atlas.

Czech ferrovanadium, in turn, was exported principally to the United States, Japan, Netherlands, and Germany (see Figure 10). Other major exporters of ferrovanadium include the Netherlands (the principal importer of South African vanadium oxide), South Korea (the principal importer of Chinese vanadium oxides), and China which, despite exporting a relatively small percentage of their production still accounts for a major portion of global exports due to the sheer size of their production.

FIGURE 10—TOP WORLD TRADE PAIRINGS 2016–2019: FERROVANADIUM (HTS 7202.92)

[In tons ferrovanadium]

| Exporter | Importer | 2016 | 2017 | 2018 | 2019 | Share of country's exports (%) | Share of world exports (%) |
|---|---|---|---|---|---|---|---|
| Netherlands | Germany | 1,902 | 1,832 | 3,758 | 1,913 | 28 | 7 |
| South Africa | Netherlands | 2,112 | 1,662 | 1,563 | 1,579 | 59 | 5 |
| China | Netherlands | 2,380 | 1,540 | 1,549 | 930 | 28 | 5 |
| South Korea | Netherlands | 1,364 | 1,714 | 1,543 | 1,333 | 53 | 4 |
| China | Japan | 1,467 | 1,323 | 1,635 | 1,370 | 25 | 4 |
| China | South Korea | 975 | 995 | 1,667 | 1,661 | 23 | 4 |

FIGURE 10—TOP WORLD TRADE PAIRINGS 2016–2019: FERROVANADIUM (HTS 7202.92)—Continued

[In tons ferrovanadium]

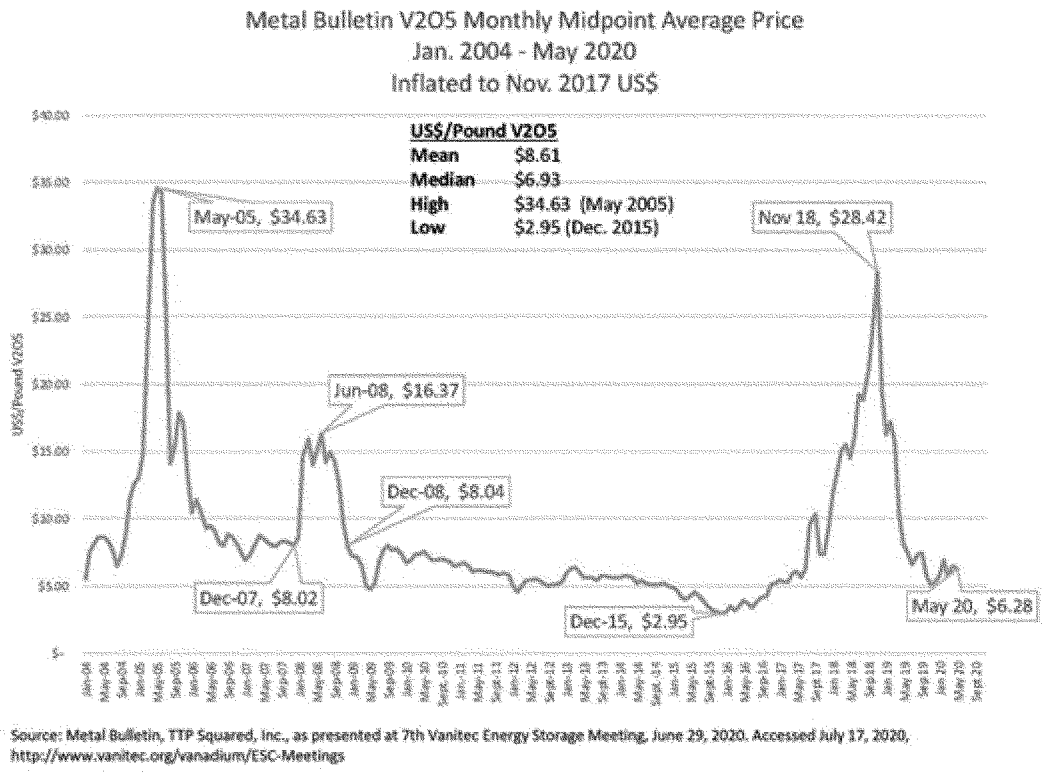
| Exporter | Importer | 2016 | 2017 | 2018 | 2019 | Share of country's exports (%) | Share of world exports (%) |
|---|---|---|---|---|---|---|---|
| Czech Republic | United States | 1,016 | 940 | 1,045 | 1,691 | 18 | 3 |
| Netherlands | United States | 1,398 | 186 | 2,091 | 893 | 13 | 3 |
| Czech Republic | Japan | 1,025 | 740 | 1,020 | 806 | 14 | 3 |
| Netherlands | Italy | 718 | 895 | 1,039 | 523 | 9 | 2 |
| China | Taiwan | 1,109 | 595 | 787 | 644 | 14 | 2 |
| Canada | United States | 142 | 767 | 869 | 1,266 | 91 | 2 |
| United States | Canada | 474 | 295 | 1,403 | 843 | 59 | 2 |
| Czech Republic | Netherlands | 870 | 457 | 270 | 1,184 | 11 | 2 |
| Czech Republic | Germany | 1,162 | 1,009 | 361 | 247 | 11 | 2 |
| Netherlands | Spain | 784 | 654 | 484 | 175 | 6 | 2 |
| South Africa | Japan | 312 | 404 | 605 | 640 | 17 | 1 |
| South Korea | Japan | 596 | 258 | 459 | 601 | 17 | 1 |
| Russia | Netherlands | 404 | 700 | 360 | 420 | 32 | 1 |
| United States | Mexico | 304 | 266 | 642 | 315 | 30 | 1 |
| All Countries | All Countries | 33,477 | 30,849 | 39,300 | 32,367 | | |

Source: IHS Markit Global Trade Atlas.

In recent years, the global vanadium market has been subject to severe price fluctuations. Three times since 2004 the benchmark vanadium pentoxide price has more than doubled in under a year, after which a precipitous drop to more typical price levels occurs (see Figure 11). These rapid price changes have led to a history of investment and expansion during price spikes and plant idlings and bankruptcies in market economies during and following price drops. Starting new primary production has been especially challenging, as new mining ventures can take many years to progress through exploration and permitting to production. The Windimurra mine in Australia, for instance, is in the midst of its fourth re-opening attempt since 1999, having operated from 2000 to 2003, invested in reopening from 2005 to 2009 that ultimately failed to materialize, reopening with new ownership from 2012 to 2014, and currently under development by a new owner.[92]

[92] McKinnon, Stuart. Vanadium Price Boom Offers Hope of WIndimurra Revival. *The West Australian,* April 2, 2018. Available at *https://thewest.com.au/business/mining/vanadium-price-boom-offers-hope-of-windimurra-revival-ng-b88792684z.*

**Figure 11: Vanadium Pentoxide Prices**




Compared to primary production facilities, secondary production facilities can have less extended lead times, but still take years to complete. The establishment of AMG Vanadium's new facility in Ohio was announced in October 2018, broke ground in August 2019, and is expected to be completed in 2021.[93] The Gladieux facility in Freeport, Texas was purchased in 2017 and is not yet operational.

*B. Prior Trade Investigations*

The U.S. government has previously taken action against artificially low-priced vanadium product imports. Several antidumping investigations conducted by the Department of Commerce and the USITC affirm that sources of imported ferrovanadium from nearly all countries that mine vanadium ore have engaged in dumping that injures U.S. producers. Among the significant miners of vanadium ore, only Brazil has not been subject to an antidumping finding. AMG Vanadium (or its predecessor) has been a petitioner for all ferrovanadium antidumping cases, joined by Bear, Gulf, and Stratcor (or its predecessor) for the petitions on China, South Africa, and Korea. Figure 12 lists USITC investigations into vanadium imports since 1995:

FIGURE 12—U.S. INTERNATIONAL TRADE COMMISSION VANADIUM CASES SINCE 1995

| Investigation | Date | Finding |
|---|---|---|
| Ferrovanadium and Nitrided Vanadium from Russia | July 30, 1995 | Affirmative. |
| Ferrovanadium and Nitrided Vanadium from Russia (First Review) | May 15, 2001 | Affirmative. |
| Ferrovanadium from China and South Africa | January 28, 2003 | Affirmative. |
| Ferrovanadium and Nitrided Vanadium from Russia (Second Review) | September 28, 2006 | Affirmative. |
| Ferrovanadium from China and South Africa (First Review) | November 24, 2008 | Affirmative. |
| Ferrovanadium from China and South Africa (Second Review) | January 28, 2015 | Affirmative. |
| Ferrovanadium and Nitrided Vanadium from Russia (Third Review) | August 22, 2012 | Negative. |
| Ferrovanadium from Korea | March 17, 2017 | Affirmative. |
| Ferrovanadium from China and South Africa (Third Review) | August 7, 2020 | Affirmative. |

Source: United States International Trade Commission.

Russia

In July 1995, the Department of Commerce found that imports of ferrovanadium and nitrided vanadium from Russia were sold in the United States at less than fair value, and the USITC found that the dumped imports were materially injuring the U.S. industry. In the course of the

[93] AMG Vanadium Muskingum County Facility website. *https://amg-v.com/muskingumfacility/.*

investigation, USITC determined that ferrovanadium and nitrided vanadium, despite having somewhat disparate end uses, constituted a single like product based on the significant vanadium content and generally interchangeable use in steel alloys.[94]

This affirmative finding was renewed following the Department of Commerce's and USITC's first five-year review of the antidumping duty order in May 2001, as well as the second five-year review in September 2006. At the third set of five-year reviews completed in August 2012, the USITC noted there had been no subject imports since 1996, and that in the case of nitrided vanadium there had been no U.S. production since 1992.[95] However, while there were no imports of ferrovanadium from Russia during the time period, there were imports of Russian vanadium pentoxide, which were then converted to ferrovanadium in the U.S., as well as imports of ferrovanadium from Russian-owned EVRAZ Nikom in the Czech Republic, made from Russian-sourced vanadium pentoxide.[96]

The USITC's third review found, contrary to the prior reviews, that imports of ferrovanadium from Russia would not be likely to significantly increase if the antidumping order was revoked. The decision noted that Russian capacity and production had declined from prior significant excesses, with less focus on exporting ferrovanadium.[97] The report also noted the increased tendency to supply the U.S. market with vanadium pentoxide, rather than the subject product ferrovanadium. On this basis, the antidumping order against Russian ferrovanadium was revoked in October 2011.

China and South Africa

In January 2003 the Department of Commerce determined that imports of ferrovanadium from China and South Africa were sold in the United States at less than fair value and the USITC found that the dumped imports were materially injuring the U.S. industry. In the first sunset reviews (completed November 2008), second sunset reviews (completed January 2015), and third sunset reviews (completed August 2020), the Department of Commerce and the USITC determined that revocation of the existing antidumping duty orders on ferrovanadium from China and South Africa would likely lead to continuation or recurrence of dumping and material injury to an industry in the United States within a reasonably foreseeable time.[98]

Following the imposition of the antidumping order in 2002, imports of ferrovanadium from China fell from an average of 497,000 kilograms of contained vanadium per year from 1999 to 2001 to ''zero or close to zero in every year since 2002.'' [99] USITC cited China's status as the world's largest producer of ferrovanadium and its continued increases in capacity as reasons for an affirmative injury finding.

Imports of ferrovanadium from South Africa showed similar declines following the initial antidumping order. From an average of 758,000 kilograms of vanadium content per year from 1999 to 2001, by 2003 imports had fallen to account for no more than 0.1% of U.S. market share.[100] As was the case with Russian providers, since the imposition of antidumping duties South African vanadium has continued to enter the United States in other forms not subject to antidumping duties, such as vanadium pentoxide and nitrided vanadium.

Korea

In March 2017 the Department of Commerce determined that imports of ferrovanadium from Korea were sold in the United States at less than fair value and the USITC found that the dumped imports were materially injuring the U.S. industry. Unlike Russia, China, and South Africa, Korea is not a significant source of vanadium production. Rather, the USITC noted that Korean ferrovanadium was produced primarily from vanadium pentoxide originally sourced from China.[101] The USITC found that ferrovanadium from Korea was sold in the United States in ''increasing and significant volume . . . at declining prices.'' [102]

*C. U.S. Duties on Vanadium Imports*

As of November 2020, all vanadium products in the scope of this investigation, with the exception of vanadium ore and concentrates (Harmonized Tariff Schedule of the United States (HTSUS) 2615.90.6090) and ash and residues containing vanadium (HTSUS 2620.40.0030 and 2620.99.1000) are subject to duties between 2 and 5.5% (see Figure 13).

FIGURE 13—DUTIES ON VANADIUM PRODUCTS

| Heading/subheading/product | 10 Digit HTS code | Duty (percent) |
|---|---|---|
| Vanadium Oxides | 2825.30.0010 | 5.5 |
| | 2825.30.0050 | 5.5 |
| Ferrovanadium | 7202.92.0000 | *4.2 |
| Vanadium Carbides | 2849.90.5000 | 3.7 |
| Vanadates | 2841.90.1000 | 5.5 |
| Vanadium Ore and Concentrates | 2615.90.6090 | Free |
| Ash and Residues Containing Vanadium | 2620.40.0030 | Free |
| | 2620.99.1000 | Free |
| Vanadium Sulfate | 2833.29.3000 | 5.5 |
| Vanadium Hydrides, Nitrides, Azides, Silicides, and Borides | 2850.00.2000 | 5.5 |

[94] U.S. International Trade Commission. *Ferrovanadium and Nitrided Vanadium from Russia.* Investigation No. 731–TA–702, Final. *https://www.usitc.gov/publications/701_731/pub2904.pdf.*

[95] U.S. International Trade Commission. *Ferrovanadium and Nitrided Vanadium from Russia.* Investigation No. 731–TA–702 (Third Review). *https://www.usitc.gov/publications/701_731/pub4345.pdf.*

[96] Ibid.

[97] Ibid.

[98] Ferrovanadium from the People's Republic of China and the Republic of South Africa: Continuation of Antidumping Duty Orders, 73 FR 77609, December 19, 2008; Ferrovanadium From the People's Republic of China and the Republic of South Africa: Continuation of Antidumping Duty Orders, 80 FR 8607, February 18, 2015; Ferrovanadium From the Republic of South Africa and the People's Republic of China: Continuation of Antidumping Duty Orders, 85 FR 51408, August 20, 2020.

[99] U.S. International Trade Commission. *Ferrovanadium and Nitrided Vanadium from China and South Africa.* Investigation Nos. 731–TA–986–987 (Third Review). *https://www.usitc.gov/publications/701_731/pub5099.pdf.*

[100] Ibid.

[101] U.S. International Trade Commission. *Ferrovanadium and Nitrided Vanadium from Korea.* Investigation Nos. 731–TA–1315. *https://www.usitc.gov/publications/701_731/pub4683.pdf.*

[102] Ibid.

FIGURE 13—DUTIES ON VANADIUM PRODUCTS—Continued

| Heading/subheading/product | 10 Digit HTS code | Duty (percent) |
|---|---|---|
| Vanadium, Unwrought and Wrought | 8112.92.7000 | 2 |
| | 8112.99.2000 | 2 |

Source: United States International Trade Commission and U.S. Department of Commerce, Bureau of Industry and Security, as of December 7, 2020.

* Ferrovanadium products from China, South Africa, and Korea are subject to additional antidumping duties.

Antidumping duties on ferrovanadium add significantly to the rates for ferrovanadium from China, South Africa, and Korea (see Figure 14).

FIGURE 14—ANTIDUMPING DUTIES ON FERROVANADIUM

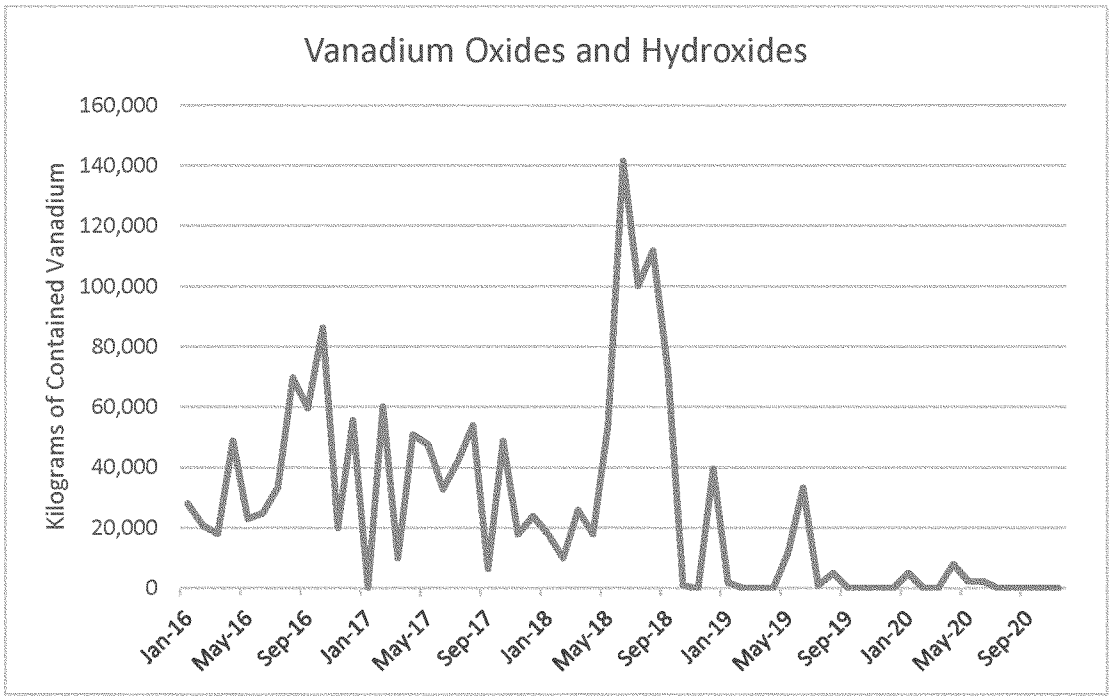
| Country | Exporter/producer | Dumping rate (percent) |
|---|---|---|
| China | Pangang Group International Economic & Trading Corporation | 12.97 |
| | China-Wide | 66.71 |
| South Africa | Highveld Steel and Vanadium Corporation, Ltd | 116.00 |
| | Xstrata South Africa (Proprietary) Limited | 116.00 |
| | All Others | 116.00 |
| Korea | Korvan Ind. Co., Ltd | 3.22 |
| | Fortune Metallurgical Group Co., Ltd | 54.69 |
| | Woojin Ind. Co., Ltd | 54.69 |
| | All Others | 3.22 |

Source: **Federal Register**; 68 FR 4168, 68 FR 4169, 82 FR 14874.

In addition to the above general and antidumping duties, China has been subject to Section 301 duties on all subject vanadium products except HTSUS 2620.40.0030 (ash and residue containing mainly aluminum and vanadium-bearing materials) of 10% starting September 21, 2018 and 25% starting August 20, 2019. Prior to the imposition of Section 301 duties, vanadium oxides was the only category of vanadium product with significant imports from China. Imports of vanadium via vanadium oxides fell from a monthly average of 31,500 kilograms in the year prior to the initial announcement of Section 301 tariffs to 7,200 kilograms per month in year following the imposition of tariffs. Between the initial announcement of Section 301 duties in April 2018 and the imposition of duties on vanadium products in September 2018, imports of vanadium oxides from China rose to 96,000 kilograms of contained vanadium per month, perhaps due to companies increasing inventories in anticipation of duties (see Figure 15).

BILLING CODE 3510–33–P

**Figure 15: Imports of Vanadium Oxides and Hydroxides from China (in kilograms of contained vanadium)**




Source: ITC Dataweb, HTS 2825.30

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## VII. Findings

### *A. Vanadium Is Essential to U.S. National Security*

#### 1. Vanadium Is Considered a Critical Mineral

Vanadium is one of the 35 minerals included by the Department of Interior (DOI) on the Critical Minerals List. This list, which President Trump directed DOI to define in E.O. 13817, includes minerals which meet the following criteria:

(i) A non-fuel mineral or mineral material essential to the economic and national security of the United States,

(ii) the supply chain of which is vulnerable to disruption, and

(iii) that serves an essential function in the manufacturing of a product, the absence of which would have significant consequences for our economy or our national security.[103]

In its report, *Critical mineral resources of the United States—Economic and environmental geology and prospects for future supply,* USGS observed that vanadium is used in steel alloys which are in turn used in critical sectors including bridges, pipelines, ships, rail cars, truck bodies, and military vehicles, and is ''irreplaceable for its role in aerospace applications'' via titanium alloys.[104] For this reason among others, and based on input from other U.S. government agencies, USGS included vanadium on the critical minerals list.

As discussed in Section V of this report, in addition to its use in alloys, vanadium is a vital component in the production of vanadium redox flow batteries (VRBs), chemical catalysts, ceramics, electronics, and other vanadium chemicals. VRBs are a potential area of large scale energy storage, a fast-growing sector that will help support the growth and reliability of the power grid. As noted above, sulfuric acid's wide array of manufacturing uses means its production is highly correlated with industrial development. Though a small percentage of overall vanadium demand, these catalyst uses are essential for multiple critical infrastructure and commercial sectors.

USGS cited continued need for steel products as a driver of vanadium demand, specifically noting expansion of Chinese demand, increased vanadium content in steel rebar in China and Japan, growing steel production in India, and expansion of energy uses of vanadium. As a result, USGS predicts that new sources of vanadium and more efficient extraction from existing sources will be required to supplement the current limited supply. Further, as vanadium is required for the manufacture of titanium products and is a significant alloying agent in high strength steel, limited vanadium production capacity could create a supply bottleneck. Such a bottleneck is

[103] White House, ''Presidential Executive Order on a Federal Strategy to Ensure Secure and Reliable Supplies of Critical Materials'', (December 20, 2017), *https://trumpwhitehouse.archives.gov/presidential-actions/presidential-executive-order-federal-strategy-ensure-secure-reliable-supplies-critical-minerals/.*

[104] Kelley, K.D., Scott, C.T., Polyak, D.E., and Kimball, B.E., 2017, Vanadium, chap. U of Schulz, K.J., DeYoung, J.H., Jr., Seal, R.R., II, and Bradley, DC, eds., Critical mineral resources of the United States—Economic and environmental geology and prospects for future supply: U.S. Geological Survey Professional Paper 1802, p. U1–U36, *https://doi.org/10.3133/pp1802U.*

one of the ''vulnerabilities'' identified in E.O. 13817.[105]

2. Vanadium Is Required for National Defense Systems

Vanadium, as a result of its use in steel and titanium alloys, is a critical input to many defense systems. The 2017 and 2019 Department of Commerce Section 232 reports on the effects of steel and of titanium sponge on national security found that those metals were required for national defense. Therefore, because vanadium is frequently used in these metals and there is no suitable substitute for vanadium in many of these products, vanadium is also required to meet national defense needs.

DLA has identified [TEXT REDACTED] defense systems that require the use of vanadium, including but not limited to the [TEXT REDACTED]. The average titanium content for military airframes that entered service after 2000 is 30%, implying vanadium content of roughly 1% by weight.[106] For example, each F–22A Raptor aircraft contains at least six separate titanium alloys, some containing as much as 15% vanadium by weight, with a finished aircraft containing approximately 9,000 pounds of titanium.[107] Building each aircraft requires significantly more material: About 50 metric tons of titanium, which in turn requires approximately 2 metric tons of vanadium content based on a standard Ti–6Al–4V alloy.[108] The F–35 Lightning II requires an estimated 15 tons of titanium per plane to build.[109] Overall, defense uses account for an estimated 10% of titanium demand, equivalent to approximately 43 tons of vanadium content per year.[110]

The Department's 2018 Steel Report aligns with this finding. The report found that the Department of Defense has ''a large and ongoing need for a range of steel products that are used in fabricating weapons and related systems for the nation's defense.'' Among the defense steel uses cited were aircraft carriers, submarines, and tanks, as well as the high-strength steel alloys used on aircraft and discussed above. The Steel Report indicated that Department of Defense's steel requirements amount to 3% of annual overall U.S. steel production, equivalent to approximately 230 metric tons of vanadium content per year.[111] In addition to direct incorporation of vanadium into defense systems, the production of these systems relies on vanadium-containing infrastructure, as tool steels and high speed steels often have a significantly higher vanadium content than other steel.

3. Vanadium Is Required for Critical Infrastructure

As with national defense systems, vanadium is a key component of much of the steel and titanium used in U.S. critical infrastructure. Vanadium is a key feature in high-strength, low-alloy (HSLA) steel products used in the construction industry, including earthquake-resistant rebar, bridges, and construction cranes. Hand tools and high-speed steel tools for cutting and boring commonly contain vanadium as a strengthening agent. The commercial aerospace industry also relies on vanadium through its use of titanium alloys, and the chemical production industry uses vanadium directly for production of sulfuric acid.

The Department's 2018 Steel Report determined that 54 million metric tons of steel per year were consumed in critical industries, accounting for half of all domestic steel consumption.[112] Steel had uses in all of the United States' 16 critical infrastructure sectors, with the transportation, energy, and water treatment sectors specifically noted as vulnerable to disruption. A conservative estimate of the use of vanadium in critical infrastructure via steel products amounts to 3,865 tons of vanadium demand annually.[113]

In the titanium industry, nearly all vanadium-bearing titanium products have end-uses in critical infrastructure and defense sectors. Beyond the 10% of titanium consumed via military uses, an estimated 55% of consumption is in commercial aerospace products—part of the transportation critical infrastructure sector—with nearly all remaining consumption in industrial or medical uses. Use of vanadium in critical infrastructure via titanium products thus amounts to between 236 tons and 365 tons per year.[114]

Nearly all non-metallurgical uses of vanadium are also related to critical infrastructure. The energy sector is a primary destination; vanadium is used as a catalyst in industrial power plants and as the electrolyte in vanadium redox flow batteries. The other significant non-metallurgical use is in the chemical production sector, where vanadium is used as a catalyst in the production of sulfuric acid and maleic anhydride. With non-metallurgical use accounting for an estimated 5% of vanadium demand, direct vanadium use in critical infrastructure amounts to approximately 430 tons per year.[115]

With indirect use in all 16 critical infrastructure sectors, direct use in the energy and chemical production sectors, and an ''irreplaceable'' status in titanium alloys used in the transportation sector, vanadium has a key role in U.S. critical infrastructure. Overall annual critical infrastructure use of vanadium amounts conservatively to 4,542 tons.

4. Vanadium Has Significant Effects on Other Critical Industries

As discussed above, vanadium has essential uses in steel and titanium production, and vanadium resources in the United States are often co-located with uranium. Titanium and uranium have been identified as critical minerals by the Department of Interior, with steel, titanium sponge, and uranium all the subjects of recent Section 232 investigations. The impact of the vanadium industry on other critical industries is significant, underscoring vanadium's status as a critical commodity.

Following the Section 232 investigation into the effect of imports

[105] White House, ''Presidential Executive Order on a Federal Strategy to Ensure Secure and Reliable Supplies of Critical Materials''.

[106] U.S. Department of Commerce. Bureau of Industry and Security. *The Effect of Imports of Titanium Sponge on the National Security (*Washington, DC: 2019) (''Titanium Report'') and based on use of standard Ti–6Al–4V alloy.

[107] Cotton, James D. et al. Titanium Alloys on the F–22 Fighter Airframe. Advanced Materials & Processes, May 2002. *https://www.asminternational.org/documents/10192/1756963/amp16005p025.pdf/c0972040-8169-4998-8699-f051fab52d9b/AMP16005P025.*

[108] Seong, Somi et al. Titanium: Industrial Base, Price Trends, and Technology Initiatives, 2009. *https://www.rand.org/content/dam/rand/pubs/monographs/2009/RAND_MG789.pdf.*

[109] Ibid.

[110] Based on average annual 2016–2019 USGS vanadium apparent consumption of 8,590 tons, titanium uses accounting for 5% of vanadium consumption, and defense use accounting for 10% of titanium demand.

[111] Based on average annual 2016–2019 USGS vanadium apparent consumption of 8,590 tons, steel uses accounting for 90% of vanadium consumption, and defense use accounting for 3% of steel demand.

[112] Based on the 16 designated critical infrastructure sectors identified pursuant to Presidential Policy Directive 21 (PPD–21). *https://www.cisa.gov/critical-infrastructure-sectors.*

[113] Based on average annual 2016–2019 USGS vanadium apparent consumption of 8,590 tons, steel uses accounting for 90% of vanadium consumption, and critical infrastructure use accounting for 50% of steel demand. Use is likely higher, as critical infrastructure sectors are more likely to use HSLA and full alloy steels.

[114] Based on average annual 2016–2019 USGS vanadium apparent consumption of 8,590 tons, titanium uses accounting for 5% of vanadium consumption, and critical infrastructure use accounting for between 55% and 85% of titanium demand; commercial aerospace estimated at 55% of titanium demand, but up to 85% of vanadium-alloyed titanium demand, with industrial and medical titanium commonly unalloyed.

[115] Based on average annual 2016–2019 USGS vanadium apparent consumption of 8,590 t.

of steel products on national security, on March 8, 2018, the President issued a proclamation concurring with the Secretary of Commerce's finding that imports of steel articles threatened to impair U.S. national security, and imposing a 25% tariff on imports. The goal of the tariff was to help ensure the economic viability of the domestic steel industry, which was threatened by low-cost imports. The basis for the President's actions, and the Secretary's findings, was the critical role of the steel industry in national security.

As discussed above, the steel industry accounts for approximately 90% of the U.S. demand for vanadium.[116] Compared to the estimated $92 billion worth of raw steel produced in the United States in 2019, vanadium costs constituted only a small expense for the overall industry. However, certain industry sectors incurred far higher cost exposure to vanadium. In an industry threatened by low-cost imports, even minor cost changes can have significant effects on domestic producers. Domestic producers challenged by low-cost imports for more than one essential ''ingredient'' for their product (*e.g.,* steel and vanadium) face even more daunting odds.

Aside from steel, the primary use of vanadium is for use in titanium alloys. In March 2019, following a petition from Titanium Metals Corporation (TIMET), the Department of Commerce initiated a Section 232 investigation into the effect of imports of titanium sponge on U.S. national security. The Secretary's report found that imports of titanium sponge and scrap depressed U.S. prices and constituted a threat to national security, but did not recommend adjustment of imports, favoring other measures. The President issued a proclamation on February 27, 2020 concurring with the Secretary's finding.[117] In preparing its report, the Department found that an area of particular concern for the U.S. titanium industry is the advance of Russian and Chinese producers in aerospace-quality titanium product capabilities.

The President's February 2020 proclamation also directed the formation of a working group to ensure U.S. access to titanium sponge. Since its formation, the Titanium Sponge Working Group (TSWG) has explored measures that may help to ensure access to titanium sponge for U.S. national defense and critical infrastructure purposes. The TWSG, co-led by the Departments of Commerce and Defense, is considering a series of recommendations to move toward this goal. [TEXT REDACTED].

Accounting for approximately 5% of domestic vanadium demand, the U.S. titanium industry consumes an estimated 430 tons of contained vanadium annually, valued at $17 million.[118] As noted in above, in a standard Ti-6Al-4V alloy, vanadium makes up 4% of the weight and between 12 and 14% of the product cost, making the titanium industry relatively exposed to vanadium cost changes.

In the United States, primary vanadium production is currently performed only in conjunction with uranium mining. The only company to produce mined vanadium in the United States in recent years, Energy Fuels, was one of the applicants in the Section 232 investigation into the effect of imports of uranium on national security. The Section 232 report on uranium was completed and sent to the President in April 2019. In his report, the Secretary found that uranium was being imported in such quantities and under such circumstances as to threaten to impair national security.

The President's responsive proclamation, issued in July 2019, expressed concern about domestic uranium supplies and directed the establishment of a Nuclear Fuel Working Group (NFWG) to carry out a ''comprehensive review of the entire domestic nuclear supply chain.''[119]

In April 2020, the Secretary of Energy announced the NFWG's findings and recommendations in a *Strategy to Restore American Nuclear Energy Leadership.* The Strategy recommended ''taking immediate and bold action to strengthen the uranium mining and conversion industries.''[120] The report also cited the inclusion in the President's Fiscal Year 2021 Budget Request of $150 million for a domestic uranium reserve. The Fiscal Year 2021 Budget passed by Congress included $75 million for establishment of a uranium reserve.

As demonstrated by the comments submitted by several companies with uranium mining resources in response to the Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Vanadium, industry sees a clear connection in the critical nature of vanadium and uranium. For example, Energy Fuels submitted a comment supporting a recommendation for Section 232 relief for vanadium, in part on the basis that there was ''significant uncertainty'' about a successful outcome for implementation of the NFWG's recommendations.[121] Energy Fuels also wrote that vanadium relief ''together with a reasonable uranium price'' would enable the company to mine both uranium and vanadium in the future. Another uranium mining company, Nuvemco, LLC, submitted a comment that included their submission to the NFWG, based on the adjacency of the two mining sectors in the United States.

*B. Imports of Vanadium Have Mixed Effects on the Economic Welfare of the U.S. Vanadium Industry*

1. The U.S. is Presently Reliant on Imports of Vanadium

Though the scope of this investigation covers 12 discrete 10-digit HTS codes, the bulk of the vanadium imported into the United States consists of just two products: vanadium pentoxide and ferrovanadium. The third most frequently imported vanadium product is carbides, a product sector heavily dominated by South Africa exports of vanadium carbide nitride, which is used as an alternative to ferrovanadium in steel production. The remaining vanadium products imported into the United States that are covered under the scope of this investigation either constitute niche application areas or are used as inputs or feedstock in order to produce vanadium products.

[116] Equivalent to 7,731 tons contained vanadium, valued at $297 million based on U.S. Geological Survey Vanadium Mineral Commodity Summary, apparent consumption and average vanadium pentoxide prices.

[117] Memorandum on the Effect of Titanium Sponge Imports on the National Security. Available at *https://trumpwhitehouse.archives.gov/presidential-actions/memorandum-effect-titanium-sponge-imports-national-security/.*

[118] Based on U.S. Geological Survey Vanadium Mineral Commodity Summary, apparent consumption and average vanadium pentoxide prices.

[119] Memorandum on the Effect of Uranium Imports on the National Security and Establishment of the United States Nuclear Fuel Working Group. *https://trumpwhitehouse.archives.gov/presidential-actions/memorandum-effect-uranium-imports-national-security-establishment-united-states-nuclear-fuel-working-group/.*

[120] Department of Energy, Secretary Brouillette Announces The Nuclear Fuel Working Group's Strategy To Restore American Nuclear Energy Leadership. April 23, 2020. *https://www.energy.gov/articles/secretary-brouillette-announces-nuclear-fuel-working-groups-strategy-restore-american.*

[121] Energy Fuels Resources (USA) Inc. Comment in response to Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Vanadium, July 20, 2020. *https://www.regulations.gov/document?D=BIS-2020-0002-0016.*

FIGURE 16—U.S. IMPORTS OF VANADIUM PRODUCTS, 2017–2020

[in millions of USD]

| HTSUS | Description | 2017 | 2018 | 2019 | 2020 (projected) |
|---|---|---|---|---|---|
| 7202.92.0000 | Ferrovanadium | $94.60 | $232.65 | $167.90 | $56.65 |
| 2825.30.0010 | Vanadium pentoxide (anhydride) | 60.32 | 168.95 | 109.92 | 36.90 |
| 2849.90.5000 | Carbides, whether or not chemically defined, nesoi * (excluding of boron, of chromium, or of tungsten). | 49.38 | 90.84 | 98.89 | 27.57 |
| 2620.99.1000 | Ash & residues (except from the manufacture of iron or steel), containing mainly vanadium. | 14.51 | 63.90 | 54.48 | 0.48 |
| 8112.99.2000 | Vanadium and articles thereof, wrought, waste and scrap, powders, nesoi. | 10.75 | 17.22 | 17.64 | 6.08 |
| 2620.40.0030 | Ash and residues (other than from the manufacture of iron or steel), containing mainly aluminum, vanadium-bearing materials. | ..... | ..... | 4.29 | 9.99 |
| 2841.90.1000 | Vanadates, (vanadium content) | 6.24 | 17.46 | 3.26 | 2.04 |
| 2615.90.6090 | Vanadium ores and concentrates | 0.28 | 8.45 | 9.49 | 0.54 |
| 2825.30.0050 | Vanadium oxides and hydroxides, except vanadium pentoxide, nesoi. | 3.68 | 5.45 | 6.84 | 3.02 |
| 8112.92.7000 | Vanadium and articles thereof, unwrought, powders, except waste and scrap. | 2.60 | 2.21 | 4.10 | 0.07 |
| 2850.00.2000 | Hydrides, nitrides, azides, silicides and borides, whether or not chemically defined, of vanadium. | 1.08 | 0.92 | 0.85 | 0.65 |
| 2833.29.3000 | Vanadium sulfate | 0.05 | 0.12 | 0.62 | 0.27 |
| Total | | 243.49 | 608.17 | 478.28 | 144.26 |

Source: ITC Dataweb, 2020 data through November.
*nesoi indicates "not elsewhere specified or indicated."

Any measurement of the United States' reliance on imports of vanadium must take into account the wide array of vanadium products and end uses. U.S. vanadium import reliance varies depending on the type of vanadium product. Additionally, because some vanadium products are used to produce other vanadium products, import reliance calculations must consider domestic capabilities for both the vanadium end products and their vanadium-bearing feedstocks.

Domestic production capabilities exist for ferrovanadium (50% and 80%), vanadium oxides and hydroxides (including regular grade and high purity vanadium pentoxide), vanadates, vanadium ore and concentrates, vanadium master alloys, and vanadium sulfates. The United States does not currently have domestic capability for vanadium carbides (HTS 2849.90.5000) or vanadium hydrides, sulfides, nitrides, azides, silicides, and borides (HTS 2850.00.2000), [TEXT REDACTED].[122] The United States has very limited capacity to produce vanadium ore and concentrates, with recent production intermittent and linked to uranium production.

The following import analysis focuses primarily on ferrovanadium and vanadium pentoxide, recent import trends for these products and their feedstocks, and the United States' reliance on imports to satisfy domestic demand.

Ferrovanadium

Ferrovanadium imports to the United States have fluctuated significantly in the past decade, generally tracking higher prices with lower imports, with sources increasingly concentrated in Europe and Canada (see Figure 17). In 2019, the last year for which full data is available, the United States imported roughly 2.3 million kilograms of contained vanadium of ferrovanadium, from Canada (43%), Austria (25%), Russia (6%) and others (26%). These imports accounted for approximately [TEXT REDACTED] of total U.S. demand for ferrovanadium in 2019, with the remaining demand filled by the domestic ferrovanadium producer AMG Vanadium and converter Bear Metallurgical. Import reliance fluctuated between [TEXT REDACTED] from 2016 to 2019, averaging roughly [TEXT REDACTED] over the period.[123]

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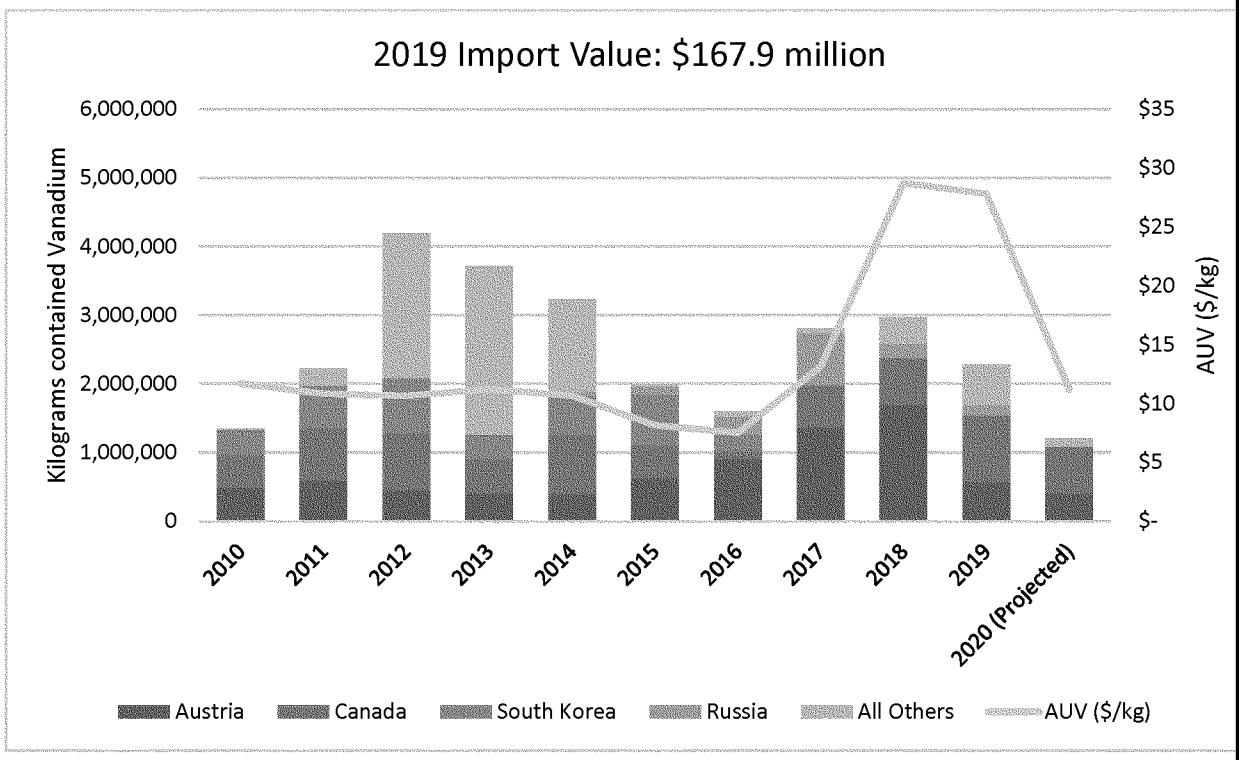
[122] U.S. Department of Commerce, Bureau of Industry and Security, Section 232 Investigation into Imports of Vanadium Survey.

[123] Data from U.S. Department of Commerce, Bureau of Industry and Security, Section 232 Investigation into Imports of Vanadium Survey. U.S. ferrovanadium producers produced and sold enough material to satisfy an average of [TEXT REDACTED] of apparent domestic consumption between 2016 and 2019. The U.S. exported an average of 373,154 kilograms of contained vanadium in ferrovanadium each year, resulting in domestic production filling approximately [TEXT REDACTED] of domestic demand.

**Figure 17: Imports of Ferrovanadium, 2010 – 2020 (projected)**




Source: ITC Dataweb

BILLING CODE 3510–33–C

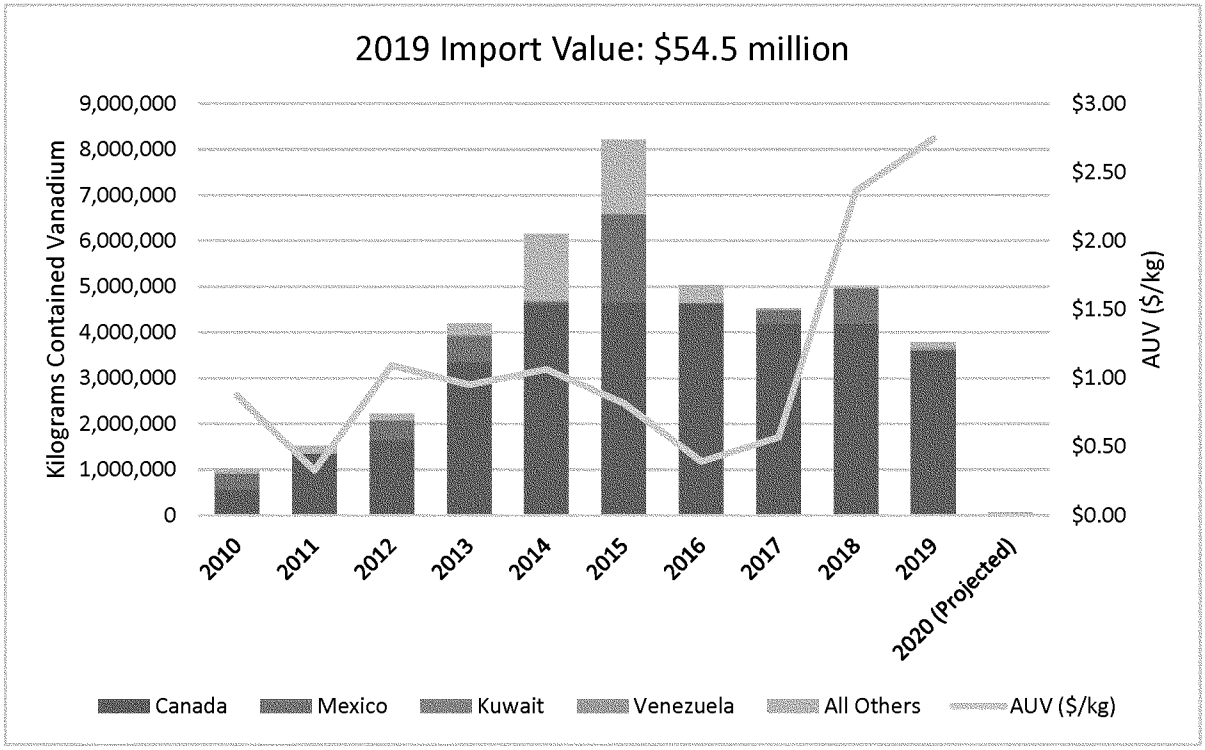
While the United States' two domestic producers of ferrovanadium have produced and sold enough material to satisfy [TEXT REDACTED] of U.S. demand from 2016 to 2019, the companies' operations require sourcing vanadium-bearing feedstock in order to produce ferrovanadium. These U.S. producers convert either vanadium-bearing waste products (ash, residues, and spent catalysts) or vanadium pentoxide in order to produce ferrovanadium. Therefore, in order to fully capture the U.S.'s level of reliance on imports for ferrovanadium, U.S. ferrovanadium producers' reliance on imported feedstock must be taken into account.

Ash, Residues, and Spent Refinery Catalyst Feedstock for Ferrovanadium Production

AMG Vanadium, one of the U.S.'s two current producers of ferrovanadium, produces ferrovanadium by recycling spent refinery catalysts. Between 2016 and 2019, the [TEXT REDACTED].[124] In 2019, U.S. imports of vanadium-bearing waste product were almost exclusively sourced in Canada, with Mexico as the primary other source since 2010, [TEXT REDACTED]. (See Figure 18).

[124] U.S. Department of Commerce, Bureau of Industry and Security, Section 232 Investigation into Imports of Vanadium Survey.

**Figure 18: Imports of Vanadium-Bearing Waste, 2010 – 2020 (projected)**




HTSUS Codes: 2620.40.0030 and 2620.99.1000

Source: ITC Dataweb

[TEXT REDACTED].[125] [TEXT REDACTED]. However, the company's initiative to double its production capacity (via the opening of a new facility) means that the company will soon have the ability to [TEXT REDACTED]. [TEXT REDACTED].[126]

Vanadium Pentoxide Feedstock for Ferrovanadium Production

Another feedstock source used to produce ferrovanadium is vanadium pentoxide. Evergreen Metallurgical (dba Bear Metallurgical (Bear)) operates a Pennsylvania facility that converts customer-provided vanadium pentoxide into ferrovanadium with 80% vanadium content (FeV–80). Bear does not source its own vanadium pentoxide, but instead acts as a service provider by toll-producing vanadium pentoxide into FeV–80 for customers. Since the idling of the only U.S. facility that produces regular grade vanadium pentoxide (less than 99% purity), Bear has been heavily reliant on imported vanadium pentoxide feedstock from its customers.[127] That facility was owned by Bear's parent (Gulf Chemical) prior to their bankruptcy and the idling and sale of the facility in 2017 to Gladieux.

Therefore, although Bear's conversion of vanadium pentoxide into ferrovanadium satisfied approximately [TEXT REDACTED] of total U.S. demand for ferrovanadium between 2016 and 2019, the company [TEXT REDACTED].[128]

In summary, while domestically-produced ferrovanadium was sufficient to meet approximately [TEXT REDACTED] of total domestic demand for ferrovanadium from 2016 to 2019, both domestic ferrovanadium producers [TEXT REDACTED].

The following section addresses U.S. import trends for vanadium oxides and hydroxides, including regular grade vanadium pentoxide, high purity vanadium pentoxide, and other vanadium oxides and hydroxides. These products are used in Bear's ferrovanadium conversion activities as well as in the company's production of vanadium products used for chemical and aerospace applications.

Vanadium Oxides and Hydroxides

Demand for vanadium oxides and hydroxides—driven by vanadium pentoxide—accounts for close to half of all vanadium demand in the United States. On average, imports of vanadium pentoxide account for over 90% of all oxide imports each year.[129] Since 2010, overall vanadium oxide and hydroxide imports, including imports of vanadium pentoxide, have ranged between 2 million and 4.5 million kilograms of contained vanadium (imports in 2020 are projected to fall below two million, the lowest level since 2009) (see Figure

[125] U.S. Department of Commerce, Bureau of Industry and Security, Section 232 Investigation into Imports of Vanadium Survey.

[126] Ibid.

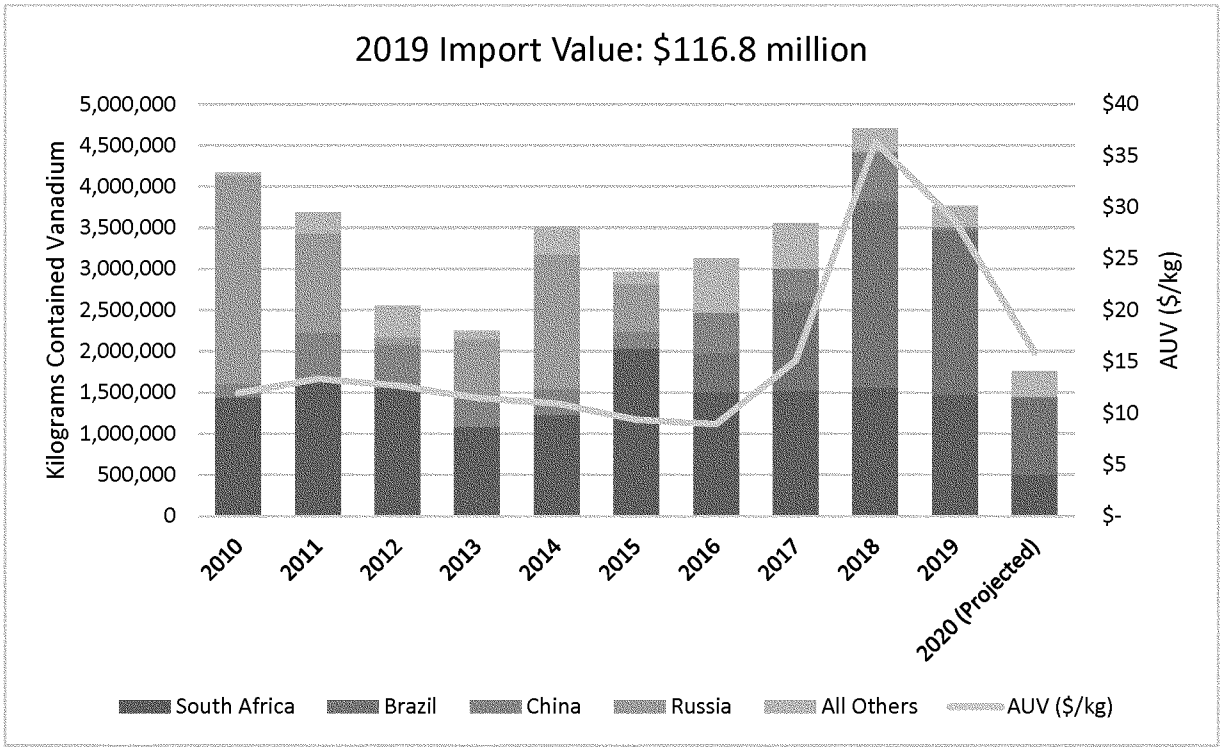
[127] Gladieux Metals Recycling (GMR) owns a Freeport, Texas facility that converted vanadium-bearing waste products (spent catalysts) into vanadates and vanadium pentoxide (including high purity vanadium pentoxide). The facility was in operation until 2017 when it was idled and sold to new ownership from previous owners Gulf Chemical & Metallurgical Corp. Gladieux has not produced and sold any material since 2017, but is in the process of upgrading the facility, and plans to restart [TEXT REDACTED] U.S. Vanadium operates a facility that produces high purity vanadium pentoxide, typically used in titanium or chemical uses rather than ferrovanadium production.

[128] U.S. Department of Commerce, Bureau of Industry and Security, Section 232 Investigation into Imports of Vanadium Survey.

[129] ITC Dataweb.

19). Between 2010 and 2015, Russian-sourced oxides and hydroxides were a major portion of U.S. imports, accounting for nearly 35% of imports, but were largely replaced by growing imports from Brazil and South Africa beginning in 2016.

**Figure 19: Imports of Vanadium Oxides and Hydroxides, 2010 – 2020 (projected)**




HTSUS Codes: 2825.30.0010 and 2825.30.0050

Source: ITC Dataweb

BILLING CODE 3510–33–C

Russian ferrovanadium, which had been absent from the U.S. market from 1997, returned to U.S. markets in 2014 following the October 2011 revocation of the antidumping order. Imports of Russian vanadium oxides have been largely replaced by imports of Russian ferrovanadium, though not at levels approaching the 2010 to 2014 period.

Vanadium oxides and hydroxides cover a range of vanadium products with different application areas. A nuanced measurement of the U.S.'s import reliance for this category of goods must take into account each type of product with the category, including regular grade vanadium pentoxide, high purity vanadium pentoxide, and other oxides and hydroxides.

Vanadium Pentoxide

Vanadium pentoxide can generally be divided into high purity (suitable for use in the chemical and titanium industries) and regular purity (more commonly converted to ferrovanadium for use in the steel industry). No domestic producers are currently producing regular purity vanadium pentoxide, though Gladieux is planning to restart production [TEXT REDACTED]. With Gladieux's facility idled since 2016, the U.S. has been close to 100% reliant on imports for regular grade vanadium pentoxide. U.S. Vanadium is the primary domestic producer of high purity vanadium pentoxide; Energy Fuels also provided small amounts in 2019.

Much of the regular purity vanadium pentoxide in the United States is converted into FeV–80 at Bear's Pennsylvania facility. With annual vanadium pentoxide imports from 2016 to 2019 averaging 3.8 million kilograms of vanadium content, and the company processing regular purity vanadium an annual average of [TEXT REDACTED] of vanadium content during this period, at least [TEXT REDACTED] of vanadium pentoxide imports were provided to Bear for conversion into ferrovanadium.[130]

U.S. import reliance on vanadium pentoxide has risen significantly, from 55% in 2016 to 87% in 2017 and to close to 100% in 2018, due in part to the sole domestic producer of regular purity vanadium pentoxide (the Gulf/Gladieux facility in Freeport, Texas) idling operations in order to modernize the facility. The other major producer of vanadium pentoxide—the Hot Springs, Arkansas facility operated by EVRAZ Stratcor until its sale to U.S. Vanadium in 2019, which produces high purity vanadium pentoxide—has reportedly had a history of feedstock supply difficulties leading to production difficulties, which were exacerbated in 2017 following sanctions prohibiting

[130] U.S. Department of Commerce, Bureau of Industry and Security, Section 232 Investigation into Imports of Vanadium Survey.

imports from Venezuela.[131] As a primary producer of vanadium, Energy Fuels is the only domestic entity entirely independent of foreign sources for generating vanadium pentoxide.

Energy Fuels has moderate vanadium pentoxide production capacity, producing high purity vanadium pentoxide containing 460,000 kilograms of vanadium in 2019, of which only a small portion was sold (approximately 410,000 kilograms was unsold and remained in the company's inventory). However, should vanadium prices rise, Energy Fuels has the capability to restart vanadium mining operations, with the capacity to produce [TEXT REDACTED].[132] With Gladieux planning to resume operations and U.S. Vanadium increasing production levels of high purity vanadium pentoxide [TEXT REDACTED], direct U.S. import reliance for vanadium pentoxide will likely decrease in the future. [TEXT REDACTED] [133]

However, because U.S. secondary producers are reliant on imports of vanadium-bearing wastes for most of their feedstock, the United States will likely continue to be dependent on foreign sources of vanadium to meet domestic demand for vanadium pentoxide.

Other Vanadium Products

While ferrovanadium and vanadium oxide products are the most heavily traded vanadium products, the United States is also reliant on imports for other vanadium products including vanadates, vanadium carbides, vanadium sulfates, and vanadium hydrides, sulfides, nitrides, azides, silicides, and borides.

Of these products, the United States has production capacity for only vanadium sulfate and vanadate production, and is completely import reliant for vanadium carbides and vanadium hydrides, sulfides, nitrides, azides, silicides, and borides.[134] Of these products, vanadium carbides comprised the largest share of trade by a significant margin during the period of study. Imports of vanadium carbides averaged $67 million annually from 2016 to 2019, while the imports of vanadium sulfate, vanadates, and vanadium hydrides, sulfides, nitrides, azides, silicides, and borides combined averaged $9 million annually during the same time period.[135]

Imports of vanadium carbides, relatively stable since 2010, have come overwhelmingly from South Africa (see Figure 20). The most commonly imported carbide product is in the form of nitrided vanadium carbide sold as Nitrovan®. As noted in the USITC's 2012 antidumping report for the third sunset review on imports of ferrovanadium and nitrided vanadium from Russia, the U.S. has not produced nitrided vanadium since 1992.[136]

**BILLING CODE 3510–33–P**

[131] Bushveld Minerals Limited. Comment in response to Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Vanadium, July 20, 2020. *https://www.regulations.gov/document?D=BIS-2020-0002-0013.*

[132] U.S. Department of Commerce, Bureau of Industry and Security, Section 232 Investigation into Imports of Vanadium Survey.

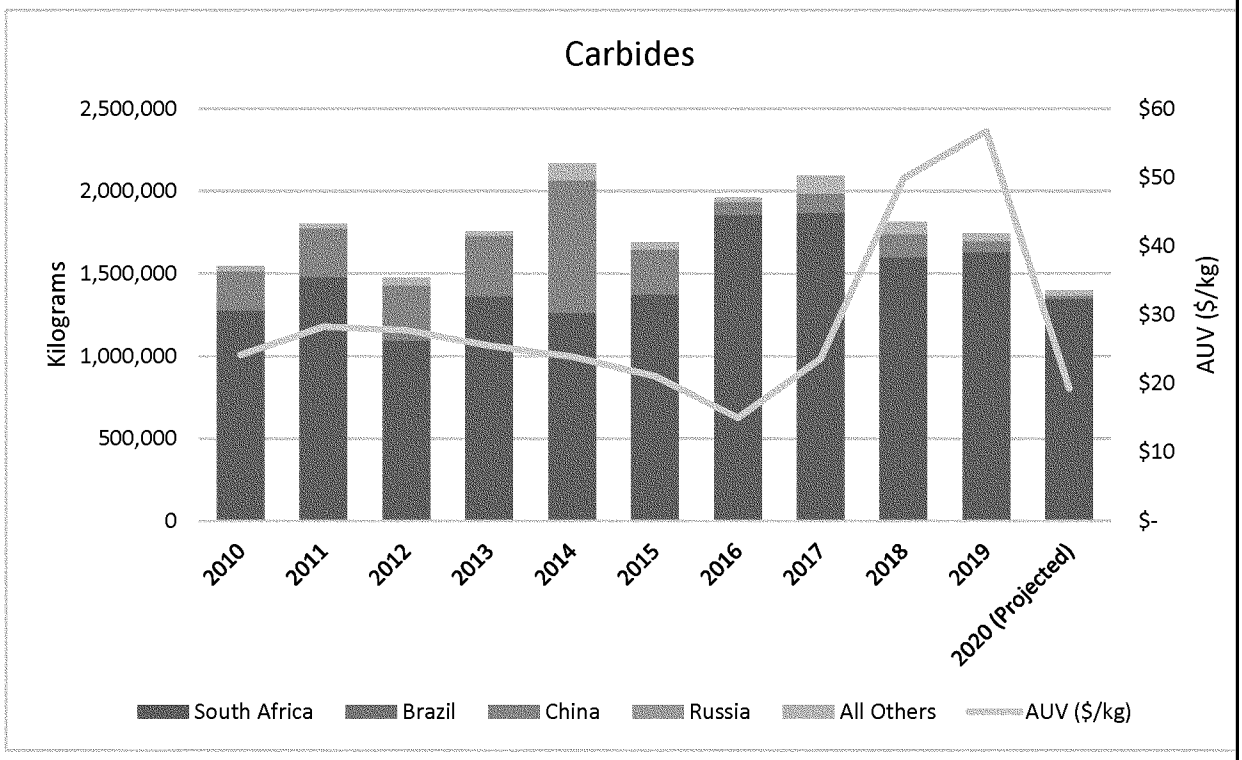
[133] Ibid.

[134] U.S. Department of Commerce, Bureau of Industry and Security, Section 232 Investigation into Imports of Vanadium Survey.

[135] ITC Dataweb.

[136] U.S. International Trade Commission. *Ferrovanadium and Nitrided Vanadium from Russia.* Investigation No. 731–TA–702, (Third Review). *https://www.usitc.gov/publications/701_731/pub4345.pdf.*

**Figure 20: Imports of Vanadium Carbides, 2010 – 2020 (projected)**




HTSUS Code: 2849.90.5000

Source: ITC Dataweb

In summary, understanding the overall U.S. import reliance on vanadium must take into account the structure of the vanadium supply chain, including the original feedstock of the vanadium products. [TEXT REDACTED]. The United States has no producers of vanadium carbides, nor of vanadium hydrides, nitrides, azides, silicides, and borides. For the balance of vanadium products the United States is not directly import reliant, but to the extent that it is reliant on imports of vanadium feedstock and vanadium pentoxide, it is because these products depend on non-U.S. origin inputs.

[TEXT REDACTED]

| | | | | |
|---|---|---|---|---|
| [TEXT REDACTED] | [TEXT REDACTED] | [TEXT REDACTED] | [TEXT REDACTED] | [TEXT REDACTED] |
| | [TEXT REDACTED] | [TEXT REDACTED] | [TEXT REDACTED] | [TEXT REDACTED] |
| [TEXT REDACTED] | [TEXT REDACTED] | [TEXT REDACTED] | [TEXT REDACTED] | |
| [TEXT REDACTED] | [TEXT REDACTED] | [TEXT REDACTED] | [TEXT REDACTED] | [TEXT REDACTED] |
| | [TEXT REDACTED] | [TEXT REDACTED] | [TEXT REDACTED] | |
| [TEXT REDACTED] | [TEXT REDACTED] | [TEXT REDACTED] | [TEXT REDACTED] | [TEXT REDACTED] |
| [TEXT REDACTED] | [TEXT REDACTED] | [TEXT REDACTED] | [TEXT REDACTED] | [TEXT REDACTED] |

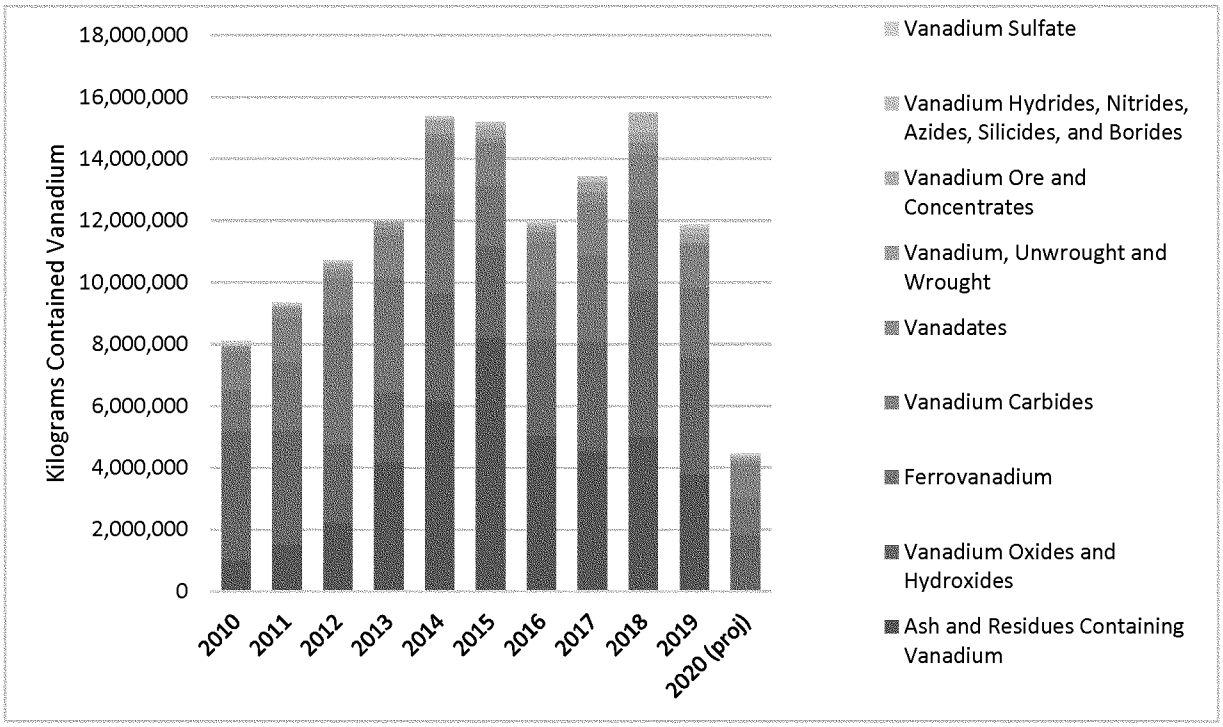
[TEXT REDACTED]—Continued

| | | | | |
|---|---|---|---|---|
| [TEXT REDACTED] | [TEXT REDACTED] | [TEXT REDACTED] | [TEXT REDACTED] | [TEXT REDACTED] |
| [TEXT REDACTED] | [TEXT REDACTED] | [TEXT REDACTED] | [TEXT REDACTED] | [TEXT REDACTED] |
| [TEXT REDACTED] | [TEXT REDACTED] | [TEXT REDACTED] | [TEXT REDACTED] | [TEXT REDACTED] |
| [TEXT REDACTED] | | | | |

2. U.S. Reliance on Imports of Vanadium Is Not Increasing

Imports of contained vanadium to the United States have not increased since 2014 and have decreased moderately since that time (see Figure 22). Even before the 2020 plunge in imports (driven by COVID–19-related demand declines), overall contained vanadium imports in 2019 were 4% below the 2010–2019 average.

**Figure 22: Imports of Contained Vanadium, 2010 – 2020 (projected)**




Source: ITC Dataweb

BILLING CODE 3510–33–C

Further, import reliance is not likely to increase. Major U.S. producers of ferrovanadium and vanadium pentoxide are in the process of expanding or restarting operations. U.S. capacity for ferrovanadium production from vanadium-bearing waste will more than double in 2021 with the opening of AMG Vanadium's new facility; the production increase will exceed annual average imports of ferrovanadium. U.S. capacity for vanadium pentoxide production from vanadium-bearing waste will also [TEXT REDACTED].

However, despite these upcoming significant increases in vanadium pentoxide and ferrovanadium production capacity, the United States will remain heavily reliant on foreign sources of vanadium, as significant quantities of the feedstock that U.S. producers use are sourced from outside the country. Mitigating factors on this reliance include that [TEXT REDACTED].[137]

In addition, several mining companies with locations in the United States have idle production capacity, significant inventory, and/or are exploring the development of vanadium mines. For example, Energy Fuels retains 410,000 kilograms of vanadium in inventory from 2019 production, and has

[137] U.S. Department of Commerce, Bureau of Industry and Security, Section 232 Investigation into Imports of Vanadium Survey.

indicated the ability to produce [TEXT REDACTED].[138] The Gibellini project in Carlin, Nevada expects to receive permits in 2021 and begin production in 2023, with an annual production forecast of 2.4 million kilograms of vanadium content per year.[139] Should both of these producers achieve their full capacity, their production would equal [TEXT REDACTED] of vanadium content per year, or [TEXT REDACTED] of annual domestic demand from 2016 to 2019. An increase in the availability of domestic primary vanadium, expansion of secondary production, and the addition of domestic feedstock for secondary production would mitigate current high reliance on imports.

3. Prices

Vanadium prices have a long history of volatility, with resulting impacts on the availability of vanadium resources and the viability of vanadium producers, as well as patterns of investment. The benchmark vanadium pentoxide price has more than doubled in short spans three times since 2004, most notably rising from $7 per pound in September 2004 to nearly $35 per pound in May 2005 before falling to $10 per pound by June 2006.

Such cycles may be more the standard than an anomaly in the vanadium industry. In 1977, the primary U.S. producer of vanadium oxide—Union Carbide—cut its production due to low prices and, in 1978, announced the idling of its Arkansas mine and mill.[140] Less than a decade later, in 1985, the U.S. Bureau of Mines wrote that the domestic vanadium industry was in the midst of a ''major restructuring . . . triggered by (1) the sharp decline in ferrovanadium consumption by U.S. steel producers during the 1982–83 recession, and (2) continuing depressed prices for co-product uranium oxide.'' [141] Just four years later, they reported:

> The year 1988 proved to be a boom year for vanadium producers as tight supply and strong demand by the steel industry and other consumers pushed up the price of vanadium compounds. . . . By the end of 1989, vanadium's fortunes had turned full circle as the market witnessed prices headed for levels lower than at any time since the early 1980s.[142]

Price-related closures and investments have continued. The Australian Windimurra mine, for instance, closed as the result of low prices in 2003 only to be purchased by a new company when prices spiked in 2005. After an investment of more than $100 million, prices fell and the mine was not reopened.[143] In the United States, during the latest price spike, AMG Vanadium announced the approval for construction of its new facility (in October 2018); [144] the owners of the Gibellini property completed its Preliminary Economic Assessment (PEA) (in May 2018); and First Vanadium carried out its maiden mineral resource classification (in February 2019).

The introduction of new capacity is tied to vanadium prices, as extraction that is not viable at $6 per pound vanadium pentoxide can become profitable at $12 per pound. First Vanadium's PEA assumes a vanadium pentoxide price of $10.65 per pound, well above current prices, and a cost of production of $5.17 per pound.[145] Only [TEXT REDACTED] U.S. producers of vanadium pentoxide or vanadium ore indicate the ability to produce at current prices, though the number of producers rises [TEXT REDACTED] once prices increase to $10 per pound of vanadium pentoxide and [TEXT REDACTED] at $13 per pound.[146] This is consistent with the world cost curve, which shows most currently viable production operates below a cost of $8 per pound (see Figure 23).

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[138] Ibid.

[139] Silver Elephant Mining Corporate Presentation: Gibellini Vanadium, *https://www.silverelephantmining.com/projects/gibellini-vanadium/*.

[140] Bureau of Mines Minerals Yearbook, Vanadium 1977.

[141] Bureau of Mines Minerals Yearbook, Vanadium 1985.

[142] Bureau of Mines Minerals Yearbook, Vanadium 1989.

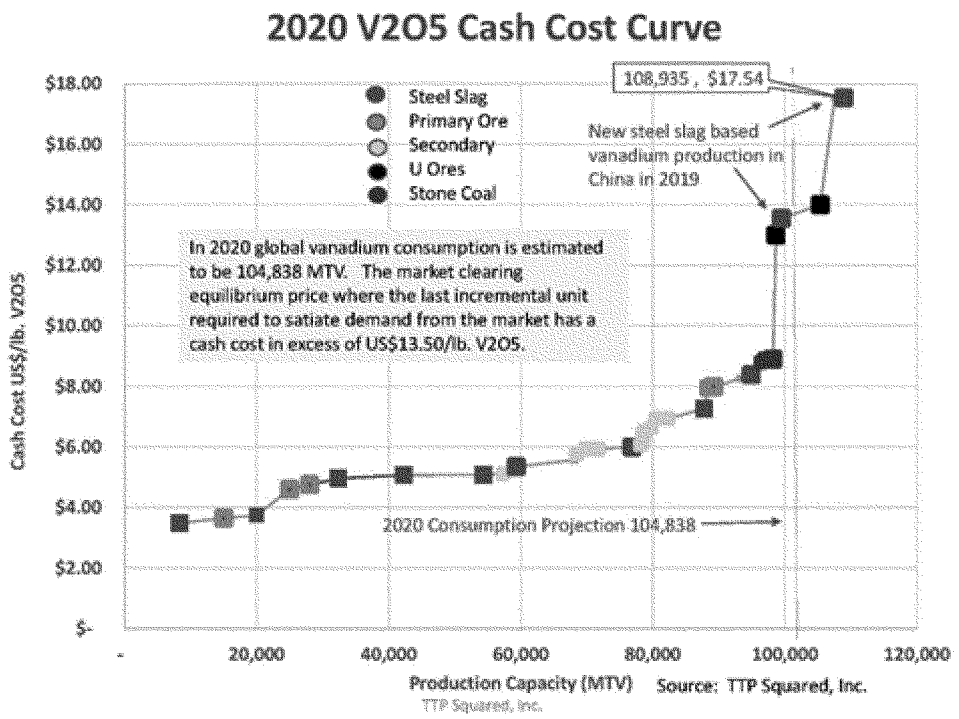
[143] McKinnon, Stuart. Vanadium Price Boom Offers Hope of WIndimurra Revival. *The West Australian,* April 2, 2018. Available at *https://thewest.com.au/business/mining/vanadium-price-boom-offers-hope-of-windimurra-revival-ng-b88792684z*.

[144] AMG ADVANCED METALLURGICAL GROUP N.V. COMPLETES FEASIBILITY STUDY TO EXPAND SPENT CATALYST PROCESSING CAPACITY. *https://amg-v.com/oct-16-18-news/*.

[145] First Vanadium Announces Positive Preliminary Economic Assessment for the Carlin Vanadium Project in Nevada *https://www.firstvanadium.com/index.php/news/2020/548-irstanadiumnnouncesositive reliminaryconomicsse20200511*).

[146] U.S. Department of Commerce, Bureau of Industry and Security, Section 232 Investigation into Imports of Vanadium Survey.

**Figure 23: Vanadium Pentoxide Production Costs**



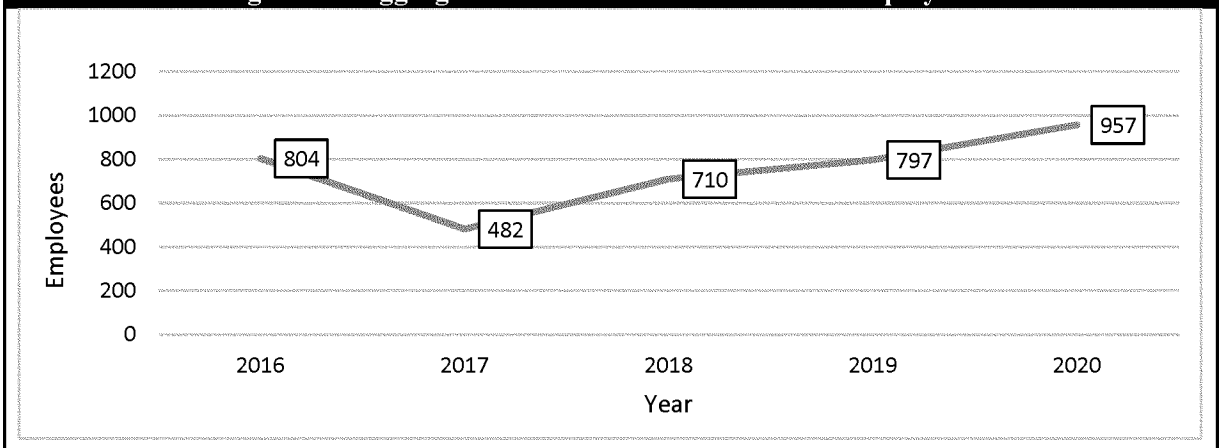

Source: Terry Perles, Ferroalloynet.com Vanadium Forum, March 7, 2019.
http://www.spartonres.ca/wp-content/uploads/2019/03/Presentation-Terry-10-Ex-China-Vanadium-Market.pdf

4. Employment

Although never a major employer, aggregate employment in the U.S. vanadium industry has waxed and waned during the last decade. The sector currently employs more people than it has during that time period, however, this current increase has not been shared equally across industry participants. While some producers have added employees, others have not.

Employment levels among vanadium producers were most notably affected by the 2017 idling and ongoing refurbishment of Gladieux's Texas facility. The facility's closure caused aggregate industry employment to drop sharply in 2017 but the numbers rebounded sharply in 2018 (see Figure 24).

**Figure 24: Aggregate U.S. Vanadium Production Employment**




Source: U.S. Department of Commerce, Bureau of Industry and Security, Vanadium Survey
Includes employees and contractors

BILLING CODE 3510–33–C

[TEXT REDACTED]

Most U.S. producers of vanadium products indicate that the volatility of vanadium prices make it difficult to recruit and retain employees. [TEXT REDACTED]

5. Financial Outlook

The U.S. vanadium production industry is small and in the midst of significant restructuring, making the industry's overall financial outlook difficult to characterize. However, it is clear that the industry has been significantly impacted by rapid changes in vanadium prices, particularly the collapse in price in 2019 from a high of approximately $30 per pound of vanadium pentoxide in November 2018 to less than $7 per pound by the end of 2019 and by the ongoing impacts of COVID–19 on the steel and titanium industries.

[TEXT REDACTED]

[TEXT REDACTED] [147]

Given its acquisition of EVRAZ Stratcor's Arkansas facility in October 2019, it is difficult to fully assess the financial health of U.S. Vanadium, as the facility's business practices are in transition. [TEXT REDACTED]

[TEXT REDACTED]

The facility of the remaining U.S. secondary producer, Gladieux, remains idle as the company completes the extensive modernization started after Gladieux purchased the facility from Gulf Chemical in 2017. [TEXT REDACTED]

[TEXT REDACTED]

The only other company that has produced vanadium production since 2016 is Energy Fuels Resources, whose primary business line is uranium mining. [TEXT REDACTED]

[TEXT REDACTED]

6. Exploration

In addition to Energy Fuels' primary production capacity, several other companies have properties that have mined vanadium in the past or are now under exploration. However, future profitable production at any of these properties is dependent upon an increase in the price of vanadium.

Western Uranium & Vanadium [TEXT REDACTED].[148]

Nuvemco, LLC owns the Last Chance Mine in Colorado, which has been idle since 2009 but the company says can return to operations within 120 days.[149] [TEXT REDACTED]

Two additional projects are under development: First Vanadium Corporation's Carlin Vanadium Project and Nevada Vanadium LLC's (Nevada Vanadium) Gibellini Vanadium Project. The Gibellini project is in the permitting process, with BLM expected to reach a decision by August 2021.[150] Nevada Vanadium plans to begin production in late 2023, producing vanadium pentoxide with 33 million kilograms of vanadium content over 14 years.[151] [TEXT REDACTED]

First Vanadium Corporation completed the PEA for its Carlin project in 2020, forecasting 16 years of vanadium production capabilities totaling 46 million kilograms of vanadium content.[152] [TEXT REDACTED]

7. Capital Expenditures

U.S. producers of vanadium have made significant capital expenditures in the last four years, with the construction of AMG Vanadium's new Ohio facility and Gladieux's overhaul of its Texas facility at the forefront. AMG Vanadium's expansion will more than double its ferrovanadium production capacity, adding over 2.5 million kilograms per year of capacity and 100 new jobs at an estimated cost of $200 million.[153] [TEXT REDACTED] Gladieux has invested more than [TEXT REDACTED] in the restart of its Texas facility, planning to open vanadium pentoxide production [TEXT REDACTED] with [TEXT REDACTED].

[TEXT REDACTED]

Among potential primary producers, [TEXT REDACTED]

8. Environmental Factors

Vanadium-bearing waste products—the primary source material for vanadium production in the United States—are classified by the EPA as hazardous wastes.[154] The recycling of these materials and reclamation of critical minerals constitutes an important step in both protecting human health and promoting an assured supply of critical minerals. AMG Vanadium claims a ''99% conversion rate for all raw material,'' and has a policy not to send spent catalyst to landfill.[155]

However, the recycling and reclamation process is expensive and subject to fines if not implemented correctly or fully. For example, one of the causes of Gulf's 2016 bankruptcy was the challenge and resulting costs of managing the pollutants from its Texas facility. The company spent more than $60 million on environmental protection-related expenditures and fines between 2010 and 2016. As noted above, since Gladieux purchased the facility in 2017, it has invested more than [TEXT REDACTED] in updating the facility to ''best in class'' standards.

Most vanadium-bearing spent catalysts are covered by a rule published by the EPA on August 26, 1998.[156] That rule identifies spent catalysts from hydrotreating and hydrorefining as hazardous wastes, does not comment on spent hydrocracking catalyst. In 2002, the EPA later issued a clarification of the scope of the hazardous waste listings; as part of that rulemaking process, the agency gathered industry data on quantities of spent catalyst generated and recycled in the United States.[157] This data showed that the country generated 31,313 tons of spent catalyst classified as hazardous waste in 1999, with 55% of it recycled/reclaimed. The EPA estimated the cost of reclamation at $725 per ton, while the cost of landfilling the catalyst was $240 per ton; low vanadium prices were cited as one potential reason for the difference in cost.

Safe processing of refinery byproducts is essential for continued oil refining in the United States. With valuable minerals contained in these waste products and human health and environmental risks stemming from their improper disposal, encouraging safe full value extraction will support the long term economic health and competitiveness of the country. However, solutions to the recycling of refinery byproducts in the United States attractive to current producers, especially while vanadium prices

[147] AMG Annual General Meeting Minutes (May 1, 2019), as provided in public comments by Bushveld Minerals Limited, available at *https://www.regulations.gov/document?D=BIS-2020-0002-0013*.

[148] U.S. Department of Commerce, Bureau of Industry and Security, Section 232 Investigation into Imports of Vanadium Survey.

[149] *http://www.nuvemco.com/Projects.html*.

[150] Bureau of Land Management Accepting Comments for Gibellini Mine, August 17, 2020. Available at *https://www.blm.gov/press-release/bureau-land-management-accepting-comments-gibellini-mine*.

[151] Silver Elephant Mining Corporate Presentation: Gibellini Vanadium, *https://www.silverelephantmining.com/projects/gibellini-vanadium/*.

[152] ''First Vanadium Announces Positive Preliminary Economic Assessment for the Carlin Vanadium Project in Nevada'', *https://www.firstvanadium.com/index.php/news/2020/548-irstanadiumnnounce sositivereliminaryconomicsse20200511*.

[153] AMG Vanadium Constructing a Second Ohio Plant, Investing More Than $200 Million. *https://www.jobsohio.com/news/posts/amg-vanadium-constructing-a-second-ohio-plant-investing-more-than-200-million/*.

[154] 63 FR 56710.

[155] *https://amg-v.com/wp-content/uploads/2019/11/The_Gold_Standard_Risk_Mitigation_Handbook_Nov_2019.pdf*.

[156] 63 FR 42110.

[157] *https://archive.epa.gov/epawaste/hazard/web/pdf/backdoc.pdf*.

remain below levels that allow for profitable production, are essential.

*C. Displacement of Domestically-Produced Vanadium by Imports Affects Our Internal Economy, but Is Mitigated by Ongoing Actions*

1. U.S. Production of Vanadium Is Well Below Domestic Demand

Between 2016 and 2019, the United States produced an annual average of 3.4 million kilograms of contained vanadium from primary or secondary production while importing 7.8 million kilograms of contained vanadium in the form of ferrovanadium, vanadium pentoxide, and carbides. Production capacity in 2020 remained insufficient to meet domestic demand, with non-conversion production capacity totaling [TEXT REDACTED] of contained vanadium.

Domestic production capacity will greatly expand in the near future with AMG Vanadium's expansion in Ohio planned to open in 2021 with capacity to produce ferrovanadium with [TEXT REDACTED] from spent catalyst, and Gladieux's overhaul of their Texas facility expected to be completed [TEXT REDACTED].[158] These additions will raise U.S. production capacity [TEXT REDACTED]. Additionally, should vanadium prices increase sufficiently, Nevada Vanadium's Gibellini mine could begin production in 2023 with an estimated annual production level of 2.4 million kilograms of contained vanadium.[159]

2. Domestic Production Is Highly Concentrated and Limits Capacity Available for a National Emergency

There were just three companies that carried out vanadium production in 2019—AMG Vanadium, US Vanadium, and Energy Fuels—with one additional company—Gladieux—idle for renovation. [TEXT REDACTED] Several companies have undertaken major investments in vanadium production capacity in anticipation of higher prices, but should prices not increase, one or more secondary producers may face challenges to continue production and additional mine capacity is unlikely to come on line.

Producers of high purity vanadium pentoxide face particular challenges because the primary destination of their product is the titanium industry, which has been significantly impacted by the COVID–19-related drops in air travel and, accordingly, aerospace industry production. There is no clear marker for when domestic aerospace production will begin to recover. Additionally, other than the approximately 10% of industry demand from titanium and non-metallurgical uses, domestic producers of vanadium pentoxide are reliant on toll converter Bear to supply product to the steel industry. [TEXT REDACTED]

Reactivation of idle capacity is not a quick process. [TEXT REDACTED]

However, adding new capacity would take significantly longer than reactivating existing facilities. While AMG Vanadium's new facility is projected to take about two years to complete, this is a relatively short time period that reflects the company's experience and the fact that the facility under construction is similar to its existing facility. The exploration and construction of primary production facilities in the United States takes significantly longer than the secondary production facility construction illustrated by AMG Vanadium. A more typical timeline may be Nevada Vanadium's Gibellini mine—the new project most likely to receive a permit—which carried out its PEA in 2018, is expected to receive permitting from BLM in 2021, and hopes to begin production in 2023, more than five years after its PEA.

These limitations represent a threat to the continued availability of domestically produced vanadium pentoxide, as needed to support national defense and critical infrastructure needs.

3. Domestic Vanadium Production Currently Requires Significant Imports of Vanadium Feedstock, Limiting Capacity Available for a National Emergency

Vanadium production in the United States is reliant on imports of vanadium feedstock to produce all vanadium products. The only vanadium producer in recent years to use entirely U.S. origin material is primary producer Energy Fuels, which has produced 460,000 kilograms of contained vanadium since 2016, accounting for 1.4% of U.S. apparent consumption.

Secondary producers AMG Vanadium, U.S. Vanadium, and Gladieux have all historically used foreign sources of vanadium-bearing wastes to provide portions of their feedstock. [TEXT REDACTED]

Current sourcing practices leave the United States unable to meet domestic demand with U.S.-sourced material; [TEXT REDACTED]. Although Energy Fuels' 2019 production of high purity vanadium pentoxide with 460,000 kilograms of vanadium content [TEXT REDACTED] is likely sufficient to meet defense system requirements (which are estimated above at less than 300,000 kilograms of contained vanadium per year), other national security requirements cannot currently be met using only U.S.-origin vanadium.

4. Trade Actions Have Been Successful in Mitigating Artificially Low-Priced Imports of Vanadium

Of the four countries with significant primary production of vanadium, three (Russia, China, and South Africa) have been subject to the imposition of antidumping duties on ferrovanadium by the Department and the USITC. Although not a primary producer, Korea has also been subject to antidumping duties. In all cases, after the duties were imposed, imports of ferrovanadium decreased significantly.

These cases show the longstanding and repeated success of antidumping duties in countering imports of ferrovanadium products sold in the United States at less than fair value.

5. Critical Minerals Agreements Will Help Ensure Reliable Supplies of Vanadium

In June 2019 the Department issued a report, *A Federal Strategy to Ensure a Reliable Supply of Critical Minerals.* This report ''outlines a coordinated approach by the Federal Government in response to Executive Order 13817 to reduce the Nation's vulnerability to disruptions in the supply of critical minerals.'' The Federal Strategy includes six calls to action, covering 24 goals and 61 recommendations, to achieve the goals put forth in E.O. 13817. One of these calls to action is ''Enhance International Trade and Cooperation Related to Critical Minerals,'' and recommends working with allies to ensure access to critical minerals as well as ''robust enforcement of U.S. trade laws and international agreements.''[160]

To achieve this goal, the Federal Strategy proposes that the USG establish intergovernmental agreements with partner countries, focused on ensuring continued access to critical minerals. The Federal Strategy recommends that the USG continue to expand cooperation and collaboration with interested parties on critical minerals issues related to:

(1) Resource identification and exploration;

[158] U.S. Department of Commerce, Bureau of Industry and Security, Section 232 Investigation into Imports of Vanadium Survey.

[159] Silver Elephant Mining Corporate Presentation: Gibellini Vanadium, *https://www.silverelephantmining.com/projects/gibellini-vanadium/.*

[160] *https://www.commerce.gov/sites/default/files/2020-01/Critical_Minerals_Strategy_Final.pdf.*

(2) processing and recycling;

(3) mitigating supply risk and preventing supply chain disruptions;

(4) research and development related to critical mineral materials and manufacturing and;

(5) tracking and sharing information on foreign investment and acquisitions of mineral rights, property, and development.

Among the achievements resulting from this call to action to date are:

U.S.-Canada Joint Action Plan on Critical Minerals

In January 2020, the United States and Canada announced the finalization of the U.S.-Canada Joint Action Plan on Critical Minerals Collaboration.[161] The plan aims to facilitate development of secure supply chains for critical minerals that are key to strategic industries. This bilateral initiative addresses concerns about reliance on other countries for the supply of minerals critical to defense, aerospace, communications, and other strategic industries.

As part of the joint action plan, Canada and the United States have identified areas for cooperation, including: (i) Securing critical mineral supply chains for strategic industries and defense; (ii) improving information sharing on mineral resources and potential; (iii) engaging with the private sector; (iv) collaborating in multilateral fora and with other countries; (v) undertaking research and development initiatives; (vi) engaging in supply chain modeling; and (vii) increasing support for the metals and mining industry.

As a result of its strong political and economic ties to the United States, the shared border, its stable regulatory environment, and an abundance of mineral resources, collaboration with Canada provides the United States a path to expanded secure supplies of critical minerals, including vanadium. Although not a current producer of vanadium, Canada has several projects underway, including BlackRock Metals' Chibougamou mine, which may begin production in 2021 with planned annual production of more than 4,000 tons of vanadium, close to half the U.S.'s average annual consumption from 2016 to 2019 of 8,590 tons.

U.S.-Australia Critical Minerals Plan of Action

In November 2019, the United States and Australia formalized a partnership to collaborate on research and increase critical minerals capacity.[162] The activities under the Plan of Action include focusing on resource mapping and quantitative assessments, determining geological controls on critical minerals distribution, and improving understanding of supply and demand scenarios for shared critical minerals trade between the United States and Australia.

As Australia is one of six countries in the world with USGS-recognized vanadium reserves, and has five exploration projects in advanced stages, this partnership holds significant promise to support U.S. access to reliable sources of vanadium.

*D. Increased Global Capacity and Production of Vanadium Will Further Impact the Long-Term Viability of U.S. Vanadium Production*

1. China Possesses an Outsized Role in the Global Price of Vanadium

China accounts for an estimated 50 to 60% of global vanadium production, with a similar level of demand. This concentration of production and consumption means that policy changes in China can have large effects on the global vanadium market. As Energy Fuels' vice president Curtis Moore said in 2019, ''the biggest driver of vanadium prices is economic and industrial policy in China, which is opaque to say the least.'' [163]

The spike in vanadium prices from 2017 into 2018 was largely attributed to a change in Chinese steel rebar standards to require the addition of more vanadium.[164] Similarly, the precipitous fall in prices following the implementation of the standard on November 1, 2018 has been linked to ''enforcement of the standards not being as stringent as previously expected,'' as well as the substitution of niobium for vanadium due to price increases.[165] Finally, Chinese vanadium pentoxide production in the first half of 2019 was 30% higher than in the first half of 2018, increasing supply more than anticipated and further driving prices down.[166] China's ability to influence vanadium markets through supply, demand, and policy changes has a significant impact on the ability of companies in the United States to plan investments and production decisions.

2. Expansion of Low-Cost Production in Several Countries Will Place Downward Pressure on Global Vanadium Prices

In 2019, total production of primary- and co-produced (mine) vanadium was 73,000 metric tons. However, there are mines in development or exploration in Kazakhstan, Canada, and Australia which have the estimated capacity to add 12,408 tons of production in 2021, and 57,000 additional metric tons in future years, should all projects enter production.[167] The owners of the Kazakh mine have claimed it can operate ''at the world's lowest cash cost of production.'' By contrast, mine facilities in the United States are expected to have the capacity to produce 3,100 tons of vanadium in 2021, with an additional 2,900 tons per year in exploration.[168] This amount would satisfy the majority of current domestic demand, but is not likely to be produced without higher vanadium prices.

In addition to primary vanadium, AMG Vanadium plans to open its new Ohio facility in 2021, with the capacity to [TEXT REDACTED].[169] The company is also exploring the construction of similar facilities in Saudi Arabia and China, and has noted that their recycling operations have little dependence on the cost of vanadium, with recycling fees driving profits.[170] The ability to generate cash flow independent of vanadium costs could result in the introduction of new capacity even at low vanadium prices. Barring significant new demand for vanadium, the addition of new sources

[161] *https://www.state.gov/united-states-and-canada-finalize-action-plan-on-critical-minerals-cooperation/.*

[162] *https://www.doi.gov/pressreleases/united-states-and-australia-formalize-partnership-critical-minerals.*

[163] Barrera, Priscili. Vanadium Outlook 2020: Is Vanadium Due for a Comeback? December 31, 2019. *https://investingnews.com/daily/resource-investing/battery-metals-investing/vanadium-investing/vanadium-outlook.*

[164] Vanadium: Prices soar as new rebar regulations take effect. November 1, 2018. *https://roskill.com/news/vanadium-prices-soar-as-new-rebar-regulations-take-effect/.*

[165] Radford, Charlotte and Lv, Amy. Focus: Why China's implementation of new rebar policy is failing to support vanadium prices. December 20, 2018. *https://www.metalbulletin.com/Article/3850389/FOCUS-Why-Chinas-implementation-of-new-rebar-policy-is-failing-to-support-vanadium-prices.html.*

[166] Lv, Amy. Oversupply to persist for China V market. August 16, 2019. *https://www.amm.com/Article/3889693/Oversupply-to-persist-for-China-V-market.html.*

[167] Data from USGS, Government of Australia, BlackRock Metals, VanadiumCorp Resources, Vanadium One Iron Corporation, and Ferro-Alloy Resources Group.

[168] Data from Energy Fuels Resources (USA), First Vanadium Corporation, and Silver Elephant Mining.

[169] U.S. Department of Commerce, Bureau of Industry and Security, Section 232 Investigation into Imports of Vanadium Survey.

[170] Bushveld Minerals Limited. Comment in response to Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Vanadium, July 20, 2020. *https://www.regulations.gov/document?D=BIS-2020-0002-0013.*

of supply will continue to impact vanadium prices.

3. Downward Price Pressure May Be Mitigated by Increased Demand for Steel, Titanium, and Energy Storage

With the steel industry consuming approximately 90% of vanadium demand, changes in vanadium consumption are largely tied to that industry. Global steel production in 2020 was affected by the COVID–19 pandemic, and had a forecasted decline of 2.4%.[171] Steel production in the United States saw a much larger decrease of approximately 18% from 2019.[172] The declines in steel production impact vanadium prices, which had not recovered since falling from a peak of nearly $34 per pound vanadium pentoxide in November 2018 to $6 per pound in December 2019.[173] While steel demand, and accordingly vanadium demand, is projected to bounce back in 2021 to 4.1% growth, longer range forecasts estimate global steel demand growing at an annual rate of 1.4% through 2035.[174] Increased vanadium use within the steel industry, such as that resulting from implementation of the 2018 regulation in China requiring the addition of vanadium to steel rebar and increased demand for high strength and tool steel, may provide additional growth in vanadium demand, with Vanitec (a global vanadium industry association) forecasting a 30% increase in vanadium demand by 2025.[175]

The titanium industry, with approximately 55% of demand coming from the aerospace sector, has been even more significantly affected by COVID–19 than the steel industry. Global titanium sponge production was projected to decline [TEXT REDACTED] from 2019 to 2020, with titanium shipments falling [TEXT REDACTED].[176] Prior to the pandemic, titanium alloy growth rates were forecasted in the 3 to 5% per year range, and expected to track closely with aircraft demand.[177] To the extent that the end of the pandemic spurs air travel to return to previous levels and growth rates, longer term titanium demand could provide support for vanadium prices.

The energy storage sector is another potential area for growth in vanadium demand. While the demand for vanadium redox flow batteries have not yet seen massive growth, Growth estimates vary wildly, from Roskill's 13% per annum growth to Bushveld Mineral's ''aggressive forecast'' of 42% annual growth.[178] The relatively conservative Roskill estimate would account for added demand by 2027 of 5,000 tons of vanadium, while Bushveld's forecast would have vanadium redox flow battery demand increasing by 93,000 tons by 2027, exceeding 2017 total vanadium production.

4. Significant Price Swings Impair the Ability of Domestic Producers To Plan and Carry Out Capital Expenditures

The historic volatility of vanadium prices make it difficult for producers to plan and follow through on investments in new capabilities. Although many industry projects take four or more years to complete, it is likely that vanadium market conditions and prices will change significantly between the beginning and the end of a project, impacting the project's viability and access to financing.

For example, when Gulf filed for bankruptcy in June 2016, vanadium pentoxide prices had recent lows of $3 per pound. At the time of Gladieux's purchase of Gulf's facility, prices had risen to close to $6 per pound. While Gladieux has been updating the facility, prices have spiked to $30 per pound in November 2018, but fell back to $6 a year later. [TEXT REDACTED]

The most advanced primary vanadium exploration project underway in the United States has had a similar experience. Nevada Vanadium completed the PEA for the Gibellini project in June 2018, when vanadium pentoxide prices were $15 per pound. The PEA used a forecast price of $12.73, and reflects a 14-year breakeven price of $7.76 per pound.[179] With current prices below the breakeven level and an estimated [TEXT REDACTED] required to construct and open the mine, completion of the project may be postponed or cancelled unless vanadium prices have risen before the expected BLM permit decision in August 2021. [TEXT REDACTED]

Similar price challenges exist at other domestic mining projects, with limited investment expected absent a rise in vanadium prices. [TEXT REDACTED] In summary, while significant domestic resources of vanadium exist, the long project lead times and volatile vanadium prices often create challenges in obtaining the investments necessary to bring the projects to completion.

*E. Unilaterally Increasing Domestic Prices of Vanadium Would Harm Critical U.S. Industries*

1. Domestic Vanadium Prices Significantly Exceeding World Prices Would Disadvantage the U.S. Steel Industry

Imports of steel products are currently subject to adjustment based on the finding of a threat to national security in the Secretary's 2018 Steel Report. That report found that the domestic steel industry was threatened by low-cost imports and recommended enhancing the industry's viability through the imposition of tariffs. In imposing a 25% tariff on imports, the President also authorized the creation of an exclusions process, whereby companies could request an exclusion from the tariff. Since the start of the exclusions process in March 2018, more than 250,000 requests for exclusion from the steel tariff have been filed, reflecting significant interest in avoiding additional costs related to the domestic sale of steel products.

With annual production in the U.S. worth $92 billion, the estimated $300 million in vanadium demand attributable to the steel industry represents less than 1% of total cost. However, in an industry with small profit margins and under threat from low-cost imports, additional costs for U.S. companies that foreign companies do not bear can be determinative on the company's survival.

While not all steel products contain vanadium, some parts of the steel industry require it. Analysis of exclusion request data showed that 24% of the requests for exclusion from the Section 232 steel tariff involved a product with at least some vanadium,

[171] Worldsteel Short Range Outlook October 2020. October 15, 2020. Available at *https://www.worldsteel.org/media-centre/press-releases/2020/worldsteel-Short-Range-Outlook-October-2020.html*.

[172] Data as of December 16, 2020. *https://www.steel.org/industry-data/*.

[173] Vanadium pentoxide flake 98% purity, China price. *Vanadiumprice.com*.

[174] Steel Demand Beyond 2030: Forecast Scenarios. Presented to OECD, Paris, September 28, 2017. Available at *https://www.oecd.org/industry/ind/Item_4b_Accenture_Timothy_van_Audenaerde.pdf*.

[175] 7th Vanitec Energy Storage Meeting, June 29, 2020. *http://www.vanitec.org/vanadium/ESC-Meetings*.

[176] Information presented to U.S. Government Titanium Sponge Working Group.

[177] Fior Markets Titanium Alloys Markets, Published May 2019; Research and Markets Titanium Alloys And Ultrafine Titanium Dioxide Global Market Opportunities And Strategies To 2023, May 2019; Titanium USA 2018 Conference, October 7–10, 2018.

[178] Bushveld Minerals, Energy Storage & Vanadium Redox Flow Batteries 101. November 13, 2018. *http://www.bushveldminerals.com/wp-content/uploads/2018/11/Energy-Storage-Vanadium-Redox-Flow-Batteries-101.pdf*.

[179] *https://www.silverelef.com/files/Gibellini_2018_PEA_Technical_Report.pdf*.

and 9% of requests required at least 1% vanadium.

Vanadium accounts for a significant percentage of the cost of the steel products in which it is an ingredient, with the result that small changes in the price of vanadium can have a major effect on the overall steel product cost. The cost per ton of vanadium is some 20 to 30 times that of steel products, meaning a 50% rise in vanadium prices would result in a more than 1% increase in the cost of rebar with 0.1% vanadium by weight.[180] For products such as high speed steel with significantly higher vanadium content, the impact can be significantly higher. In an industry such as the steel industry that is already threatened by low-cost imports, imposing additional costs could have a major impact. An increase in the domestic cost of vanadium, while beneficial in the short term to the domestic vanadium industry, would be harmful to the steel industry and encourage the import of steel products that contain vanadium, to the detriment of both the domestic steel and vanadium industries.

2. Domestic Vanadium Prices Significantly Exceeding World Prices Would Harm the U.S. Titanium Industry, to the Benefit of Russian and Chinese Titanium Producers

Although the titanium industry uses far less vanadium than the steel industry, it is much more dependent on vanadium. For most steel uses of vanadium, substitution of niobium or molybdenum is possible, but vanadium is essential to most aerospace applications using titanium. The most common titanium alloy, Ti-6Al-4V, contains 4% vanadium by weight, but represents between 12 and 14% by cost. Further, nearly all vanadium-containing titanium products are used in the aerospace and military sectors, both essential to national security.

Titanium, like vanadium and steel, is critical to national security, and was also subject to a Section 232 investigation, based on imports of titanium sponge. One significant concern for the titanium industry is the expansion of low-cost, vertically integrated Russian and Chinese titanium producers. One of the findings of the titanium sponge investigation was that increases in the Chinese and Russian premium quality sponge production threatens the viability of domestic U.S. titanium suppliers to the aerospace industry. The report found that Chinese and Russian sponge producers, underwritten by government support, have or are moving toward creating vertically integrated titanium supply chains that undercut U.S. producers. Because it is able to provide the necessary quality of titanium at lower prices than U.S. producers, Russian titanium producer VSMPO-Avisma provides 35% of Boeing's titanium products, and 50% of Airbus's titanium products.

The threat to U.S. titanium producers from low-cost imports has increased since the titanium sponge investigation ended, as a result of the impact that COVID–19 has had on global titanium demand. Titanium shipments fell [TEXT REDACTED] from 2019 to 2020. Further, demand [TEXT REDACTED]. As a result of these factors, the U.S. titanium industry is facing severe hardship, and any product cost increases in the United States will likely to further disadvantage the industry relative to Chinese and Russian suppliers.

## VIII. Conclusion

### *A. Determination*

Based on the findings in this Report, the Secretary concludes that the present quantities and circumstance of vanadium imports do not threaten to impair the national security as defined in Section 232. Although vanadium is critical to national security and the United States is dependent on imported sources of vanadium, several significant factors, including the health of the U.S. industry, the availability of idle domestic resources, ongoing USG actions, and the importance of vanadium to maintaining competitive steel and titanium industries, indicate that imports of vanadium do not threaten to impair national security.

The United States is reliant on imports to satisfy demand for vanadium products and is not producing significant amounts of vanadium from U.S.-origin material, but these conditions are not expected to deteriorate further. A number of U.S. vanadium producers are increasing their production capacity and/or modernizing currently idled facilities and mines. These initiatives will improve domestic capabilities specific to ferrovanadium and vanadium pentoxide, as well as in primary production. Even if primary production is not feasible are current vanadium prices, the availability of the resources allows for production potential in the event of national emergency. The increased availability of domestic primary vanadium, expansion of secondary production, and addition of domestic feedstock for secondary production should mitigate current abnormal levels of reliance in imports.

However, the Department recognizes that rising capacity does not necessarily mean the domestic vanadium industry is healthy. In addition to the long history of volatility of vanadium prices, the main users of vanadium—the steel and titanium industries—experienced major declines in demand in 2020 as a result of COVID–19, with the titanium industry particularly challenged due to its reliance on aerospace demand. If vanadium prices fail to rise, some of the capacity under development or exploration may not turn into production, and one or more secondary producers is likely face financial difficulty or challenges in sourcing affordable vanadium-bearing feedstock.

Further, the Department's lack of a finding of an immediate threat to national security does not indicate that a healthy domestic vanadium industry is not of vital importance to the United States. While the Secretary does not believe that imports of vanadium need to be adjusted at this time, there are steps that should be taken to support the domestic vanadium industry and related sectors, to ensure safe and reliable sources of vanadium in the event of a national emergency and to enhance and protect U.S. national security.

### *B. Recommendations*

The Department has identified several actions that would help to ensure reliable domestic sources of vanadium and lessen the potential for imports to threaten national security. These actions are not intended to be exhaustive or exclusive; the Secretary recommends pursuing all proposed actions.

Recommendation 1—Expansion of the National Defense Stockpile To Include High Purity Vanadium Pentoxide

The USG should support domestic vanadium production and ensure a source of vanadium in the event of national emergency by re-adding vanadium pentoxide to the National Defense Stockpile. Vanadium pentoxide was part of the stockpile until 1997; the stockpile held 6,200 tons of contained vanadium[181] in 1965 and had a goal of 7,000 tons though it held just 651 tons prior to the decision to reduce the target level to zero in 1993, following the end of the cold war.[182] Using high purity

[180] Average 2016–2019 vanadium pentoxide prices of $9.80 per pound, equivalent to $21,560 per ton. Rebar cost estimated at $1000 per ton.

[181] Vanadium is generally reported in terms of ''contained vanadium'', or the weight of only the vanadium portion of a vanadium compound. Vanadium represents 56% of the weight of vanadium pentoxide.

[182] USGS Vanadium Mineral Commodity Summaries. *https://www.usgs.gov/centers/nmic/vanadium-statistics-and-information.*

vanadium pentoxide—suitable for use in titanium alloys or chemical uses as well as conversion into ferrovanadium for use in the steel industry—would ensure vanadium held in the stockpile could be used for any necessary product in the event of national security.

National Defense Stockpile goals were initially set to ensure sufficient product to support one year's demand for the entire country but were later narrowed to focus on defense-specific needs, primarily due to funding constraints. Given the importance of vanadium and other critical minerals to the economy, the economic and national security of the United States would be better served by pursuing stockpile goals that support national security beyond defense-specific requirements. The re-addition of vanadium to the stockpile would require authorization and funding from Congress.

The Department recommends that the size of the proposed vanadium addition to the stockpile should be based on three benchmarks: Defense system requirements, broader national security requirements, and total domestic demand. As discussed above, defense system requirements may conservatively amount to 273 metric tons of vanadium content per year; this inventory level would be worth approximately $10.5 million based on average vanadium pentoxide prices since 2016.[183] Critical infrastructure requirements add an estimated 4,527 tons per year, resulting in a minimum stockpile goal based on total national security requirements of 4,800 tons of contained vanadium, at a cost of $184.8 million. Finally, total domestic apparent consumption (including defense and critical infrastructure needs) averaged 8,590 tons of contained vanadium annually from 2016 to 2019. Establishing a stockpile goal at this level, sufficient to meet all domestic demand would, would be valued at $330.6 million.

Beyond the minimum stockpile level, the Secretary further recommends that the stockpile of vanadium pentoxide be authorized to expand in size during periods of unusually low prices (with purchases made from domestic producers), while remaining unchanged or shrinking during periods of higher-than-average prices. This policy would help mitigate the large historic price swings that have caused significant financial distress and impeded capital investment in the domestic vanadium industry while helping to regulate domestic prices.

Implementing this policy would require legislative changes to the Strategic and Critical Materials Stockpiling Act (50 U.S.C. 98, *et seq.*) (Stockpiling Act). While the mitigation of critical mineral price swings and the purchase of critical minerals from domestic producers at a premium when prices are unusually low serves the interest of national defense, the Stockpiling Act requires that the stockpile ''not be used for economic or budgetary purposes,'' which may present a challenge in allowing the stockpile to exceed minimum defense needs based on prices. Allowing the stockpile to be used for economic purposes if such actions support the health and competitiveness of affected industries would help enhance U.S. national security.

As an additional potential benefit, once the vanadium holdings in the National Defense Stockpile are established, they could—with the authorization of Congress and in cooperation with the Department of Energy—be used without cost to support another sector: Large scale energy storage. As noted above, a potential new use for vanadium is in vanadium redox flow batteries, which have the advantage of using vanadium in both parts of the electrolyte, eliminating the risk of cross-contamination and allowing for the vanadium to be re-claimed from the batteries at a low cost with minimal yield loss.[184]

With vanadium accounting for approximately 30% of the cost of a vanadium redox flow battery and initial battery cost reductions needed to enable larger scale use, the USG could reduce the costs of the stockpile and support the energy storage sector by leasing a portion of the stockpile to be managed by vanadium redox flow battery companies, on condition of the leased vanadium being immediately reclaimable in the event of a national emergency. Given restrictions on transfers to and from the stockpile, this use of material in the stockpile would require either a legislative change to the Stockpiling Act or the designation of the leased material as still being part of the stockpile despite being used for energy storage.

Recommendation 2—Recycling Promotion

*The Federal Strategy to Ensure Secure and Reliable Supplies of Critical Minerals* (Federal Strategy) identifies an available, on-demand supply of critical minerals as ''essential to the economic prosperity and national defense of the United States.'' [185] The Federal Strategy recommends the support of recycling and reprocessing of critical minerals, including vanadium. Given that nearly all vanadium production in the United States is performed through recycling, the USG should support the vanadium industry through USG-wide actions to promote the recycling of materials containing critical minerals.

A 2002 EPA analysis, carried out in support of the May 8, 2002 final rule on the identification and listing of spent catalysts as hazardous waste, showed that in 1999, just 55% of spent catalyst was recycled, in large part because the cost of recycling was estimated to be three times that of landfill disposal.[186] Bringing the recycling of vanadium-bearing wastes generated in the United States to or near 100% has the potential to greatly expand the availability of vanadium products of domestic origin. Such recycling will occur naturally with higher vanadium prices, as refiners typically receive a metals credit from vanadium producers based on vanadium sale price, but can also be encouraged through the consideration of recycling tax deductions or credits as well as EPA review of their regulatory authority governing disposal of hazardous waste.

For example, additional information submitted by industry to the Department reported that the 2020 International Maritime Organization's (IMO) regulation requiring the reduction of allowable levels of sulfur in maritime fuels from 3.5% to 0.5% has increased refinery catalyst use, which is expected to result in increased availability of spent catalyst used to produce vanadium.[187] Similar regulations in the United States would support both the EPA mission to protect human health and the environment and domestic production of critical minerals.

Recommendation 3—Continue USG Actions to Support Critical Minerals

Many of the challenges domestic vanadium producers face are not unique to vanadium; with this investigation the Department has completed Section 232 investigations on four of the 35 critical minerals. While the specific challenges of each critical mineral are distinct,

[183] Average price per pound vanadium pentoxide from 2016–2019 of $9.80, based on data from USGS: *https://pubs.usgs.gov/periodicals/mcs2020/mcs2020-vanadium.pdf.*

[184] Vanitec estimates cost of conversion from leachate to vanadium pentoxide at $1 per pound vanadium pentoxide with a 95% yield. *http://www.vanitec.org/vanadium/ESC-Meetings.*

[185] *https://www.commerce.gov/sites/default/files/2020-01/Critical_Minerals_Strategy_Final.pdf.*

[186] 67 FR 30811 and *https://archive.epa.gov/epawaste/hazard/web/pdf/backdoc.pdf.*

[187] *https://ig9we1q348z124x3t10meupc-wpengine.netdna-ssl.com/wp-content/uploads/AMG-Annual-Report-Web-FINAL.pdf.*

many industrial trends are similar and broad solutions may be more effective than individual targeting. There are several ongoing and proposed U.S. government actions that support the domestic supply of critical minerals. Continuing to pursue these actions will provide necessary support to the domestic vanadium industry as well as to the broader critical minerals sector.

Among the key actions that will enable strong domestic critical minerals industries are Executive Order 13817 and the resulting Federal Strategy, Executive Order 13953 (*Addressing the Threat to the Domestic Supply Chain From Reliance on Critical Minerals From Foreign Adversaries and Supporting the Domestic Mining and Processing Industries*), proposals from the USG Nuclear Fuel Working Group, work being carried out by the Titanium Sponge Working Group, and legislative action to support domestic production of critical minerals. Since the list of suitable substitutions for vanadium in steel and certain chemical processes includes other minerals on the critical minerals list (including manganese, niobium, titanium, tungsten, and platinum), actions to support production of critical minerals as a whole would also help to address domestic vanadium supply challenges.

The Federal Strategy, developed pursuant to Executive Order 13817, was announced in June 2019, with six calls to action containing 24 goals and 61 recommended actions that federal agencies should pursue to improve the availability of critical minerals and their downstream supply chains in the United States to help reduce the country's vulnerability to supply chain disruptions. Many of the identified goals of the Federal Strategy are consistent with the findings and recommendations of this investigation, including:

(a) Support for downstream materials production capacity;

(b) enhancing the National Defense Stockpile's ability to meet military as well as civilian requirements;

(c) securing access to critical minerals through trade and investment with allies;

(d) identifying methods to encourage secondary use of critical minerals; and

(e) streamlining permit processes for critical mineral projects.

The President issued Executive Order 13953, ''Addressing the Threat to the Domestic Supply Chain From Reliance on Critical Minerals From Foreign Adversaries and Supporting the Domestic Mining and Processing Industries,'' (E.O. 13953), in September 2020. The Order identifies the need to ensure a consistent supply of critical minerals and declares a national emergency to reduce the threat posed by the country's undue reliance on critical minerals from foreign adversaries. Many of the actions taken pursuant to E.O. 13953 will support the domestic vanadium industry, particularly vanadium mining.

In addition to Executive actions, there have recently been several legislative proposals that would provide support for vanadium and other critical minerals. Examples include H.R. 8143 (also known as the Reclaiming American Rare Earths (RARE) Act) and S. 3694 (the Onshoring Rare Earths (ORE) Act of 2020). Both bills as written restrict the definition of critical minerals to a subset of those identified by the Department of Interior in response to E.O. 13817, and need to be expanded to include vanadium and other critical minerals, but otherwise have features of significant value to the domestic vanadium industry. In addition to allowing a tax deduction for investments in property used for mining, reclaiming, or recycling critical materials, these bills would support the function of critical minerals in the broader economy by providing grants or allowing tax deductions for critical minerals extracted in the United States. In addition to expanding the bills to include vanadium (as noted above), in order to provide the most value to the country, the Department recommends that any legislation should ensure that extraction incentives include recycling and reclamation.

Finally, the Department's Section 232 investigations into imports of Uranium and Titanium sponge resulted in the creation of USG working groups tasked with developing recommendations additional to those made in each report. Given the significant intersections between the vanadium industry and the uranium and titanium industries, the implementation of the working groups' recommendations will support the vanadium industry as well.

**Matthew S. Borman,**

*Deputy Assistant Secretary for Export Administration.*

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# FEDERAL REGISTER

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Part VI

## The President

Notice of November 16, 2021—Continuation of the National Emergency With Respect to the Situation in Nicaragua

Federal Register
Vol. 86, No. 220
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# Presidential Documents

**Title 3—**

## The President

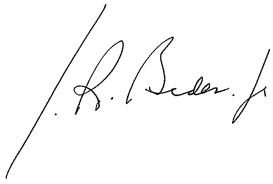
**Notice of November 16, 2021**

## Continuation of the National Emergency With Respect to the Situation in Nicaragua

On November 27, 2018, by Executive Order 13851, the President declared a national emergency pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701–1706) to deal with the unusual and extraordinary threat to the national security and foreign policy of the United States constituted by the situation in Nicaragua.

The situation in Nicaragua, including the violent response by the Government of Nicaragua to the protests that began on April 18, 2018, and the Ortega regime's systematic dismantling and undermining of democratic institutions and the rule of law, its use of indiscriminate violence and repressive tactics against civilians, as well as its corruption leading to the destabilization of Nicaragua's economy, continues to pose an unusual and extraordinary threat to the national security and foreign policy of the United States. For this reason, the national emergency declared on November 27, 2018, must continue in effect beyond November 27, 2021. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency declared in Executive Order 13851 with respect to the situation in Nicaragua.

This notice shall be published in the *Federal Register* and transmitted to the Congress.



THE WHITE HOUSE,
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# Reader Aids

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